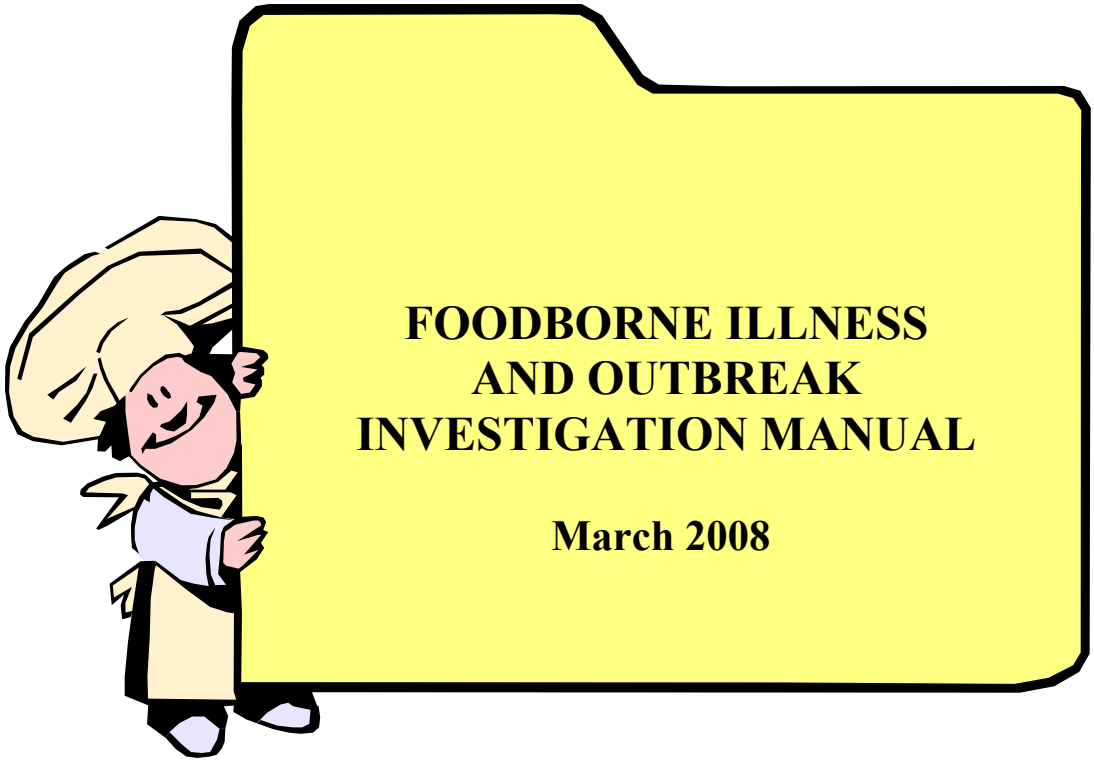

FOODBORNE ILLNESS AND OUTBREAK INVESTIGATION MANUAL

March 2008

Kansas Department of Health and Environment
Division of Health

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PREFACE

The *Foodborne Illness and Outbreak Investigation Manual* (March 2008) is an inclusive update of the previous foodborne disease outbreak investigation manuals first developed in 1997. This revised version provides more detail about the epidemiologic tools used during outbreaks investigations, offers more guidance with regards to clinical specimen and food sample collection, and includes a section on intentional contamination.

Improvements have been made based on user input. Comments, questions, and suggestions regarding this manual may be directed to Epidemiologic Services in the Office of Surveillance and Epidemiology at the Kansas Department of Health and Environment. We may be reached toll free by phone at (877) 427-7317, by fax at (877) 427-7318), or by e-mail at (EPIHotline @kdhe.state.ks.us).

An electronic version of this manual may be downloaded from http://www.kdheks.gov/epi/.

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TABLE OF CONTENTS

TABLE OF CONTENTS (continued)

TABLE OF CONTENTS (continued)

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INTRODUCTION

Foodborne pathogens cause an estimated 76 million cases of foodborne illness, 325,000 hospitalizations, and 5,200 deaths in the U. S. annually. Related medical costs and lost wages are significant, accounting for a yearly loss of up to $17 billion[1]. In Kansas, the main bacterial causes of food-related illness are *Campylobacter*, *Salmonella*, *Escherichia coli* O157:H7, and *Shigella*. Viral pathogens, specifically Norovirus (formerly known as Norwalk-like virus) and Hepatitis A virus, are also major causes of foodborne illness in Kansas.

Food-related and other diarrheal illnesses remain underreported throughout the U.S., including in Kansas. Most diarrheal illnesses resolve within 24 to 48 hours without any medical attention. As a result, many food-related illnesses are not diagnosed and associated foodborne disease outbreaks are often not recognized. This poses a challenge for public health professionals to maintain the knowledge and resources to identify and respond to these outbreaks.

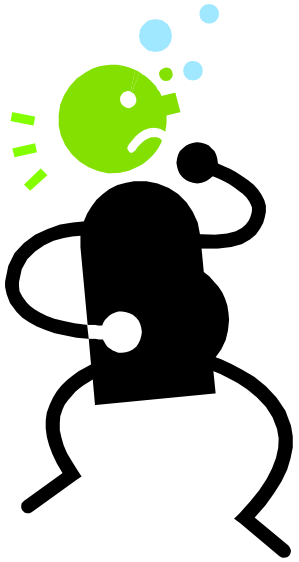
This manual is written primarily for infection control nurses, food inspectors, and outbreak investigators for the purpose of

1. Describing the fundamental concepts related to foodborne illnesses and outbreaks;
2. Discussing the roles and responsibilities of key personnel when responding to foodborne illnesses and outbreaks; and
3. Establishing guidelines for investigating foodborne disease outbreaks in Kansas.

[1] Mead, P.S., et al. "Food-Related Illness and Death in the United States." *Emerging Infectious Diseases*. 1999: 5(5), pp.607-25.

SECTION 1

Foodborne Illnesses



FUNDAMENTAL CONCEPTS

Proper and thorough investigation of foodborne disease outbreaks requires a solid understanding of the fundamental concepts related to foodborne illnesses.

> **Foodborne illnesses** refer to diseases acquired through eating or drinking contaminated food or liquids.

Characteristics of Foodborne Pathogens

The most frequent causes of foodborne illnesses include bacteria, bacterial toxins, viruses, and parasites.

Bacteria are one-celled living microorganisms ranging in size from 1 micrometer to 10 micrometers in length. They are naturally found in the environment (often in a spore form) or in various animal reservoirs. Bacteria can multiply in or on food and cause foodborne infections in persons who consume contaminated food or liquids. *Campylobacter* and *Salmonella* are the most reported causes of foodborne infections.

Toxins most often associated with foodborne illnesses are poisons produced or released by certain bacteria. (NOTE: Though certain chemicals and toxins from plants, animals, and fungi can cause illness, this manual will focus mainly on toxin-producing bacteria.) When ingested, bacterial toxins usually act locally within the human body, but may spread to other parts and damage cells, tissues, and the host immune system. *Bacillus cereus*, *Staphylococcus aureus*, and *Clostridium botulinum* are well-documented toxic foodborne agents. *E. coli* O157:H7 and *Shigella spp.* also produce toxins that cause disease, which may lead to severe complications. *Staphylococcus aureus* is the most reported cause of foodborne intoxications.

Viruses are minute organisms that reproduce only within living cells. Nonetheless, they can remain infectious in food and may cause foodborne infections in humans. Hepatitis A virus and Norovirus (formerly known as Norwalk-like virus) are the most recognized food-related viruses.

Parasites are single or multi-celled organisms with dimensions greater than 10 micrometers. Like viruses, parasites reproduce within host cells and cannot multiply in food. However, many parasites develop a cyst form that is inert and resistant to the environment. This cyst, when ingested through food or liquids, can multiply within humans and cause foodborne infections. *Giardia lamblia* is the most frequently reported foodborne parasite.

The following table summarizes the characteristics of potential foodborne pathogens.

CHARACTERISTICS OF FOODBORNE PATHOGENS			
	Bacteria	**Viruses**	**Parasites**
Cause infections	✓	✓	✓
Cause intoxications	✓		
Survive in environment	✓	✓	✓
Multiply in environment	✓		
Multiply in host	✓	✓	✓
Multiply in food	✓		
Form spores	✓		
Produce toxins	✓		
Form cysts			✓

Foodborne Transmission of Pathogens and Toxins

Food may become contaminated during food production and processing or during food preparation and handling.

Food production and processing: Animals naturally harbor many foodborne bacteria in their intestines that can cause illness in humans, but often do not cause illness in the animals. During slaughter, meat and poultry carcasses can become contaminated if they are exposed to small amounts of intestinal contents. Other foods, such as fruits and vegetables, may be contaminated if washed or irrigated with water that is contaminated with pathogens from animal or human feces. Thorough cooking of raw foods and washing ready-to-eat foods (i.e. foods not normally cooked or further processed before being eaten) with clean water can decrease the risk of infection.

Food preparation and handling:

- *Cross-contamination*: Pathogens naturally present in one food may be transferred to other foods during food preparation if the same cooking equipment and utensils are used without washing and disinfecting in between. If the foods are ready-to-eat foods, contamination can lead to illness.

- *Infected individuals*: Most foodborne pathogens are shed in the feces of infected persons and these pathogens may be transferred to others via the fecal-oral route. In other words, infected individuals, who do not adequately wash their hands after using the toilet, may contaminate the ready-to-eat food that they handle. Even minute quantities of feces, not visible to the naked eye, may contain many pathogens and cause illness. Bacteria present in pus-filled

lesions and found naturally in mucous membranes of the nose may also be transmitted from the hands of an infected foodhandler to ready-to-eat food.

> The **fecal-oral route of transmission** describes the ingestion of stool from an infected person or animal through food, water, or direct contact.

- *Inadequate cooking* or *improper holding temperatures*: Under optimal conditions, bacteria may multiply and produce toxins within food. Bacterial toxins that are produced are heat stable and may not be destroyed by cooking temperatures.

Classifications of Foodborne Illnesses

Foodborne illnesses are classified as infections or intoxications.

Foodborne infections are caused by consuming foods or liquids contaminated with bacteria, viruses, or parasites. These pathogens cause infection in one of two ways:
- Invading and multiplying in the lining of the intestines and/or other tissues.
- Invading and multiplying in the intestinal tract and releasing a toxin (*Bacteria only*).

Foodborne intoxications are caused by consuming foods or beverages already contaminated with a toxin. Sources of toxins are as follows:
- Certain bacteria. (NOTE: Viruses and parasites cannot cause intoxications.)
- Poisonous chemicals.
- Natural toxins found in animals, plants, and fungi.

Clinical Features of Foodborne Illnesses

The symptoms of most foodborne illnesses include diarrhea, nausea, vomiting, and abdominal cramping. Often mistakenly called the "stomach flu", these symptoms appear on average 24 to 48 hours after infection and last for about 1 to 2 days. Appendix E provides tables that are useful in determining potential causes of foodborne illnesses.

Incubation periods are important clues when determining possible causes of disease. For most diseases, infected individuals can transmit pathogens during the incubation period, when they show no symptoms of illness. For example, an individual, who is infected with the Hepatitis A virus, can shed the virus in stool (feces) and pass the virus to others two weeks before clinical signs appear or the person feels ill.

> **Incubation period** refers to the interval from the time an individual is infected to the time when symptoms first appear.

The recovery path that follows a foodborne illness can vary according to the pathogen, individual host factors, and antimicrobial use. Antimicrobial use may even shorten or lengthen the recovery period, depending on the pathogen. Similar to the incubation period, individuals may continue to shed the organism in their stool during the recovery period and can potentially infect others.

Recovery period refers to the period when symptoms decline and illness improves.

Individuals who harbor an infectious agent but are asymptomatic (i.e. show no symptoms of illness) are considered to be in the **carrier state**. Individuals who are in the incubation period or recovery period of an illness are known as **carriers**.

The following table summarizes the characteristics of infections versus intoxications.

INFECTIONS *vs.* INTOXICATIONS

	Infections	**Intoxications**
Organism	Bacteria Virus Parasite	Toxin
Mechanism	Invade and multiply within the lining of the intestines	No invasion or multiplication
Incubation period	Hours to days	Minutes to hours
Symptoms	Diarrhea Nausea Vomiting Abdominal cramps Fever*	Vomiting Nausea Diarrhea Double vision Weakness Respiratory failure Numbness Sensory and motor dysfunction
Transmission	Can be spread person-to-person via the fecal-oral route	Not communicable
Factors related to food contamination	Inadequate cooking Cross-contamination Poor personal hygiene Bare hand contact	Inadequate cooking Improper holding temperatures

***** The lack of fever in foodborne intoxications may aid investigators when determining the cause of the foodborne illness that is being observed.

Public Health Surveillance and Foodborne Illnesses

> **Public health surveillance** is the routine collection, analysis, summarization, and dissemination of data for the purpose of preventing and controlling the spread of disease.

The Office of Surveillance and Epidemiology (OSE) at the Kansas Department of Health and Environment (KDHE) maintains the surveillance system of notifiable diseases for the State of Kansas. This passive surveillance system depends upon the timely and accurate reporting of specific diseases by physicians, hospitals, and laboratories in Kansas to the public health system as stated in K.S.A. 65-118. Refer to Appendix B for a list of Reportable Diseases in Kansas and a copy of the Kansas Notifiable Disease Form.

Foodborne illnesses are monitored through the statewide surveillance system to assess disease impact, to detect trends, and to guide interventions. OSE also collects and monitors reports of outbreaks of gastrointestinal illness of unknown etiology. Outbreaks of disease, regardless of the cause, or an unusual occurrence of any disease, including those that appear to be food-related or of public health concern, must be reported to KDHE within four hours (K.A.R. 28-1-2).

> An **outbreak** is an unexpected, unexplained increase of disease occurring within a specific population at a given time and place.

Epidemiology and Foodborne Illnesses

> **Epidemiology** is defined as "the study of the distribution and determinants of health-related states or events within a specific population, and the application of this study to control health problems."

Last, JM ed. *A Dictionary of Epidemiology*, 3rd ed. New York: Oxford U. Press, 1995:55.

Epidemiologists utilize the elements of surveillance, sound science, and practical common sense to direct action for the purpose of promoting and protecting the public's health. Unlike clinicians who care for the health of the individual, epidemiologists focus on the health of the community. These "disease detectives" collect data to answer the "*who?"*, "*what?"*, *"when?"*, and "*where?"* of disease in the human population and conduct analyses to answer the "*why?"* and "*how?"* to prevent future disease. Infectious disease epidemiologists, in particular, study the frequency and patterns of acute diseases, including foodborne illnesses, to detect outbreaks and implement interventions to prevent further illness.

Laboratory Diagnosis of Foodborne Illnesses

Most foodborne infections are diagnosed through the identification of the pathogen in stool collected from infected persons. Vomitus has also been used to detect certain organisms and confirm the etiology. Blood samples are recommended for the laboratory diagnosis of systemic infections.

Refer to Section 4 on Laboratory Analysis for more detail about specimen collection, food sampling, and packing and shipping of specimens for testing.

The following table provides a list of reportable diseases that may be foodborne, their corresponding pathogen, recommended specimens for laboratory diagnosis, and testing capabilities at the Kansas Health and Environmental Laboratories (KHEL). Some diseases require notification to KDHE within four hours, and some require isolate submission to KHEL.

NOTIFIABLE FOODBORNE ILLNESSES AND CONDITIONS IN KANSAS

Disease or condition	Pathogen	Specimen	DHEL Testing
Bacterial			
Anthrax (gastrointestinal)[1]	*Bacillus anthracis*	Culture isolate	By request only
Botulism (foodborne)[1]	*Clostridium botulinum*	Blood, stool	Refer to CDC
Brucellosis	*Brucella spp.*	Culture isolate	By request only
Campylobacter infections	*Campylobacter spp.*	Stool	Routinely
Cholera[1]	*Vibrio cholerae*	Stool	By request only
Escherichia coli O157:H7 (and other shiga-toxin producing *E. coli*, also known as STEC)	*Escherichia coli spp.*[2]	Stool	Routinely
Hemolytic Uremic Syndrome (HUS)	*Usually E. coli*	N/A	N/A
Listeriosis	*Listeria monocytogenes*	Blood, spinal fluid	By request only
Salmonellosis, including typhoid fever	*Salmonella spp.*[2]	Stool	Routinely
Shigellosis	*Shigella spp.*[2]	Stool	Routinely
Viral			
Hepatitis A[3]	Hepatitis A virus	Blood	By request only
Parasitic			
Amebiasis	*Entamoeba histolytica*	Stool	Routinely
Cryptosporidiosis	*Cryptosporidium parvum*	Stool	By request only
Cyclospora infection	*Cyclospora cayetanensis*	Stool	By request only
Giardiasis	*Giardia lamblia*	Stool	Routinely
Trichinosis	*Trichinella spiralis*	Blood	Refer to CDC

[1] Suspect or confirmed cases must be reported to KDHE at (877) 472-7317 within four hours (K.A.R. 28-1-2)
[2] Isolates must be sent to KHEL for further analysis (K.A.R. 28-1-18)
[3] Reporting suspect cases to KDHE at (877) 427-7317 is highly recommended

NOTE: Outbreaks of disease, regardless of the cause, must be reported to KDHE at (877) 472-7317 within four hours (K.A.R. 28-1-2).

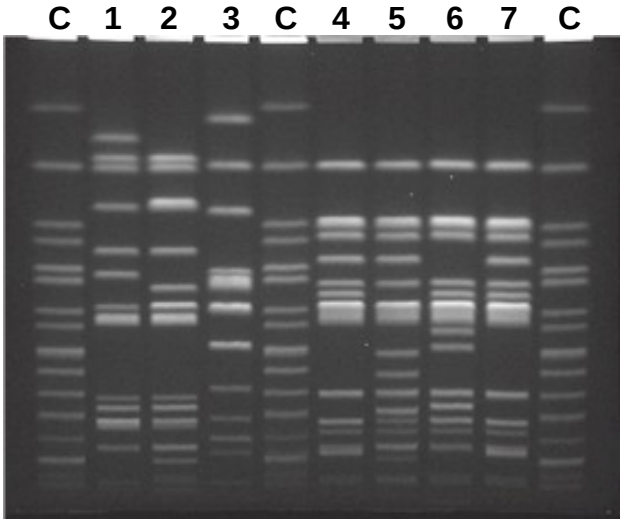
Pulsed-field Gel Electrophoresis (PFGE)

A laboratory technique frequently used to assist the surveillance and investigation of foodborne illness and outbreaks is pulsed-field gel electrophoresis (PFGE). This technique creates a unique "DNA fingerprint" or PFGE pattern for disease-causing bacteria isolated from infected persons. These patterns may be compared at the local, state, and national levels to identify potential outbreaks and to focus the epidemiologic investigation of outbreaks.

During the PFGE process, restriction enzymes are used to separate the bacterial DNA into different sized fragments. Pulsing electric currents then move the DNA fragments through a porous agarose gel. Smaller fragments move quickly through the gel while larger fragments move more slowly. The different fragments form a unique "DNA fingerprint" or band pattern for each bacterial isolate. These PFGE patterns may be analyzed to determine if the patterns are similar or indistinguishable and may provide additional information during investigations. Human isolates with indistinguishable PFGE patterns warrant further investigation to identify any potential epidemiological links among the infected individuals. PFGE may also be conducted using bacterial isolates from food, and the patterns may be compared with those of the human isolates.

The following image is an example of the "DNA fingerprint" of seven *Salmonella* isolates. The vertical lanes with a numeric label represent the PFGE pattern of a single isolate. The lanes labeled with a "C" are the control lanes.

Isolates #4 and #7 appear to have PFGE patterns that are indistinguishable. Follow-up should be conducted with the individuals from whom these bacterial isolates originated to determine if the individuals have any potential epidemiological links.



Food Handlers, Foodborne Illnesses, and Public Health

Food handlers are persons who directly handle or prepare food. They may work as paid employees or volunteers, serving food in a variety of settings: food establishments, health care facilities, day cares and schools, community functions, etc. Therefore, food handlers have an important responsibility to follow safe food preparation and handling practices to prevent illness.

Though food handlers are not at higher risk for developing a foodborne illness compared to other persons, food handlers are at higher *public health* risk for spreading pathogens. Infected food handlers, in particular, represent an extremely high risk for the transmission of pathogens to others through food when bare hand contact with ready-to-eat foods and poor hand washing are present.

The following tables are lists compiled by the Centers for Disease Control and Prevention (CDC) of (1) the pathogens often transmitted by infected food handlers and (2) the pathogens occasionally transmitted by infected food handlers[1]. Also included are the KDHE reporting requirements for the corresponding disease.

Pathogens Often Transmitted by Food Contaminated By Infected Food Handlers

Pathogen	Notifiable Disease in KS
Norovirus	No
Hepatitis A virus	Yes
Salmonella Typhi†	Yes
Shigella spp. †	Yes
Staphylococcus aureus	No
Streptococcus pyogenes	No

† Submission of isolate to KHEL is required per K.A.R. 28-1-18.

Outbreaks of disease, regardless of the cause, must be reported to KDHE at (877) 427-7317 within four hours (K.A.R. 28-1-2).

[1] Centers for Disease Control and Prevention. "Diseases Transmitted Through the Food Supply". Federal Register: November 6, 2003 (Volume 68, Number 215)

Pathogens Occasionally Transmitted by Food Contamination by Infected Food Handlers	
Pathogen	**Notifiable Disease in KS**
Campylobacter jejuni	Yes
Cryptosporidium parvum	Yes
Entamoeba histolytica	Yes
Enterohemorhagic *Escherichia coli*†	Yes
Enterotoxigenic *Escherichia coli*†	Yes
Giardia lamblia	Yes
Non-typhoidal *Salmonella*	Yes
Taenia solium	No
Vibrio cholerae 01	Yes
Yersinia enterocolitica	No

† Submission of isolate to KHEL is required per K.A.R. 28-1-18.

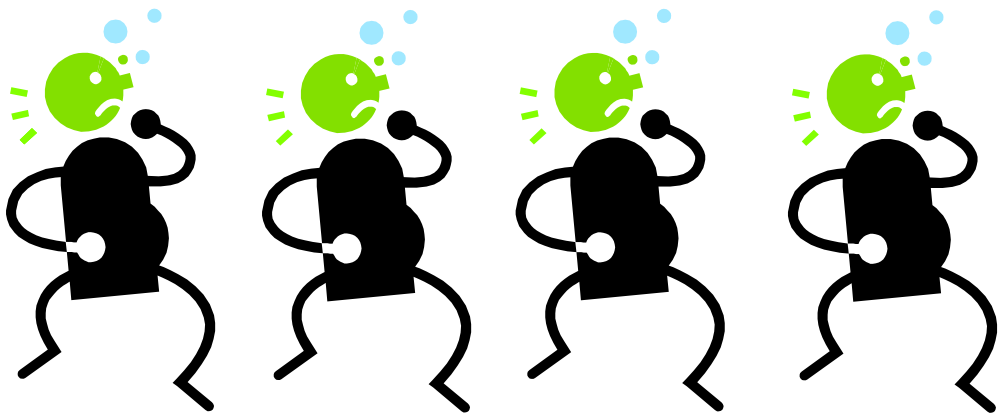
Because of the potential for food handlers to transmit pathogens through the food they serve, restriction and exclusion requirements have been established for infected food handlers in Kansas. Employees who are excluded cannot work in any capacity in the food establishment until written medical documentation is provided, stating that the person is free of the infectious agent of concern. Employees who are restricted can continue to work in the food establishment, but cannot work with exposed food, clean equipment utensils and linens, or unwrap single-service and single-use articles until restrictions have been removed.

According to the 2005 Kansas Food Code, food handlers who are diagnosed with an illness due to norovirus, *Salmonella Typhi*, *Shigella spp.*, Enterohemorrhagic or Shiga toxin producing *E. coli*, or hepatitis A virus should be excluded from working in a food establishment. Food handlers suffering from diarrhea, fever, vomiting, jaundice, or sore throat with fever or have a positive stool result for *Salmonella Typhi* or *Escherichia coli* O157:H7 should be restricted from food handling, but can serve in another capacity within a food establishment.

More information about exclusion and restriction requirements for certain health conditions is available in Appendix D.

Section 2

FOODBORNE DISEASE OUTBREAKS



FUNDAMENTAL CONCEPTS OF FOODBORNE DISEASE OUTBREAKS

Defining a Foodborne Disease Outbreak

In Kansas, a ***foodborne disease outbreak*** is defined in the following ways:

1. **Two or more individuals (from different households) who experience a similar illness after eating a common food[1] or food from a common place.**
   Household members generally share many meals together and experience close personal contact with one another. Therefore, similar illness among members of a single household is not considered to be an outbreak.

2. **An unexplained, unexpected increase of a similar illness, and food is a likely source.**
   Further investigation to identify the source of infection should be done. For example, an increased number of *Campylobacter jejuni* identified at the state laboratory may suggest that a foodborne disease outbreak has occurred.

Contact KDHE at (877) 427-7317 if an outbreak has occurred or if assistance is needed in determining if an outbreak has occurred.

NOTE: Positive laboratory identification of the disease-causing organism is not necessary to determine that a foodborne disease outbreak has occurred nor is this identification needed to begin an investigation. Many foodborne disease outbreaks have been recognized and investigated even in the absence of any laboratory testing, positive laboratory results, or a definitive diagnosis. Nonetheless, laboratory testing of clinical specimens and food samples to confirm the pathogen of a foodborne disease outbreak should always be a priority. Refer to Section 4 for more information about laboratory testing.

Identifying Foodborne Disease Outbreaks

Foodborne disease outbreaks may be identified from the following:

- Foodborne illness complaints from private citizens
- Medical evaluations of ill individuals from healthcare professionals at hospitals, clinics, or physician offices
- Routine surveillance and case investigation of reportable diarrheal illnesses by epidemiologists and public health nurses at state and local health departments
- Routine laboratory testing and techniques, including PFGE, conducted by microbiologists
- Information received through the media and public information officers
- Reports from state and federal food safety regulators and environmental health specialists

[1] Food may also include ice, milk, juices, and other liquids that are consumed.

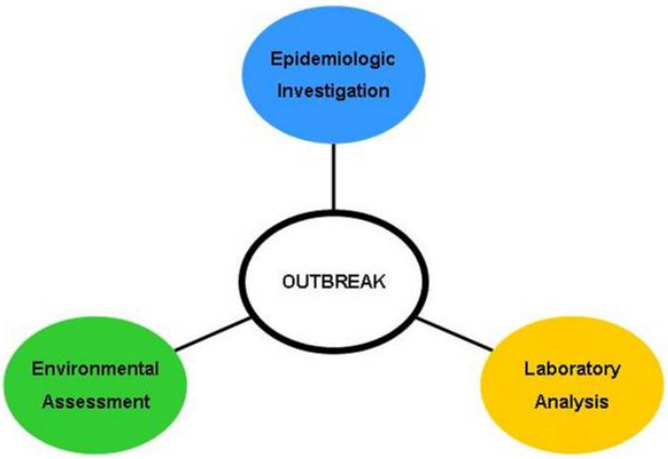
Reasons for Investigating Foodborne Disease Outbreaks

Once a foodborne disease outbreak has been identified, an outbreak investigation should be implemented for the following reasons:

- To identify the cause, the risk factor(s), or source of infection
- To implement interventions or corrective actions to prevent others from becoming ill
- To fulfill statutory obligations and respond to public and political concern
- To evaluate existing recommendations or strategies for preventing similar outbreaks
- To learn more about the public health implications of foodborne pathogens

Three Components of a Foodborne Disease Outbreak Investigation

Foodborne disease outbreak investigations are conducted to determine what factors are associated with illness and what measures can be done to prevent further illness. This is achieved through (1) an epidemiologic investigation, (2) laboratory analysis, and (3) an environmental assessment. A thorough outbreak investigation cannot be conducted without these three components, which are often performed simultaneously. See Sections 3, 4, and 5 for more detail about the three components.



Roles and Responsibilities in a Foodborne Disease Outbreak Investigation

Successful foodborne disease outbreak investigations depend upon the coordination and collaboration of key personnel. In most outbreak investigations, the core investigative team is comprised of the local health department infection control nurse, the food inspector, a medical investigator, an epidemiologist, and a microbiologist. Depending on the scope and size of an outbreak, the investigative team may include more or fewer investigators, and the different roles and responsibilities may overlap. Nonetheless, the outbreak investigators should work together to ensure that all necessary tasks are completed.

Local Health Department (LHD) Infection Control Nurse

- Oversee all infectious conditions and outbreaks within the county
- Conduct initial investigation of potential outbreaks
- Administer interviews with persons associated with outbreaks
- Distribute stool kits and collect clinical specimens to obtain a diagnosis
- Submit clinical specimens and food samples collected for laboratory testing
- Maintain correspondence and collaborate with local healthcare professionals
- Implement control and prevention measures as needed to stop the spread of infection
- Provide educational information about infectious conditions and control and prevention measures
- Coordinate with food inspector, medical investigator, and epidemiologist
- Coordinate with local law enforcement at earliest suspicion of intentional contamination

Food Inspector or Environmental Health Specialist

- Conduct inspection of food establishments
- Identify and address food safety issues that may have contributed to the outbreak
- Interview managers and food handlers about any illness experienced and their specific job duties
- Collect food and environmental samples, if feasible
- Obtain menu of food items served
- Enforce state restriction and exclusion regulations related to food handlers
- Perform Hazard Analysis and Critical Control Points (HACCP) investigation, if needed
- Coordinate with LHD infection control nurse and medical investigator or epidemiologist

Medical Investigator or Regional Coordinator

- Serve as a liaison between the LHD and KDHE
- Assist LHD infection control nurse with disease surveillance and investigation
- Provide technical guidance and overall support to an outbreak investigation
- Facilitate communication between LHDs during inter-county outbreak investigations
- Coordinate with LHD infection control nurse, epidemiologist, and food inspector

Epidemiologist

- Assist in determining if an outbreak has occurred and if an investigation is needed
- Serve as lead investigator or primary coordinator in an outbreak investigation
- Facilitate and guide the steps in an outbreak investigation
- Provide technical, statistical, and overall support to an outbreak investigation
- Coordinate with LHD infection control nurse, medical investigator, food inspector, and microbiologist
- Maintain communication channels between programs, agencies, counties, and states, as needed
- Oversee multi-county or multistate outbreaks
- Coordinate with CPHP at the earliest suspicion of an intentional contamination

Microbiologist

- Test clinical specimens or food samples to verify or confirm the diagnosis of the outbreak
- Conduct further subtyping or laboratory analysis, if appropriate
- Coordinate with reference laboratories at other state or federal laboratories
- Coordinate with LHD infection control nurse, medical investigator, or epidemiologist
- Maintain chain of custody for outbreaks of suspected intentional contamination

Other important roles that may or may not be needed for a particular investigation include the following:

Physician / Healthcare Provider

- Report notifiable diseases, including outbreaks, to local or state health department
- Provide clinical information and diagnosis for patients when available
- Assist in the collection of clinical specimens for laboratory testing

Administrator (LHD)

- Fulfill the role of infection control nurse if needed
- Assist the LHD staff with outbreak investigations
- May serve as the main liaison with local physicians, the media, or KDHE
- Enforce statutes and regulations related to the health of residents, investigation of causes of disease, and prevention of spread of diseases within the county

Local Health Officer

- Serve as medical consult to county staff
- Enforce statutes and regulations related to the health of residents, investigation of causes of disease, sanitation inspections, and prevention of spread of diseases within the county

Public Information Officer

- Deliver clear, consistent messages related to diseases and outbreaks
- Respond to media requests related to diseases and outbreaks
- Provide educational information to the general public

Federal Personnel[1]

- Provide guidance in national outbreaks or tracebacks
- Assist multistate outbreak investigations

[1] Federal personnel that may be involved in a foodborne disease outbreak investigation include the Centers for Disease Control and Prevention, the U.S. Department of Agriculture, the Food and Drug Administration, and the Environmental Protection Agency.

In the event of an intentional contamination of food, the following personnel and agencies may also be called upon during an outbreak investigation:

Law Enforcement

- Coordinate with public health during initial threat assessment and investigation
- Contact and coordinate with Federal Bureau of Investigation
- Conduct criminal investigation
- Ensure collection of evidence in manner that is admissible in court

Emergency Management

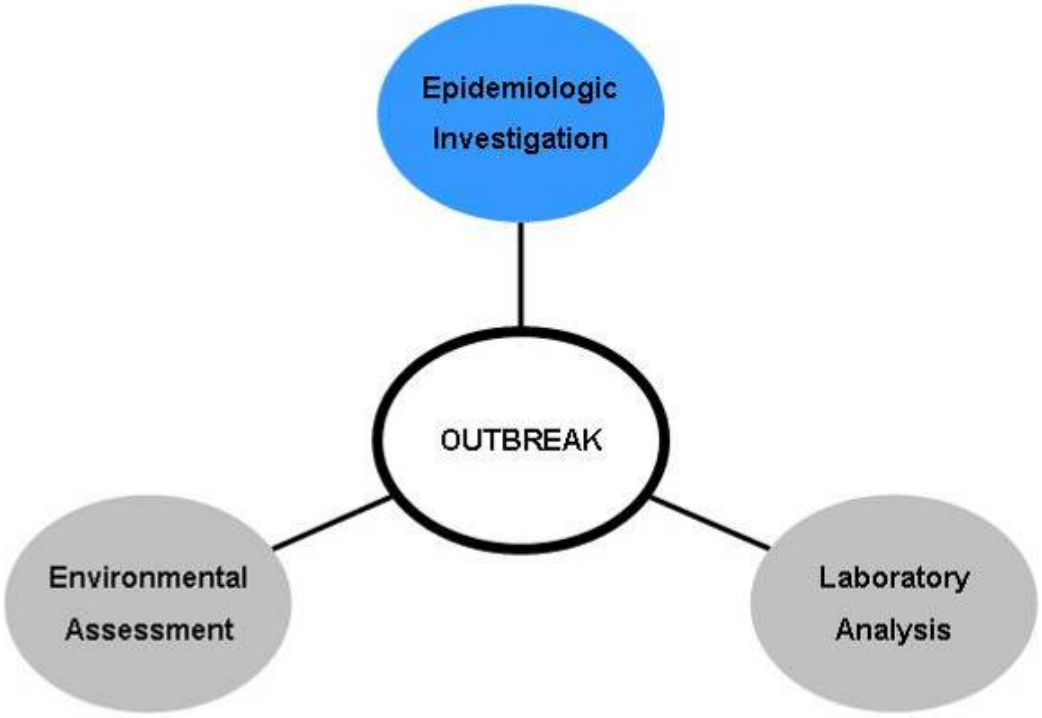
- Coordinate efforts of all responding agencies
- Provide additional supplies, if needed

The Importance of Confidentiality

Each of the key players in outbreak investigations has the crucial responsibility of maintaining confidentiality of the individuals involved in the outbreak. Identifying information should **never** be released unless absolutely necessary to properly conduct the outbreak investigation and to protect the public's health. Extreme consideration should be taken to ensure that information is released only on a "need-to-know" basis.

Section 3

THE EPIDEMIOLOGIC INVESTIGATION



CONDUCTING AN EPIDEMIOLOGIC OUTBREAK INVESTIGATION

The main objectives of an epidemiologic outbreak investigation are (1) to identify a problem, (2) to collect information related to the problem, and (3) to develop conclusions and recommendations for prevention and control. Illness and exposure histories are collected, usually using questionnaires, and comparisons are made between persons who became ill and those who did not. Conclusions about the outbreak are then formulated from the epidemiologic data, in conjunction with the results of the laboratory analysis and environmental assessment.

The following table lists the essential steps of an epidemiologic outbreak investigation.

Steps of an Epidemiologic Outbreak Investigation	
1.	Determine that an outbreak has occurred.
2.	Contact and coordinate with key personnel.
3.	Obtain clinical specimens and food samples for laboratory testing.
4.	Implement control and prevention measures.
5.	Define cases and conduct case finding.
6.	Describe the outbreak by time, place, and person.
7.	Develop possible hypotheses.
8.	Plan and conduct an epidemiologic study to test hypotheses.
9.	Analyze the data collected and interpret results.
10.	Report the findings of the outbreak investigation.

The order presented in this manual reflects the logical process of most outbreak investigations conducted in Kansas. However, each outbreak is unique and the investigation should be conducted in a way that ensures that all steps are completed. Several steps may be and sometimes should be conducted simultaneously, emphasizing the importance of a teamwork approach. For instance, control and prevention measures should be implemented as soon as the source of the foodborne outbreak is identified. Nonetheless, the first step in any investigation should be determining if an outbreak has occurred.

Good, self-study computer-based learning modules may be downloaded from www2a.cdc.gov/epicasestudies/dwnload_case.htm.

STEP 1. Determine that an outbreak has occurred.

The most important step in any outbreak investigation is to answer the following question:

"Has an outbreak occurred?"

Most reports of foodborne illness are sporadic and are often not associated with a recognized outbreak. The information collected during the initial report may help determine if a foodborne illness complaint is suggestive of an outbreak and whether or not an outbreak investigation is necessary. This preliminary information may also provide important clues about the cause and source of the outbreak and will help guide the direction of the investigation. Depending upon who receives the initial foodborne illness complaint, a LHD nurse, food inspector, medical investigator, or epidemiologist is an appropriate person to collect this initial information.

Detailed information that should be collected as soon as possible includes, but is not limited to, the following:

- Information about the person reporting the potential outbreak
- Number of persons reporting illness
- Date and time of illness onset for each ill person
- Specific symptoms experienced
- Number of doctor visits and hospitalizations
- Number of stool samples collected for testing
    - Recommend testing if not yet done
    - Testing may still be beneficial even if symptoms have ceased
- Specific diagnosis identified, if known
- Total number of persons exposed, both ill and not ill
- Date and time food was consumed
- Location where food was prepared and eaten
- Specific food or drink consumed, including ice
- Other commonalities, including other shared meals or activities
    - Earlier shared meals may be a source of infection
- Additional information, including specific activities and medications taken before the onset of illness
    - Other factors besides food may have influenced illness
- List of contact information of all persons exposed

The LHD nurse or outbreak investigator may use the "Enteric Outbreak Worksheet" and "List of Individuals Affected" Template in Appendix B to capture much of this information. Food inspectors may use the "Complaint Investigation Report" in Appendix D, which is provided by the KDHE Bureau of Consumer Health.

As mentioned in Section 2 , a **foodborne disease outbreak** is defined as two or more individuals (from different households) who experience a similar illness after eating a common food or different food from a common place. If only one person reports illness or if only one household is affected, then the report should be handled as a foodborne illness complaint. If one or more

similar reports of illness from different households are received, then the definition of an outbreak has been met, and the steps of an outbreak investigation should be conducted.

In some instances, the LHD nurse or outbreak investigator may detect a foodborne outbreak through routine surveillance and observing an unexplained, unexpected increase of a similar illness. This situation suggests the need for further investigation to determine the potential sources of infection. Completion of the "Enteric Disease Supplemental Form" in Appendix B or the disease-specific investigation form should be administered to collect pertinent information.

Medical investigators or epidemiologists at KDHE are available at (877) 427-7317 to assist infection control nurses or food inspectors with determining if an outbreak has occurred.

When verifying the existence of a foodborne outbreak, other reasons for the increased illness should also be considered, including changes in surveillance criteria, improved reporting, or the introduction of new or revised laboratory detection methods.

STEP 2. Contact and coordinate with key personnel.

Once the existence of an outbreak is verified, the next step is to answer the following question:

"Who needs to know that an outbreak has occurred?"

Because of the nature of outbreak investigations, personnel who fulfill key roles in an outbreak investigation should be notified as soon as possible. A successful investigation requires a teamwork approach and collaboration among, but not limited to, medical investigators, epidemiologists, infection control nurses, food inspectors, microbiologists, healthcare providers, regulators, and the media. Occasionally, foodborne outbreaks may involve individuals in a day care or an adult care setting, and personnel from these entities should also be notified.

Most communication will occur between the LHD infection control nurse, the food inspector assigned to the outbreak, the regional medical investigator and an epidemiologist. Depending upon the county affected and the source of the food (i.e., licensed food establishment, retail food establishment, or food processing plant), food inspectors at contract counties or state agency may need to be contacted.

Medical investigators and epidemiologists at KDHE are available at (877) 427-7317 to assist with coordination and communication of key personnel, especially between state and federal entities.

The table on the following page lists the agencies that may be involved in an outbreak investigation. This list is by no means exhaustive. Communication and collaboration with individuals within these agencies should be established prior to an outbreak occurring.

List of Agency Contacts

Agency	Phone No.	When to Contact
Local Health Departments (LHDs)		
Communicable Disease	See directory†	For all outbreaks
Environmental Health	See directory†	If food establishment‡ is involved
Administration	See directory†	If needed
Kansas Department of Health and Environment (KDHE)		
Epidemiologic Services	(877) 427-7317	For all outbreaks
Food Safety and Consumer Protection	(785) 296-5600	If a KDHE-regulated establishment is involved*
Diagnostic Microbiology Laboratory	(785) 296-1633	If specimens are submitted
Child Care Licensing and Registration	(785) 296-1270	If day care is involved
Public Information	(785) 296-5795	If needed
Kansas Department on Aging (KDOA)		
Complaint Program	(785) 296-1265	If nursing home, adult care, or long-term care facility is involved
Kansas Department of Agriculture (KDA)		
Retail Food Inspection Program	(785) 296-3511	If KDA-regulated establishment is involved**
Laboratory Program	(785) 862-0108	If needed
Public Information	(785) 296-2653	If needed
Centers for Disease Control and Prevention (CDC)		
Outbreak Response and Surveillance Team	(404) 639-2198	If needed
Food and Drug Administration (FDA)		
Kansas City District Office	(913) 752-2100	If a traceback is involved
U.S. Department of Agriculture (USDA)		
Food Safety and Inspection Service (FSIS) Office of Public Health Science	(402) 344-5162	If a traceback is involved

† The Kansas Public Health Directory is found at www.kdhe.state.ks.us/olrh/download/health_directory.pdf

‡ See Appendix A – Glossary of Terms for definitions.

*The Food Protection and Consumer Safety Program at KDHE regulates stand-alone restaurants, school food service operations, senior meal sites, and mobile food units.

**The Retail Food Inspection Program at KDA regulates grocery stores, restaurants in grocery stores, convenience stores, food wholesalers and warehouses, food processers, and food manufacturers.

Once an outbreak has been identified, the other two components of an investigation, Laboratory Analysis and Environmental Assessment, should be initiated. Refer to Sections 4 and 5 for information about these components.

STEP 3. Obtain clinical specimens and food samples for laboratory testing.

The question to be answered in Step 3 is the following:

"What is the organism that has caused illness?"

For most foodborne disease outbreaks, stool samples are collected from persons experiencing diarrhea to identify or confirm the pathogen. Blood cultures or serology testing are recommended for systemic infections, such as *Listeria monocytogenes* or hepatitis A virus. However, serology is less useful for most other foodborne illnesses.

When collecting clinical specimens for testing, keep the following in mind:

- **Stool collection should be encouraged whenever a person is experiencing or has recently experienced a diarrheal illness.** If possible, requests for stool samples should begin during the initial foodborne illness report, and such requests may continue throughout the outbreak investigation.
- Testing of all ill individuals is not useful nor is it a good utilization of resources. Collection of five specimens is usually sufficient to confirm the diagnosis.
- Laboratory testing may still be beneficial even after symptoms have ceased. For many foodborne illnesses, an ill person may continue to shed the pathogen in their stool even a few days after symptoms have disappeared and stool appears normal.
- Laboratory testing of individuals who are not ill is not routinely recommended, except when required to remove specific exclusion or restriction guidelines.
- Even in the absence of any laboratory confirmation, positive results, or definitive diagnosis, pathogens may still be implicated and public health measures may be implemented solely based on information collected during the outbreak investigation.

The pathogen, specifically bacteria or bacterial toxins, may also be identified through food samples. Viral and parasitic identification is extremely difficult. However, food samples will generally not be tested until the investigation yields a specific food or set of foods suspected and a specific pathogen identified by clinical specimens.

Refer to Section 4 for more information about collecting clinical specimens and food samples.

STEP 4. Implement control and prevention measures.

Although the source or the cause of the outbreak may remain unknown, the following question should be addressed:

"What can be done now to stop the spread of infection?"

Investigators should respond and implement appropriate public health action as soon as possible. Important control and prevention measures related to foodborne disease outbreaks may include, but should not be limited to, the following:

- Removal of contaminated food
- Exclusion and restriction of persons who are at high risk of spreading illness, including food handlers, day care attendees and providers, and persons involved with direct patient care
- Emphasizing good handwashing
- Closing the food establishment, if implicated and necessary

As more information becomes available, corresponding measures should also be taken as needed:

- Hosting conference calls with key agencies and investigators to discuss and coordinate the public health response
- Sending notices to healthcare professionals, schools, daycares, or nursing homes and other entities about the public health recommendation
- Developing a press release to educate the public about protecting oneself from foodborne illness

STEP 5. Define cases and conduct case finding.

Important questions to ask at this stage in an outbreak investigation are the following:

"What criteria should be used to determine if an ill person is part of an outbreak?"
"Who else is ill?"

Outbreaks and their corresponding investigations can quickly become complex. As a result, it is important to establish a clear understanding of the outbreak as early as possible. Organizing the preliminary information will help in the development of a case definition and may also provide clues about the pathogen and its transmission.

Line list

A line list or line listing is a table or a spreadsheet that summarizes information about persons who may be associated with an outbreak. Each row or observation represents a single individual, and each column represents a variable or a specific characteristic about the person. Column

information often includes identifying information, demographic information, clinical information, and other epidemiologic information, including risk factors possibly related to illness.

Preliminary information obtained during the early stages of an outbreak investigation can be organized using a line list. As the investigation progresses, the line list can be updated with any additional information that is collected.

Line List Example

ID	Name	Age	Sex	Ill	OnsetD	OnsetT	D	N	V	C	Wed
1	G.H.	45	F	Y	July 1	1:00a	Y	Y	Y	N	Y
2	C.T.	57	F	Y	June 30	11:00p	Y	Y	N	Y	Y
3	T.M.	39	M	Y	June 30	11:45p	Y	N	N	Y	Y
4	B.O.	32	M	N			N	N	N	N	Y
5	R.A.	27	M	N			N	N	N	N	Y
6	D.S.	16	M	Y	June 30	6:00a	N	Y	N	Y	Y

Key:

ID:	Identification number		
Name:	Person's initials	D:	Diarrhea (3 or more loose stools in a 24-hour period)
Age:	Age in years		
Sex:	Female or Male	N:	Nausea
Ill:	Reported illness	V:	Vomiting
OnsetD:	Date of illness onset	C:	Abdominal Cramping
OnsetT:	Time of illness onset	Wed:	Attended wedding reception on Saturday, June 29

This line list shows that four ill individuals experienced similar symptoms around the same time period. In addition, they all attended the same wedding. Based on this information, it is highly likely that these individuals became ill after eating something served at a wedding reception they attended two days earlier.

Line listings are working documents that are important for organizing information during an outbreak investigation. They are used to identify the criteria that may be included in a case definition, to arrange detailed data about those affected, and to provide a "bird's-eye view" of the outbreak. Refer to Appendix B to learn more about creating a line listing.

Case definition

A case definition is a set of criteria for determining who should be classified as a "case", or a person with the particular item(s) of interest. The case definition in the setting of an outbreak investigation usually includes four criteria: clinical information and information related to time, place, and person.

A case definition should be developed for every outbreak to ensure that ill persons are classified appropriately. Good case definitions often include simple and objective clinical criteria (e.g., diarrhea defined as three or more loose stools in a 24-hour period, vomiting, or nausea with a fever ≥ 101ºF). Laboratory confirmation may also be a criterion for classifying an ill person as a case. The criterion for time includes onset of illness during a specific time period (e.g., onset of illness in the past two weeks or onset of illness after June 15). For the place criterion, the case definition may include the location of exposure or the community the ill persons reside or work (e.g., Shawnee county or Curtis State Office Building). Regarding the person criterion, the case definition may focus on individuals with certain characteristics (e.g., persons who attended an event).

Early on in an investigation, it may be worthwhile to have a more inclusive case definition or several case classifications (e.g., confirmed, probable, or suspect). Such flexibility allows the investigator to better characterize the extent of the outbreak, to identify more persons potentially affected, and to start formulating hypotheses. For example, a case might be classified as confirmed if laboratory confirmation of the disease is available and if the time, place, and person criteria have been met. A case that exhibits the typical clinical characteristics of the disease and meets the time, place, and person criteria, but has no laboratory confirmation, might be considered a probable case. A case with some, but not all, of the criteria might be classified as a suspect case.

As more information becomes available, the case definition can be refined to ensure that the definition is as specific as needed and that as many of the "actual" cases are captured. Unfortunately, no case definition is 100% accurate, and persons with a mild infection may be missed.

Regardless of what criteria are used or the number of case classifications developed, the case definition should be applied consistently and without bias to all persons under investigation. Also, the definition should not include any exposure or risk factor that will later be evaluated or analyzed.

Case Definition Example

Component of definition	Question asked	Factual item
Clinical criteria	What were the predominant symptoms?	Acute onset of gastroenteritis
Time	When did infection occur?	Saturday evening
Place	Where did infection occur?	Wedding reception
Person	Who may have been affected?	Wedding attendee

Using the information from the line list presented earlier, a case may be defined as "an illness in any person who experienced an acute onset of gastroenteritis after attending the wedding reception on Saturday, June 29". Persons with ID numbers 1, 2, 3, and 6 may be considered cases based on this proposed definition.

If the definition is later refined to state that a case is "an illness in any person who experienced *diarrhea or vomiting* after attending the wedding reception on Saturday, June 29", then only persons with ID numbers 1, 2, and 3 will be classified as a case for this outbreak. Person with ID number 6 did not report diarrhea or vomiting, therefore does not meet the refined definition of a case.

The line list has been updated to include a variable labeled "Case". Each person has been assigned a "Y" or an "N", depending on if the person met the refined case definition or not.

ID	Name	Age	Sex	Ill	OnsetD	OnsetT	D	N	V	C	Wed	Case
1	G.H.	45	F	Y	July 1	1:00a	Y	Y	Y	N	Y	Y
2	C.T.	57	F	Y	June 30	11:00p	Y	Y	N	Y	Y	Y
3	T.M.	39	M	Y	June 30	11:45p	Y	N	N	Y	Y	Y
4	B.O.	32	M	N			N	N	N	N	Y	N
5	R.A.	27	M	N			N	N	N	N	Y	N
6	D.S.	16	M	Y	June 30	6:00a	N	Y	N	Y	Y	N

Case finding

When an outbreak is first recognized, investigators should attempt to "cast the net wide" to determine the extent of the outbreak and identify additional cases.

Case finding methods might include the following:

- Asking affected persons to provide the names and contact information of other ill persons
- Directly contacting physicians' clinics, hospitals, laboratories, schools, or nursing homes, as appropriate
- Alerting the public directly if needed to protect the public's health

The data obtained during case finding can provide clues about the outbreak and potential risk factors associated with illness. The "Enteric Disease Supplemental Form" in Appendix B may be used to systematically gather information from the ill persons, including identifying information, demographic information, clinical information, and risk factor information.

STEPS 6 – 10 describe steps that LHDs in Kansas may rely on KDHE medical investigators and epidemiologists for assistance, if needed. LHDs may elect to perform these steps themselves if resources permit.

STEP 6. Describe the outbreak by time, place, and person.

"What information about the outbreak is available thus far?"

Descriptive epidemiology should be performed to describe the information about the outbreak. As new and updated information becomes available during the course of an investigation, this process may need to be repeated.

Tools that are used to organize and depict the outbreak by time, place, and person include epidemic curves, maps, and frequency tables.

Epidemic Curves

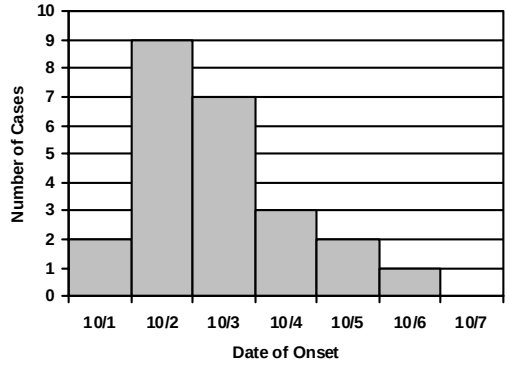
An epidemic curve (epi curve, for short) is a special type of histogram that provides a visual depiction of the outbreak and offers information related to time. An epi curve provides information about the extent of the outbreak, the potential period of exposure, and the possible mode of transmission. Investigators use an epi curve to determine where they are in the course of an outbreak – is the outbreak on an upswing, on the down slope, or has the outbreak ended? An epi curve also helps filter out "background noise" or outliers that may be "red herrings" and are not associated with the outbreak.

Most often, an epi curve plots the incubation period or date of onset of illness on the *x*-axis and the number of ill persons or cases on the *y*-axis. (NOTE: The maximum time period on the *x*-axis should not exceed ¼ to ⅓ of the incubation period, if the incubation period is known.) If the number of cases increases, then new cases are likely to appear in the future and the outbreak is continuing. On the other hand, if the number of cases begins to dwindle, then the outbreak has peaked and is coming to an end. Such information can aid investigators in determining what measures should be taken.

Refer to Appendix B for more information about how to create an epidemic curve.

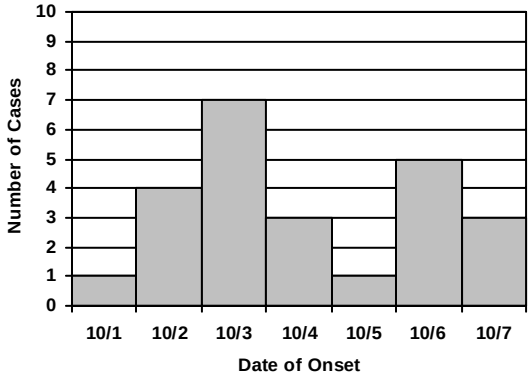
The following page describes the three main types of outbreaks which may be visually displayed through epi curves: common-source or point-source outbreaks, propagated-source or person-to-person outbreaks, and continual-source outbreaks.

Common-source or point-source outbreaks occur when individuals are exposed to some source of infection at the same time. An example of a point-source foodborne disease outbreak is illness experienced by guests who attended and ate food served at the same wedding reception. Foodborne disease outbreaks are most often point-source outbreaks.



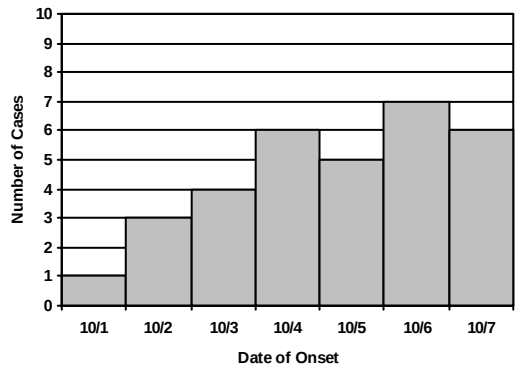
Epidemic curves of common-source outbreaks are characterized by a sharp rise in the number of cases that slowly tapers off. Most illness appears within one incubation period.

Propagated-source or person-to-person outbreaks occur when infection is spread from one person to another via the fecal-oral route. An example of a person-to-person outbreak is noroviral infections within a nursing home. Infection spreads from one resident to another because of poor handwashing and inadequate disinfection.



Epidemic curves of propagated outbreaks are characterized by progressive peaks, approximately one incubation period apart.

Continual-source outbreaks occur when a source remains contaminated and persons continue to be exposed to this source. An example of a continual-source outbreak is a community that continues to use water obtained from a contaminated well.

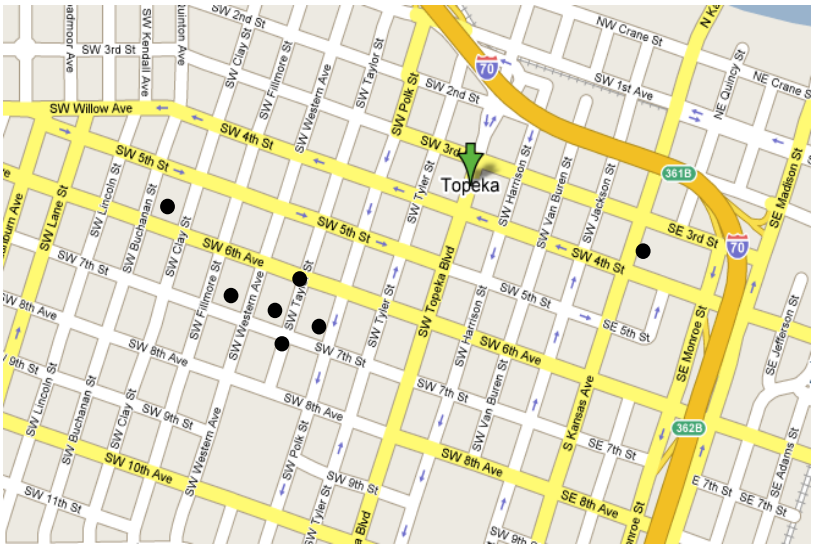


Epidemic curves of continual-source outbreaks are characterized by a gradual rise in cases that often plateaus.

Maps and pictures

Maps and pictures are helpful in showing the geographical location or layout of the place in which an outbreak has occurred. This spatial information may be crucial to the outbreak investigation and may provide clues about the source of the outbreak.

The "spot map" is a well-used pictorial of the spatial distribution of illness within a specific setting or area. In the following example of a spot map, ill individuals are plotted onto a map, with each point representing the residence of an individual. The cluster of cases may indicate a local exposure in the community. Other spot maps, such as place of employment or school attended, may be useful in some situations.



Frequency Tables

Frequency tables may be used to summarize the different attributes of the cases and may provide information related to person. A special characteristic identified among a majority of the cases may assist the investigators with potential exposures.

Frequency Table Example

Characteristic	No. of Cases	(%)
Age, < 1 yr	15	(30)
Age, 1 to 4 yrs	25	(50)
Age, 5 to 19 yrs	5	(10)
Age, 20 to 49 yrs	5	(10)
Age, 50+ yrs	0	(0)
Sex, Male	28	(56)

This table shows that of the 50 cases identified, 80% are under the age of five years. Investigators should consider exposures that affect mainly persons of this age group, such as foods or drinks most often eaten by children.

STEP 7. Develop possible hypotheses

After the preliminary information has been organized, the next question to answer is the following:

"What educated guesses can be made?"

A hypothesis is an educated guess about the cause of the outbreak and the factors that may have contributed to illness. Investigators develop possible hypotheses to guide the direction of the investigation and to initiate appropriate control measures. In most instances, investigators begin to formulate hypotheses during the initial phone call and continue to refine these hypotheses as more information becomes available.

The symptoms experienced, the incubation period, the recovery period, the food items served, the biological plausibility of pathogens, and the tools used to organize the outbreak information provide invaluable clues about the source and cause of illness. The sooner those hypotheses are developed, the sooner that public health interventions may be implemented. Hypotheses may need to be revised during the outbreak investigation, as new information becomes available.

Appendix E provides a table that lists foodborne illnesses and their corresponding incubation periods, signs and symptoms, recovery periods, and foods typically associated with illness. This table may be useful in developing hypotheses related to foodborne disease outbreaks.

STEP 8. Plan and conduct the epidemiologic study to test hypotheses.

STEP 8 is the focal point of any epidemiologic outbreak investigation. It involves a systematic way of evaluating the hypotheses already developed, of collecting more information about the illness and outbreak, and of answering the following questions:

"Why and how did illness occur?"
"What external factors or exposures were associated with illness?"

The STEPS conducted thus far have focused on the ill persons. However, a thorough outbreak investigation depends upon comparing exposures or risk factors among those who are ill and those who are not ill. These comparisons help to determine what happened, to identify what may have caused disease, and to recommend what can be done to prevent illness in the future.

The questionnaire and the study design are important tools used to further analyze an outbreak and make comparisons. Careful planning should be taken when designing the questionnaire, determining the appropriate study design, and organizing the logistics of carrying out the outbreak investigation.

Questionnaire
The questionnaire is a set of questions that captures detailed information from both ill and not-ill persons associated with a foodborne disease outbreak. A questionnaire can revolve around a specific event, a specific menu, or be generalized for foods commonly eaten and establishments frequented. In many instances, the questionnaire may serve as a means of finding more cases and for developing hypotheses. In general, an epidemiologist will be involved in producing an appropriate questionnaire.

The following are the main components of a questionnaire:

- Identifying information
  - Name
  - Address
  - City, County, State, Zip code
  - Phone number (day, evening, and cell)
- Demographic information
  - Age
  - Sex
  - Race
  - Occupation
- Clinical information
  - Specific symptoms experienced, if any
  - Date and time of illness onset
  - Date and time of recovery or duration of illness
  - Medical visits / hospitalizations
  - Specific diagnoses
- Exposure or risk factor information
  - Information related to specific food items consumed
  - Other potential exposures, including specific activities
- Knowledge of illness in others

When possible, a menu should be obtained, and specific food items, including ice, should be listed in the exposure or risk factor section. This will help the respondent remember the food items eaten.

Study Design
Two types of studies that are often used in foodborne disease outbreak investigations are retrospective cohort studies and case-control studies.

Retrospective Cohort Studies
A retrospective cohort study is often conducted for outbreaks involving a well-defined group of individuals. The investigator develops a questionnaire and retrospectively collects exposure and illness information from all persons in the group. Each person reports what exposures he or she had and whether or not he or she became ill following the exposures. The investigator then

analyzes the data collected to assess which exposure(s) are associated with the highest risk of illness.

For example, 150 individuals attended a wedding reception, and many of the attendees consumed the food items served at this reception. A few days later several attendees reported symptoms of diarrhea, vomiting, and abdominal cramping.

In this scenario, a well-defined group of individuals attended and ate food at a wedding reception. Some of the attendees subsequently reported illness following the shared experience. Based on this information, the investigator may conduct a retrospective cohort study to determine how many of the 150 persons experienced illness after the reception and to identify the specific food item(s) associated with illness.

Case-control Studies

A case-control study is appropriate for outbreaks in which individuals are not part of a well-defined group of individuals. During a case-control study, the investigator develops a questionnaire that is to be administered to persons with disease ("cases") as well as persons without disease ("controls"). Both groups of individuals are then asked to answer questions about specific exposures they may have had. The investigator analyzes the data and compares the odds of having an exposure among the cases versus the odds of having an exposure among the controls.

For example, eight cases of *Salmonella typhimurium* were reported during the same week in County X. Because County X normally observes one salmonellosis case within a one-month period, the investigator suspected that an outbreak had occurred. Case investigations were conducted, and the preliminary information revealed that five of the eight cases reported eating at Restaurant X before becoming ill.

In this scenario, the total number of persons at risk is unknown and not well-defined. The investigator has no means of knowing how many persons in the community may have eaten at Restaurant X during a certain time period. Moreover, even though five of the eight cases mentioned eating at this restaurant, the association between illness and eating at Restaurant X has not yet been well established. Based on this information, the investigator may conduct a case-control study to determine if there is an association between illness and eating at Restaurant X or if another exposure may be linked with illness.

Selecting controls in a case-control study

An essential component of the case-control study is selecting controls with whom the cases may be compared. Ideally, controls should be similar to cases except they do not have the disease. Controls should also represent the same population as the cases. If a certain exposure is reported more often by cases than controls, then this exposure is considered to be associated with illness.

Controls may be found in the following ways:

- Credit card slips from the food establishment, if one is implicated
- Neighbors or individuals from the same community as cases
- Patients from the same physician practice or hospital with a different disease diagnosis
- Friends of cases
- Persons in the phone book who share the same phone prefix

In the above case-control scenario, controls may be found in the community where Restaurant X is located.

The following table highlights the key similarities and differences between a cohort study and a case-control study used during an outbreak investigation.

RETROSPECTIVE COHORT STUDY *vs.* CASE-CONTROL STUDY in OUTBREAK INVESTIGATIONS

	Retrospective Cohort Study	**Case-Control Study**
Similarities		
Uses questionnaire to gather data	Yes	Yes
Makes comparisons between ill and not-ill persons	Yes	Yes
Evaluates associations between risk factors and illness	Yes	Yes
Differences		
Population affected	Well-defined	Poorly defined or unknown
Basis for inclusion into study	Common exposure	Presence or absence of illness
Question to be asked	"Did you become ill?"	"Were you exposed?"
Statistical analysis	Attack rates Food-specific attack rates Relative Risk ratios Odds ratios, but less frequently	Odds Ratio

Logistics

When the questionnaire has been developed and the study design has been selected, the logistics of carrying out the investigation should be considered, including the following:

- For a cohort study, a complete list of the group of individuals and their contact information is needed
- For a case-control study, the method for selecting controls needs to be decided
- If possible, the questionnaire should be tested for clarity prior to administration
- The personnel assigned to the study should become familiar with the questionnaire and any potential questions that may arise — LHD nurses and local or KDHE epidemiologists and medical investigators often share the task of conducting interviews
- A feasible method for administering and distributing the questionnaire should be discussed — self-administered or personal interview? In person, by phone, by mail, by electronic mail, or via the Internet?
- The data entry program or spreadsheet and method of entering data into the program should be considered

Once a plan of action has been developed, the outbreak study should be initiated as soon as possible. It may occasionally be necessary for phone calls to be made after hours or on the weekends. The longer the time lapse between exposure and the request for information, the poorer the quality of data that might be collected.

STEP 9. Analyze the data collected and interpret results.

After the data are collected, analysis and interpretation of the data should be conducted to answer these questions:

"What do the data reveal?"
"What can be concluded from all the information collected?"

Important tasks that should be performed to finalize the data include the following:

- Re-evaluate the case definition and ensure that persons classified as cases meet the case definition
- Update any epidemic curves previously plotted
- Calculate frequencies and percentages
- Compute the median and ranges for the incubation period and recovery period
- If the study design was a retrospective cohort study, calculate the attack rate, food-specific attack rates, and relative risk ratios
- If the study design was a case-control study, calculate the odds ratios
- Determine if results obtained are statistical significant (e.g., 95% confidence intervals)

More information about analyzing data obtained through a retrospective cohort study or a case-control study may be found in Appendix B.

Following analysis of the data, the results should be interpreted. Information gathered from the epidemiologic investigation should be compared with the findings obtained during the environmental assessment and the laboratory analysis. General knowledge about foodborne illnesses should be collectively used to help explain what happened, what measures should be taken immediately, and what steps should be taken to prevent similar situations from occurring in the future.

STEP 10. Report the findings of the outbreak investigation.

Although the outbreak has been contained, documentation is extremely important as a written record of the public health rationale for the activities as well as the findings of the investigation. Written reports answer the following questions:

"What public health lessons can be learned from this outbreak?"

In addition to documentation of activities and findings, a written report provides a record of performance, provides an account of the outbreak for potential medical and legal issues, and can improve the quality of future investigations.

Proper reporting of the investigation includes the following:

- Completion of the CDC eFORS form in Appendix B and submission to the Foodborne Disease Surveillance Coordinator at KDHE [Fax: (877) 427-7318]. This form is used to report foodborne outbreaks in Kansas to the CDC for national surveillance purposes.
- Preparing and writing a report that follows a scientific format of introduction, background, methods, results, discussion, recommendations, and supporting documents. Appendix B provides more information about the final report. Because final reports can be lengthy, a one-page preliminary or summary report should be prepared and disseminated until the final report is completed.
- Dissemination of the preliminary, summary, and final reports as widely as needed. At a minimum, the submitter should retain a copy, and additional copies should be provided to the outbreak investigators (local and at KDHE) and any facility involved in the outbreak. Synopses may also be used for press releases and postings on websites. Publications in local, regional or statewide documents offer wider review, allowing many others to learn from the experience.
- For outbreaks of intentional contamination, the dissemination of information in the form of reports and press releases should be coordinated with law enforcement officials.

INTENTIONAL CONTAMINATION OF FOOD

In an era of preparedness and a heightened threat of terrorism, investigators must consider intentional contamination of food when unintentional causes do not seem plausible.

From the epidemiologic perspective, the steps required to detect, diagnose, and reduce foodborne illness and outbreaks are the same ones required to prevent, identify, and respond to a terrorist attack on food. Epidemiologists depend upon science-based approaches to identify the cause, risk factor(s), or source of infection and to implement interventions to prevent others from becoming ill.

Unfortunately, foodborne disease outbreaks are common occurrences and attributing the cause of illness to an intentional contamination event can be difficult. Moreover, intentional events may involve diseases or characteristics of diseases that are often investigated. A number of clues may alert outbreak investigators to consider that a foodborne disease outbreak might be intentional.

Epidemiologic Clues

- Unusual agent or vehicle
- Multiple unusual or unexplained diseases in a single person
- High attack rate or severe outcomes or deaths
- Failure of patients to respond to conventional treatments
- Multiple exposure sites or vehicles with no apparent link
- Many ill persons presenting near the same time
- Deaths or illness among animals that may be unexplained and occur before illness in the human population

Law Enforcement Clues

- Intelligence or threat information
- Unlawful possession of pathogens by an individual or group
- Evidence of a credible threat in a specific area
- Identification of literature pretaining to the development or dissemination of particular agent

Source: International Association for Food Protection. *Procedures to Investigate Foodborne Illness*. 5th ed. 1999. Reprinted 2007.

Investigators in both law enforcement and environment will also have to work together to find the answers to the following questions:

- How would perpetrators gain access to food?
- How could a pathogen be introduced?
- How was the agent mixed or distributed?
- How might the pathogen spread in the environment?

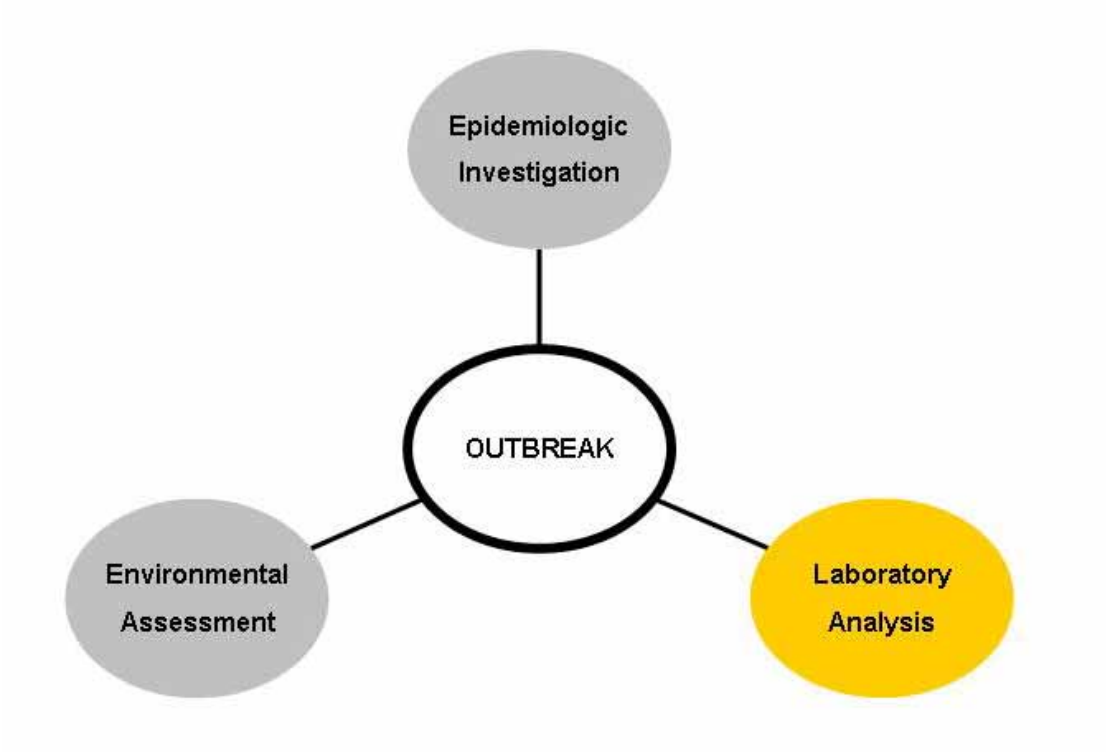
Although the epidemiologic approach remains the same regardless if the event is deliberate, these additional steps will need to be performed during the investigation of an intentional foodborne disease outbreak.

- Public health officials should work closely with law enforcement and emergency management agencies at all levels if an intentional event is suspected or identified.
- Local, state, and federal law enforcement agencies should be notified and will be the lead agencies in investigating the criminal activity.
- The KDHE Center for Public Health Preparedness (CPHP) should be notified in addition to other state and local emergency management agencies.
- Depending on the food vehicle and nature of the threat, other federal agencies that should be notified include the Food and Drug Administration, the U.S. Department of Agriculture, and the U.S. Department of Homeland Security.

A strong and flexible public health infrastructure is the best defense against any disease outbreak – naturally or intentionally caused. As with all public health events, coordination and cooperation among all agencies are critical to the success of any response.

Section 4

THE LABORATORY ANALYSIS



LABORATORY ANALYSIS DURING OUTBREAK INVESTIGATIONS

The main objectives of laboratory analysis during outbreak investigations are (1) to confirm the clinical diagnosis through identification of the causative agent from human specimens, (2) to ensure proper identification of the disease, and (3) to determine if the causative agent is present in the implicated environmental source, such as food.

General Guidelines for Clinical Specimen Collection

One of the most important factors in the identification of etiologic agents responsible for foodborne disease outbreaks is the collection of clinical specimens as early in the course of the investigation as possible. Most foodborne infections are diagnosed through the identification of the pathogen in stool collected from infected persons. Vomitus has also been used to detect certain organisms and confirm the etiology. Serology and blood cultures are recommended for the laboratory diagnosis of systemic infections.

Stool Specimens

Proper collection of stool specimens requires having stool kits readily available, using the appropriate kit for the suspected disease, and encouraging ill persons to submit a stool specimen.

Types of Stool Kits

The Kansas Health and Environmental Laboratories (KHEL) provide (1) an enteric stool kit and (2) an ova and parasite (O&P) kit.

Enteric stool kits contain a vial of modified Cary-Blair medium (0.16% agar concentration). These kits are used to test for *Campylobacter spp.*, *Salmonella spp.*, *Shigella spp.*, *Staphylococcus aureus, Bacillus cereus, Clostridium perfengens,* and Shiga toxin producing *E. coli* for culture and identification. These kits may also be used to test for norovirus and bacterial toxins. Testing for norovirus at KHEL is conducted only in outbreak situations and must be cleared by KDHE Epidemiologic Services at (877) 427-7317.

O&P stool kits contain a vial of formalin and a vial of polyvinyl-alcohol (PVA). These kits are used to identify intestinal parasites, including *Cryptosporidium parvum, Cyclospora cayetanensis, Entamoeba histolytica,* and *Giardia lamblia*. Testing for *Cryptosporidium parvum* and *Cyclospora cayetanensis* at KHEL is available, but must be requested.

Five sets of each kit (enteric and O&P) are recommended to be kept on hand at each local health department. The kits have expiration dates, so rotation or replacement is essential. A "Universal Laboratory Specimen Submission Form" must also accompany each kit.

Distributing Stool Kits and Obtaining Stool Specimens

The following list describes the steps that a local investigator should take to obtain stool specimens from ill persons.

1. Provide one stool kit to persons experiencing diarrhea, defined as three or more loose stools within a 24-hour period. In outbreak situations, stool specimens from five to eight ill individuals are ideal.
2. Instruct the ill person to use newspaper, a bedpan, plastic wrap, or aluminum foil to collect the stool specimen. The lining should be placed under the toilet seat and pushed slightly down in the center, but not touching the water, creating a "bowl" in which the specimen may be collected. The person should pass feces directly onto this lining. Prior to passing feces, the person should try to urinate so as not to mix the fecal specimen with urine.
3. If a bacteria, bacterial toxin, or norovirus is suspected, provide one enteric kit.
    a. Collect a marble-sized mass of feces and place into the specimen bottle containing the Cary-Blair medium (media should be pink to red in color, if not do not use). A plastic spoon or tongue depressor may be used to collect the specimen.
    b. Mix thoroughly by shaking the bottle vigorously after the bottle cap has been tightened securely and keep refrigerated until shipped.

4. If a parasite is suspected, provide one O & P kit.
    a. Collect two marble-sized specimens and place into each vial (formalin and PVA). The fecal material should be put in the preservative as soon as it is passed.
    b. Mix both vials thoroughly and keep at room temperature (do not refrigerate).
5. After the specimen has been collected, the person should dispose of the excess material into the toilet and discard the soiled lining.
6. Ask person(s) to return stool specimens to the health department by mail or in person.
7. Contact KDHE Epidemiologic Services at (877) 427-7317 and provide the epidemiologist with the names of the persons for whom specimens will be submitted for testing at KHEL.
8. Fill out the "Universal Laboratory Specimen Submission Form" for each specimen obtained. Under the subheading "Submitter Comments", indicate that the specimen is associated with an outbreak and that KDHE Epidemiologic Services has been notified. Refer to Appendix C for complete instructions on filling out this form and for associating the form with each specimen.
9. Refer to Appendix C for specific instructions on packing and shipping enteric kits to KHEL.
10. Refer to Appendix C for specific instructions on packing and shipping parasite kits to KHEL.

Vomitus Specimens

Vomitus can be tested for viruses and certain bacterial toxins. Specimens should be collected as soon as possible after onset of illness.

Obtaining Vomitus Specimens

The following list describes the steps that a local investigator should take to obtain vomitus specimens from ill persons.

1. Instruct the ill person to vomit directly into a sterile specimen container, such as a screwcapped jar or cup (a urine specimen container works well). If this is not possible, vomit in a container, bowl or plastic bag and transfer the vomitus to the screwcapped container with a clean spoon.
2. Place the cap securely on the container and tape the lid in place.
3. Place the container in a zip-top bag and seal the bag.
4. Refrigerate until shipped. DO NOT FREEZE.
5. Ask person(s) to return to health department by mail or in person.
6. Contact KDHE Epidemiologic Services at (877) 427-7317 and provide the epidemiologist with the names of the persons for whom vomitus specimens will be submitted for testing at KHEL.
7. Fill out the "Universal Laboratory Specimen Submission Form" for each specimen obtained. On Page 2 under "Submitter Comments", indicate that the specimen is related to an outbreak investigation and that KDHE Epidemiologic Services has been notified.

Refer to Appendix C for complete instructions on filling out this form and for associating the form with each specimen.

8. Place in a cardboard box with cushioning material, secure the box with a strip of tape and ship the box to KHEL.

Culture Isolates

The reference laboratory at KHEL will assist Kansas clinical laboratories and physicians in the identification, confirmation, and characterization of bacterial isolates such as *Brucella spp.*, *Bacillus anthracis*, and *Listeria spp.* Cultures should be clinically relevant. Only pure cultures should be submitted on agar slants with screw caps to prevent leakage during transit. These types of specimens will usually be submitted by a clinical laboratory.

Serology for Hepatitis A

Serum can be tested for hepatitis A IgM but must be preapproved by calling KDHE Epidemiologic Services at (877) 427-7317. Only serum is acceptable for hepatitis A serological testing (either a red top tube or separated sera).

The following steps should be taken when submitting serum for hepatitis A testing at KHEL:

1. Write the patient's name and date of specimen collection on the specimen tube.
2. Collect a minimum of 3 ml of serum.
3. Place the specimen tube in a bottle containing a Styrofoam insert and place in an outer cardboard box.
4. Complete the "Universal Laboratory Specimen Submission Form" for each specimen. On Page 2, select the HAV-IgM test under "Hepatitis". Under "Submitter Comments", indicate that the specimen is related to an outbreak investigation and that KDHE Epidemiologic Services has been notified. Refer to Appendix C for specific instructions on packing and shipping serum specimens to KHEL.

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Requesting Stool Kits, Mailers, and Submission Forms from KHEL

Enteric and Parasite stool kits, universal specimen submission forms, and mailers for serum samples may be ordered by contacting KHEL at (785) 296-1620 or downloading a copy of the "Requisition for Laboratory Specimen Kits" form from http://www.kdheks.gov/labs/packaging_and_shipping.html. A copy of this form is also found in Appendix C.

The following steps should be done when completing the Requisition Form:

1. Obtain a copy of the form.
2. Under the subheading "Bacterial", indicate the number of kits requested next to the label "Enteric Mailer".
3. Under the subheading "Parasite (O&P)", indicate the number of kits requested next to the label "Feces Mailer".
4. For Universal Specimen Submission Forms, specify the number required.
5. Under the subheading Serology, indicate the number of mailers requested next to the label "Multi-tube bottle with mailing box (5 tube box)
6. Fax completed form to KHEL at (785) 296-1641. If the kits are needed for outbreak purposes, contact KHEL directly at (785) 296-1620 to verify that the form has been received and to expedite the process.

For questions regarding patients and symptoms, contact KDHE Epidemiologic Services at (877) 427-7317. For questions regarding laboratory specimen submission, contact the KDHE Laboratory at (785) 296-1620.

General Guidelines for Food Sample Collection During an Outbreak Investigation

Microbiological analysis of food supports the epidemiologic investigation of a foodborne disease outbreak. The purpose of testing is to isolate and identify pathogenic microorganisms in food samples, which have been implicated in the outbreak. Samples collected as part of the investigation should be treated as official samples and should be collected in a manner that reflects the food as it was prepared, served, or used in preparation of the suspected meal.

Submission of Food Samples for Analysis at KHEL

Food sample collection is most often conducted by a food inspector. However, occasionally ill individuals will have food samples that can be brought to the local health department (LHD). However, all requests for laboratory examination of food or food-related samples must be made through KDHE Epidemiologic Services at (877) 427-7317. Laboratory examination of food will be performed only when pre-approved and after a foodborne pathogen has been detected in clinical specimens. Results of food analysis will be reported to Epidemiologic Services and the LHD responsible for submission.

Method for Collecting Food Samples

The value of laboratory results in microbiology depends on the quality of the samples submitted. Suspected foods should be collected as early in the investigation as possible. Food samples must be collected using aseptic techniques and appropriate containers. Samples must be refrigerated during storage and transport and must arrive at the food microbiology laboratory within three days of collection. Samples collected frozen should be stored and transported frozen on dry ice.

The following list describes the steps that should be taken when collecting food samples.

1. Whenever possible, food samples should be submitted in the original container as contamination of a sample may occur during manipulation.
2. If the food is a solid food item and shipping in the original container is not feasible, a representative sample should be taken. Take a sample from the geometric center and also take samples from several other locations in the food item.
3. If the food item is liquid and shipping in the original container is not feasible, stir or shake the liquid food item and pour or ladle the sample into a sterile leak-proof container.
4. Samples collected that are not in their original container should be collected using sterile collection implements and sterile collection containers that are leakproof.
5. Collect an adequate amount of the food sample—a minimum of 4-6 ounces or 100 grams (1/4 pound), if possible.
6. Fill containers no more than ¾ full and use adhesive tape to seal containers.
7. Keep food cold by placing in styrofoam coolers with ice packs.
8. Clearly document how the product was handled and who handled it after the sample is taken.

Labeling Food Samples

Information about the food samples should be properly documented, including the following

- Name and type of product
- Brand of product
- Product manufacturer and code or lot number
- Inspector name
- Date, time, and place of collection
- Establishment name

Transporting Food Samples

The following steps should be conducted when transporting food samples to KHEL.

1. Submit sample to the LHD infection control nurse in the county where the outbreak occurred.
2. LHD nurse should complete a KDHE "Universal Laboratory Specimen Submission Form" for each food sample submitted. On Page 1, under "Sample Information" and subheading "Clinical Source", mark "Other" and write 'Food Sample'. On Page 2, under the subheading "Submitter Comments", indicate that the food is related to an outbreak investigation and that testing was approved by KDHE Epidemiology at (877) 427-7317.
3. The food samples should be kept in their sealed containers and should be kept refrigerated until shipped to KHEL (or kept frozen if collected frozen).
4. The sealed containers should be placed into a Styrofoam cooler with ice packs or dry ice, the cooler should be placed into a cardboard box, and the box should be taped shut.
5. Ship the box to KHEL. Food should be kept cold during transportation and placed in a refrigerator when not in transit.

Recommended List of Sampling Equipment

- Sterile sample containers
  - Plastic bags (Whirl-Pak)
  - Screwcapped jars or tubes
- Sterile individually wrapped sample collection implements
  - Spoons
  - Knives
  - Spatulas
- Supporting equipment
  - Individually wrapped disposable gloves
- Sterilizing and sanitizing agents
  - Alcohol swabs
- Refrigerants
  - Ice pack
  - Thermometer
  - Insulated container (Styrofoam cooler)

Chain of Custody Procedures for Food Samples

Chain of custody establishes how environmental samples are collected, shipped, and received by KHEL. These procedures ensure that samples collected during an epidemiological investigation are valid, maintained under proper control, and their handling is documented so that any analytical results are viewed as reliable during any legal proceedings that may result from the investigation. The validity of sampling procedures as well as the handling of samples is increasingly under scrutiny in legal cases resulting from foodborne illness investigations. Chain of custody procedures begins with sample collection and follows the sample through until its destruction by the laboratory.

A sample is in someone's "custody" when:

1. It is in one's actual physical possession;
2. It is in one's view, after being in one's actual physical possession;
3. It is in one's actual physical possession and then locked up so that no one can tamper with it; or
4. It is kept in a secured area and restricted to authorized personnel only.

Chain of custody procedures

1. After food samples have been collected, sample containers should be sealed in one of the following ways:
    a. If a bottle or jar with a lid is used, the lid should be sealed with adhesive tape so that the ends overlap. Affix a bar code from the "Universal Submission Form" over the overlapped tape sealing the container.
    b. For sample containers that do not have a lid (such as a sack of flour or a Styrofoam container)
        i. Place the container in a larger plastic container or bag (ziplock bag).
        ii. Completely wrap the bag or plastic container with an unbroken strip of adhesive tape overlapping the ends of the tape.
        iii. Place another unbroken strip of tape at ninety degrees to the first strip of tape and wrap the tape completely around the package, overlapping the ends of the tape as before.
        iv. Affix a bar code from the "Universal Submission Form" over both tape overlaps.

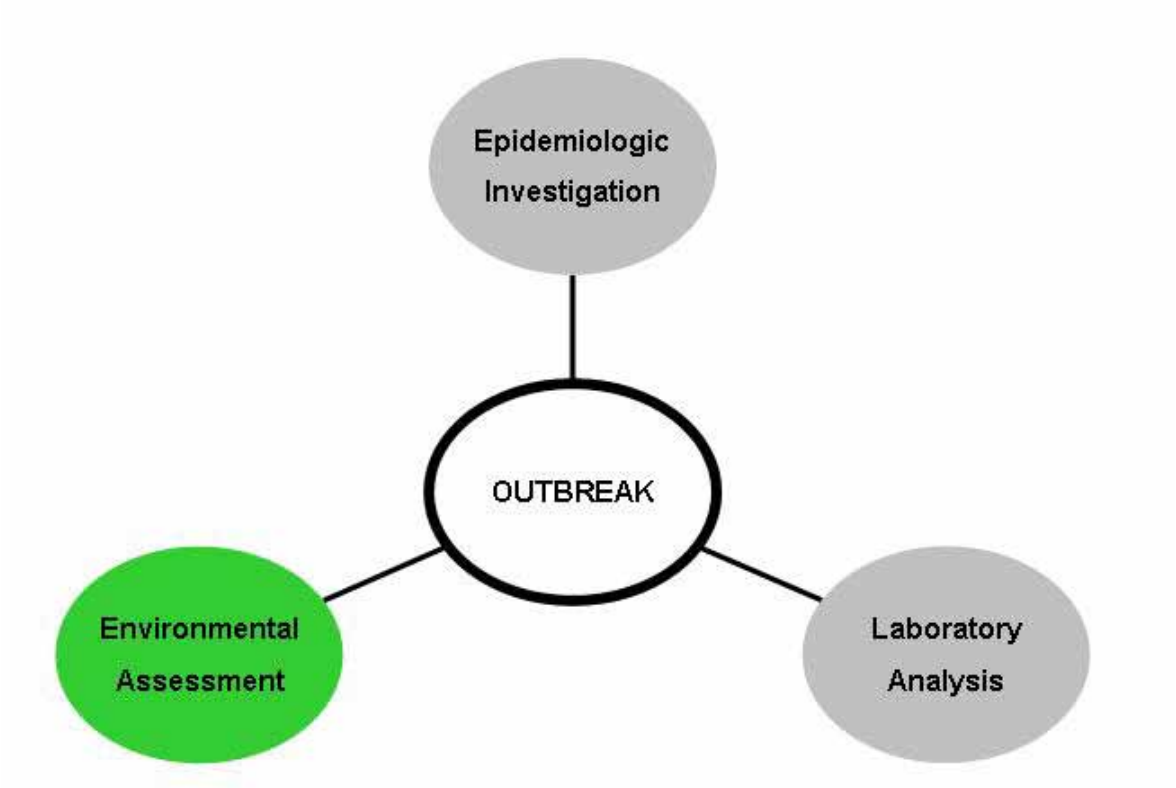
2. The food inspector should deliver the food samples to the local health department for shipping by the courier or FedEx. (Case law has determined that use of a parcel service or common carrier does not break the chain of custody, provided the seal(s) are intact after delivery of the package.)

3. The seal of the packages should only be broken in one of the following ways:
    a. By the receiving laboratory
    b. If the seal is broken by anyone other than the receiving laboratory:
        i. The person breaking the seal must initial and date the seal
        ii. The broken seal must remain with the package
        iii. A new bar code seal from the original universal submission form should replace the broken seal.

4. The chain of custody should be described on a separate form and include the following:
    a. Indicate when (date and time), where and from whom the sample was obtained.
    b. Describe where the sample had been kept and what type of container it had been stored in (i.e. plastic bag in consumer's refrigerator).
    c. Describe where and how the sample was held while in the custody of the food inspector and local health department and how it was transported to the lab
    d. Include signatures and dates from all persons who had custody of the sample during transfers to the lab.

Section 5

THE ENVIRONMENTAL ASSESSMENT



FUNDAMENTAL CONCEPTS OF FOOD MICROBIOLOGY

Familiarity with certain fundamental concepts related to food microbiology is essential to understanding the steps of an environmental outbreak investigation. Such concepts include potentially hazardous foods and the three main hazard categories.

Potentially Hazardous Foods

> **Potentially Hazardous Foods** (PHF) include any food or food ingredient (natural or synthetic) that is capable of supporting rapid and progressive growth of microorganisms. Examples of PHFs include beef, poultry, pork, shellfish, dairy products, eggs, some raw or cooked vegetables, and starchy foods (tofu, rice, potatoes, grains).

Certain conditions favor the growth of foodborne microorganisms within the environmental setting. Such conditions include the food, acidity, time, temperature, oxygen and moisture, collectively known as FAT TOM. (**NOTE**: Viruses and parasites cannot multiply in food or produce toxins.)

The following table describes the concepts of FAT TOM.

Condition	Explanation
Food	Nutrient-rich foods provide a good environment for microorganisms to thrive
Acidity	Bacterial growth is best in neutral or slightly acidic environments — foods with a pH range between 6.6 and 7.5
Time	Microorganisms proliferate if placed in optimal temperatures for longer than two hours
Temperature	Microorganisms thrive in the "danger zone" (temperatures between 41ºF and 135ºF) and some thrive in refrigerated temperatures
Oxygen	The presence or absence of oxygen influences growth of microorganisms
Moisture	Moisture content in foods influences microbial growth — high water activity (>.86) supports rapid growth

The optimum growth temperature range for most pathogens is between 60°F and 120°F. When bacterial spores are heat shocked into a vegetative state and the contaminated food is held at this temperature range, the bacteria can double in number every 15-20 minutes. Some pathogens, such as *Staphylococcus aureus* and *Bacillus cereus*, can also produce heat-stable toxins when the contaminated food is stored at optimum growth temperatures. These toxins, which cannot be destroyed by heating, can remain toxic even after reheating. Other pathogens, particularly *Listeria monocytogenes*, proliferate when placed under refrigeration temperature ranges.

Most foodborne pathogens survive, but do not grow, at below freezing temperatures and are destroyed at temperatures above 135°F.

High-Risk Factors in Food Preparation

Though some foods possess conditions that increase the likelihood of contamination, non-PHFs can still become contaminated and cause foodborne illnesses. Certain risk factors or practices and procedures pose the greatest potential for foodborne illness. The following list provides the three hazard categories and highest risk factors as determined by the CDC and FDA.

Contamination hazard

- Food Source
  - Food from unapproved or uninspected source (e.g., unpasteurized milk)
  - Adulterated food
- Cross-Contamination
  - Raw meats not separated from ready-to-eat foods
  - Equipment not properly cleaned and sanitized
- Poor personal hygiene
  - Lack of appropriate hand washing
  - Bare hand contact with ready-to-eat food
  - Ill food workers
- Environmental contamination
  - Improper storage, labeling, or usage of chemicals
  - Presence of insects or rodents
  - Lack of potable water
  - Improper sewage disposal

Survival hazard

- Inadequate cooking
- Improper reheating temperatures

Growth/Toxin production hazard

- Improper holding
- Unsafe cooling or inadequate refrigeration
- Improper cold/hot holding temperatures
- Preparation several hours before serving

CONDUCTING AN ENVIRONMENTAL ASSESSMENT

The main objectives of an environmental assessment are (1) to identify the contributing factors or source of contamination that may have increased the risk of illness and (2) to implement corrective actions to remove the contamination and enforce safe food preparation and handling practices.

Food Inspections in Kansas

As of March 2008, inspections of food establishments in Kansas are conducted by the Kansas Department of Health and Environment (KDHE) and the Kansas Department of Agriculture (KDA). The Food Safety and Consumer Protection Section (FSCPS) within the Bureau of Consumer Health (BCH) at KDHE regulates stand-alone restaurants, school food service operations, senior meal sites, and mobile food units. The Retail Food Inspection Program at KDA regulates grocery stores, restaurants in grocery stores, convenience stores, food wholesalers and warehouses, food processers, and food manufacturers. Both agencies have the responsibility of conducting environmental assessments during foodborne disease outbreak investigations in their regulated establishments.

Steps of an Environmental Assessment during an Outbreak Investigation

Similar to epidemiologic investigations, some of the steps may occur simultaneously depending on the situation. Each foodborne disease outbreak is unique, but following an established protocol may help ensure procedural uniformity.

Steps of an Environmental Assessment	
1.	Determine that an outbreak has occurred.
2.	Contact and coordinate with key personnel.
3.	Conduct food establishment inspection within 24 hours.
4.	Conduct a Hazard Analysis Critical Control Points (HACCP) Inspection as directed.
5.	Report findings.
6.	Revisit establishment and conduct after action meeting.

STEP 1. Determine that an outbreak has occurred.

Many of the foodborne disease outbreaks in Kansas are identified through foodborne illness complaints reported by private citizens to the food inspection programs at KDHE and KDA.

During the initial phone call with the complainant, it is important to obtain as much information as possible to determine if a foodborne disease outbreak has occurred. Information that should be collected includes the following:

- Date complaint received
- Complainant's name and contact information
- Establishment name and address
- Date and time person(s) ate at establishment
- Date and time of illness onset
- Symptoms experienced by ill person(s), including diarrhea, vomiting, nausea, abdominal cramps, fever
- Total number of persons reporting illness
- Of those reporting illness, number of households involved
- Of those reporting illness, any medical visits, hospitalizations, stool specimens collected?
- Total number of persons in the group, including those who did not become ill
- General food items eaten
- Any food items available for testing?
- Any other common activities or meals shared during the three days prior to illness?

As stated in Section 2, a foodborne disease outbreak is defined as one of the following:

1. Two or more individuals (from different households) who experience a similar illness after eating a common food or different food from a common place. This includes multiple foodborne illness complaints about the same facility within a 14-day time period.
2. An unexplained, unexpected increase of a similar illness, and food is a likely source.

Medical investigators and epidemiologists at KDHE are available at (877) 427-7317 to assist food inspectors with determining if an outbreak has occurred.

Refer to Appendix D for a copy of the Complaint Investigation Form that food inspectors at KDHE use to collect the information listed above.

STEP 2. Contact and coordinate with key personnel.

A successful investigation requires a teamwork approach and collaboration with key personnel. Early communication ensures that all steps in an epidemiologic investigation and environmental assessment are conducted in a timely manner.

If one of the definitions of a foodborne disease outbreak is met, the food inspector should contact and coordinate efforts with the following personnel:

- Supervisor or Contract Manager
- If KDHE inspector - the Topeka Office at (785) 296-5600
- KDHE Epidemiologic Services at (877) 427-7317, if not already notified
- Local health department infection control nurse, if not already notified

STEP 3. Conduct food establishment inspection within 24 hours.

When a foodborne illness complaint is reported, a food inspector should conduct an inspection of the food establishment within 24 hours of receiving the complaint. Often times, complaints are reported days after food is consumed. Nonetheless, timeliness is still important.

The purpose of the food inspection is to identify high-risk food preparation and handling practices, to enforce safe food handling practices, and to support the epidemiologic investigation.

Identifying High-Risk Food Preparation and Handling Practices

During the assessment, the inspector should identify factors which may increase the likelihood of contamination, the survival of etiologic agents, and the growth or production of toxins in potentially hazardous foods. (Refer to "Fundamental Concepts of Food Microbiology" for more information.) The information gathered may provide clues about the potential sources of infection and modes of contamination.

Occasionally, the food inspection may reveal that a food item may have become contaminated even before arrival to the food service establishment. In these instances, it is important to trace the implicated food item backwards through the production and distribution chain to identify the contaminated item and remove it from the food market.

Important information that food inspectors should collect when conducting a traceback investigation include the following:

- Label and package information
- Brand name
- Product name
- Package code/lot number
- Expiration/sell by/use by date
- Product size/weight
- Date of purchase
- Manufacturer name and address
- Distributor name and address (invoice information)
- All retail food establishments where purchased
- Whether or not food is an imported product

Communication with the U.S. Department of Agriculture or the Food and Drug Administration should be conducted as appropriate during traceback investigations. Epidemiologists at KDHE at (877) 427-7317 are available to assist with coordination of efforts with these national agencies.

Enforcing Safe Food Handling Practices

The Kansas Food Code provides a system of pro-active preventive safeguards designed to minimize the hazards that lead to foodborne illness thus ensuring safe food and acceptable levels of sanitation in food establishments. If the food inspector observes any high-risk practices or critical violations, corrective actions should be taken. Such actions include voluntary destruction of a food items found to be unfit for human consumption and exclusion or restriction of ill employees.

Supporting the Epidemiologic Investigation

During the food inspection, the inspector should conduct several tasks to support the epidemiologic investigation. These include (1) interviewing the manager and employees, (2) obtaining a copy of the menu, and (3) collecting food samples.

1. **Interview the manager and employees**
   The inspector should verify the number of employees working at the facility and ask about any illnesses observed or reported among the establishment employees. To better identify ill food handlers and their specific food handling duties, the inspector should distribute the "Gastroenteritis Surveillance Form for Employees" to all employees. This process has proven to be useful in several outbreaks and allows for more honest

responses from the employees. Refer to Appendix D for a copy of the form and related guidance.

NOTE: As previously mentioned, the key players in outbreak investigations have the crucial responsibility of maintaining confidentiality of the individuals involved in the outbreak. Identifying information should **never** be released unless needed to properly conduct the outbreak investigation and protect the public's health. Extreme consideration should be taken to ensure that information is released only on a "need-to-know" basis.

2. **Obtain a copy of the menu**
   The menu provides a list of the specific food items that may have been consumed. This list may be used to develop the epidemiologic questionnaire and will help respondents remember the food items eaten.

3. **Collect food samples**
   The food inspector should collect samples of suspect food(s), if still available. Though inspections are sometimes initiated days after the suspect food was prepared, sampling of similar foods may still be helpful. Methods for collecting and submitting food samples are discussed in Section 4.

Medical investigators and epidemiologists at KDHE are available at (877) 427-7317 to discuss the inspection and the findings.

STEP 4. Conduct a Hazard Analysis Critical Control Points (HACCP) Inspection.

In response to the foodborne disease outbreak notification, the food inspector may need to conduct a Hazard Analysis Critical Control Points (HACCP) inspection as directed.

HACCP (pronounced HAS-SIP) is a systematic approach to the identification, evaluation, and control of food safety hazards.

Source: *FDA Backgrounder*. "HACCP: A State-of-the-Art Approach to Food Safety." http://www.cfsan.fda.gov/~lrd/bghaccp.html

State and local food inspectors are trained to conduct a HACCP inspection, a science-based method of evaluating food handling procedures to identify hazards within the flow of food in an establishment. During a HACCP inspection, the food inspector identifies at critical points the biological, chemical, or physical hazards that may contribute to foodborne illnesses and outbreaks. Specific control measures are subsequently recommended to prevent, eliminate or reduce the hazards.

Refer to Appendix D for more detail about the HACCP principles and the procedures conducted by a food inspector during a HACCP inspection.

STEP 5. Report findings.

When the environmental outbreak investigation has been completed, the food inspector should communicate the findings with the investigation team. The Complaint Report Form, the inspection report, and the HACCP Inspection Report should be completed and submitted to the KDHE Topeka Office or to the KDA Topeka Office as appropriate. This information should also be provided to the corresponding LHD and KDHE Epidemiologic Services.

STEP 6. Revisit establishment and conduct after action meeting.

To prevent future occurrences, the establishment should be revisited. Reports which describe the findings of the epidemiologic investigation, the laboratory analysis, and the environmental assessment should be provided to the manager. Education and prevention measures should also be discussed to ensure that the establishment serves food that is safe, unadulterated, and honestly presented.

INTENTIONAL CONTAMINATION OF FOOD

As mentioned in Section 3, intentional contamination of food should be considered if epidemiologic clues and law enforcement clues suggest that an outbreak may have been deliberately caused.

From the perspective of the environmental assessment, unusual findings observed during the inspection may provide evidence that a pathogen or chemical was deliberately added.

Environmental Clues

- Reports of unusual color, odor, or appearance of food
- Evidence of tampering in food packaging
- Unusual agent or vehicle
- Chemicals that do not belong at the site
- Sick or dead animals in the vicinity of the food preparation facility

Source: International Association for Food Protection. *Procedures to Investigate Foodborne Illness*. 5th ed. 1999. Reprinted 2007.

In response to intentional contamination of food, food inspectors may need to conduct the following tasks:

- Collect samples of the suspected food vehicle, ingredients used to prepare the food, and environmental samples where the food was prepared or stored.
- Implement "Chain of Custody" procedures because all samples collected will be considered evidence in a criminal investigion. Refer to Section 4 for more information about "Chain of Custody".
- Follow special procedures to handle or destroy intentionally contaminated foods.
- Depending on the causative agent identified, provide assistance with the special decontamination of the facility where the food was prepared, stored, eaten, or purchased.

A strong and flexible public health infrastructure is the best defense against any disease outbreak – naturally or intentionally caused. As with all public health events, coordination and cooperation among all agencies are critical to the success of any response.

APPENDIX A
Glossary of Terms

GLOSSARY OF TERMS AND ACRONYMS[†]

Asymptomatic: Showing no symptoms of illness.

Attack rate: The occurrence of disease observed among a defined population over a limited period of time.

Bacterium: A one-celled living microorganism that can cause foodborne infections and intoxications.

Bare hand contact: Having bare hands in direct contact with prepared or ready-to-eat food items.

Biological hazard[*]: A bacterial, viral, or parasitic agent that may make food unsafe to eat. Often associated with microorganisms naturally found in raw meat and poultry products or microorganisms introduced during processing of meat and poultry products.

Carrier: Individuals who harbor an infectious agent but are asymptomatic.

Case definition: A set of criteria for determining who should be classified as a case. The definition is comprised of clinical information and should include information related to time, place, and person.

Case: A person with the particular item of interest or disease.

Case-control study: An observational, analytical study in which individuals are not part of a well-defined population. Inclusion into the study is dependent upon the presence or absence of illness or disease.

Chemical hazard[*]: Chemicals that are naturally occurring in foods (i.e., aflatoxins, mucotoxins, and shellfish toxins) or added during the processing of foods. Intentional or unintentionally added chemicals may include components of animal feed or drinking water, animal drugs, pesticides, food ingredients themselves, or chemicals used in the processing establishment, like lubricants, cleaners, paints, and coatings.

Cohort study: An observational, analytical study involving a well-defined group of individuals. Inclusion into the study is dependent upon a common experience of exposure.

Common-source outbreak: A type of outbreak that occurs when individuals are exposed to some point-source of infection at the same time.

[†] Many definitions were taken from (1) Last, JM ed. *A Dictionary of Epidemiology*, 3rd ed. New York: Oxford U. Press, 1995 and (2) Chin, J ed. *Control of Communicable Diseases Manual*, 17th ed. Washington DC: American Public Health Association, 2000.

[*] USDA – FSIS. *Guidebook for the Preparation of HACCP Plans.* September 1999.

Confidence intervals: **A**n estimated range of values within which the true relative risk (RR) or odds ratio (OR) is likely to fall 95% of the time.

Confidentiality: The obligation to not disclose identifying information unless needed to protect the public's health.

Confirmed disease outbreak: A foodborne disease outbreak in which laboratory analysis of appropriate specimens confirms a causative agent and epidemiologic analysis implicates the food as the source of the illness. [NOTE: Positive laboratory identification of the disease-causing organism is not necessary to determine that a foodborne disease outbreak has occurred nor is this identification needed to begin investigation.]

Consumer: A person who is a member of the public, takes possession of food, is not functioning in the capacity of an operator of a food establishment or food processing plant, and does not offer the food for resale.

Continual-source outbreak: A type of outbreak that occurs when a source remains contaminated and exposure and illness continues.

Control: In a case-control study, a person without illness or disease.

Control measure[‡]: Any action or activity that can be used to prevent, eliminate, or reduce a significant hazard.

Control point[‡]: Any step at which biological, chemical, or physical factors can be controlled.

Corrective action[‡]: Procedures that are initiated when a deviation or problem in the flow of food preparation is identified.

Critical limit[‡]: The maximum and/or minimum value at which a biological, chemical, or physical hazard must be controlled at a given critical control point to ensure food safety.

Critical control point (CCP)[‡]: A step at which control can be applied to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Cross-contamination: The transfer of pathogens from one food item to another food item during food preparation through cooking equipment, utensils, and the hands of food handlers.

Deviation[‡]: Failure to meet a critical limit.

Epidemic curve (epi curve): A histogram or graph that provides a visual depiction of the outbreak over time.

Epidemiology: The study of the distribution and determinants of health-related states or events within a specific population, and the application of this study to control health problems.

FAT TOM: Conditions that favor the growth of foodborne microorganisms within the environmental setting, specifically food, acidity, time, temperature, oxygen, and moisture.

Fecal-oral route: The ingestion of stool from an infected person or animal through food, liquids or direct contact.

Food establishment: An operation that stores, prepares, packages, serves, vends, or otherwise provides food for human consumption. Food establishments include a restaurant; satellite or catered feeding location; catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people; market; vending location; conveyance used to transport people; institution; or food bank.

Food handler: A person who directly handles or prepares food.

Food processing plant: A commercial operation that manufactures, packages, labels, or stores food for human consumption and does not provide food directly to a consumer.

Foodborne disease outbreak (FBDO): (1) Two or more individuals (from different households) who experience a similar illness after eating a common food or different food from a common place or (2) an unexplained, unexpected increase of a similar illness, and food is a likely source.

Foodborne illness: A disease acquired through eating or drinking contaminated food or liquids.

Foodborne infection: A disease caused by consuming food or liquids contaminated with bacteria, viruses, or parasites.

Foodborne intoxication: A disease caused by consuming food or liquids contaminated with toxins.

Gastroenteritis: Inflammation of the stomach and intestines.

HACCP[‡]: Hazard Analysis Critical Control Point. A science-based, systematic approach of identifying, evaluating, and controlling food safety hazards.

HACCP plan[‡]: A written documentation of food processing and handling procedures that is based upon the HACCP principles.

HACCP system[‡]: A HACCP plan in operation. The implementation of a HACCP plan.

Hazard: A biological, chemical, or physical agent that may cause foodborne illness.

Highly susceptible population: A group of persons who are more likely than other populations to experience foodborne disease because they are immunocompromised or older adults and in a

[‡] FDA. *HACCP: A State-of-the-Art Approach to Food Safety*. http://www.cfsan.fda.gov/~lrd/bghaccp.html.

facility that provides health care or assisted living services, such as a hospital or nursing home; or preschool age children in a facility that provides custodial care, such as a day care center.

Hypothesis: An educated guess based on observations.

Incubation period: The interval from the time an individual is infected to the time when symptoms first appear.

Jaundice: Yellowing of the skin and eyes as a result of accumulation of bile pigment in the blood.

Line listing: A table that summarizes information about persons associated with an outbreak. Information often includes identifying information, demographics, clinical information, and exposure or risk factor information.

Notifiable disease: A disease that is required by law to be reported to the public health authority. See Appendix C for the list of notifiable diseases in Kansas.

Odds ratio (OR): The ratio of the odds. This measure of association is used to determine whether a specific exposure is associated with a certain disease.

Onset: The date and time when clinical signs or symptoms first appear.

Outbreak: An unexpected, unexplained increase of disease occurring within a specific population at a given time and place.

Parasite: A single or multi-celled organism that can cause foodborne infections.

Pathogen: A disease-causing organism.

Person-to-person outbreak: See propagated-source outbreak.

Physical hazard[*]: A foreign material, such as glass, metal, or plastic, that may cause illness or injury

Point-source outbreak: See common-source outbreak.

Potentially Hazardous Food (PHF): Any food or food ingredient (natural or synthetic) that is capable of supporting rapid growth of microorganisms under certain temperatures. Examples include cooked or raw animal products, heat treated vegetables and starches, sprouts, and melons.

Propagated-source outbreak: A type of outbreak that occurs when infections is spread from one person to another via the fecal-oral route.

[*] USDA – FSIS. *Guidebook for the Preparation of HACCP Plans.* September 1999.

Public health surveillance: The routine collection, analysis, summarization, and dissemination of data for the purpose of preventing and controlling the spread of disease.

Pulsed-field gel electrophoresis (PFGE): A laboratory method used to separate bacterial isolates into genetic fragments, thus forming a unique "DNA fingerprint".

***p*-value:** The probability that a difference observed could have occurred by chance alone.

Questionnaire: A predetermined set of questions used to collect data. The main components include identifying information, demographics, clinical information, exposure or risk factor information, and knowledge of illness in others.

Ready-to-eat food: A food item that can be consumed without further preparation. Examples include raw vegetables and fruits, deli meats, bread, and ice.

Recovery period: The period when symptoms decline and illness improves.

Relative risk or relative risk ratio (RR): The ratio of the attack rate for ill persons who were exposed and the attack rate for ill persons who were not exposed.

Reservoir: The source of infection for a susceptible host.

Retail food store: Any establishment or section of an establishment where food and food products are offered to the consumer and intended for off-premises consumption, including delicatessens that offer prepared food in bulk quantities only.

Risk factor: An attribute or exposure that is associated with an increased occurrence of disease or other health-related event or condition.

Spot map: A pictorial of the spatial distribution of illness within a specific setting or area.

Stool: Feces.

Toxin: A poison produced or released by certain bacteria that can cause foodborne intoxications.

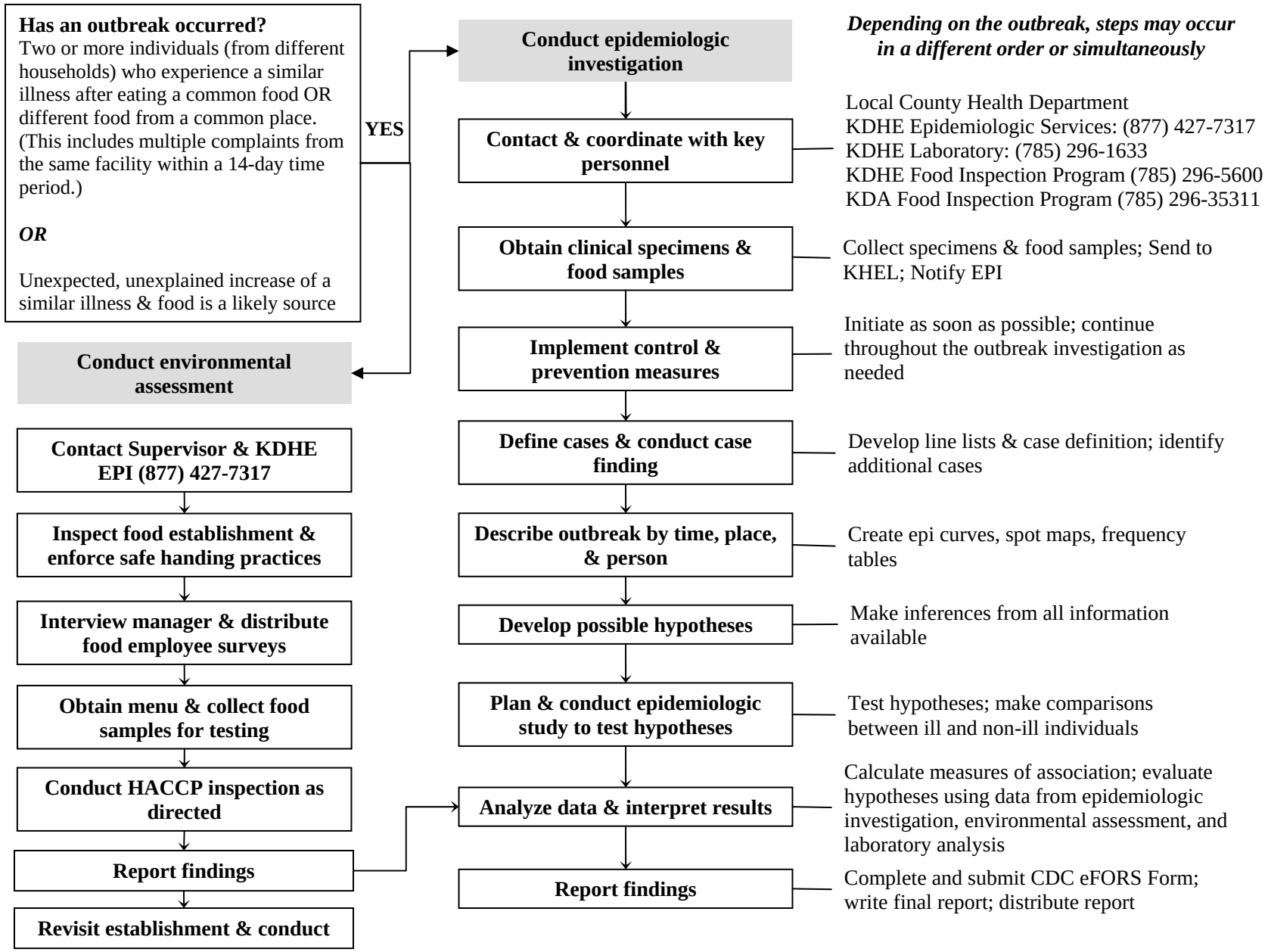
Traceback: The method of tracing implicated food items backwards through the production and distribution chain to identify the contaminated item and remove it from the food market.

Verification[‡]**:** Those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan.

Virus: A minute organism that can cause foodborne infections.

APPENDIX B
Supplemental Documents for Epidemiologic Investigations

FOODBORNE OUTBREAK INVESTIGATION FLOWCHART



Foodborne Disease Outbreak Checklist for Local Health Departments

The following checklist provides general steps that infection control nurses or administrators should take during a foodborne disease outbreak investigation.

- ❑ Confirm that a foodborne disease outbreak has occurred. Does it meet the definition for a foodborne disease outbreak?
  - Use the "Enteric Outbreak Worksheet" to collect preliminary information

- ❑ Contact and coordinate with KDHE Epidemiology at (877) 427-7317 for all outbreaks.

- ❑ Contact food inspector, if food service establishment is involved and the inspector has not already been notified.

- ❑ Contact initial complainant and administer the enteric questionnaire.

- ❑ Collect the names and contact information for all individuals (even those that did not become ill) that attended the event or meal.

- ❑ Contact all individuals that attended the event or meal and became ill and administer the enteric questionnaire.

- ❑ Ask each ill individual if they will submit a stool specimen. Stool specimen kits can be picked up at the local health department or they can be mailed to the individual's home address. Provide stool specimen kits to ill persons (5-8 persons) and send specimens to KDHE Laboratory.
  - Have stool kits available for distribution.
  - Submit human and food samples to KDHE Laboratory using the "Universal Laboratory Specimen Submission Form" for each sample.
  - Call KDHE Epidemiology at (877) 427-7317 to notify that specimens have been sent.

- ❑ Implement prevention and control measures.
  - Give special restriction or exclusion instructions to ill persons who are food handlers, are associated with day care, or involved with direct patient care.
  - Emphasize good handwashing.

- ❑ Conduct case finding among other family members, others attending common functions.

- ❑ Continue coordination with KDHE and food inspector assigned to outbreak.
  - Assist in the administration of questionnaires if a cohort or case-control study is conducted.

- ❑ If disease is a notifiable disease, report information to KDHE via KS-EDSS, fax, or mail.

- ❑ Write final report, if resources permit. At the minimum, provide lead KDHE investigator with pertinent information to write the final report.

ENTERIC OUTBREAK WORKSHEET

Date _____/_____/_____ **Investigator:** _____

COMPLAINANT INFORMATION

Name: _____ **Phone:** (_____) _____- _____

Address: _____ **City:** _____

County: _____ **Zip Code**: _____ **Email:** _____

ILLNESS INFORMATION

Date First Person Became Ill: **Date** _____/_____/_____ **Time** _____:_____ ❑ a.m. ❑ p.m.

Date of First Known Exposure: **Date** _____/_____/_____ **Time** _____:_____ ❑ a.m. ❑ p.m.

Symptoms Reported:

☐ Diarrhea ☐ Vomiting ☐ Nausea ☐ Abdominal cramps

☐ Fever ☐ Bloody stool ☐ Headache ☐ Muscle aches

☐ Chills ☐ Loss of appetite ☐ Fatigue ☐ Dizziness

☐ Other symptoms: _____

Number of individuals who:

Number of Ill Individuals: _____ **Had physician visits:** _____

Number of Households: _____ **Had ER visits:** _____

Total Number in Group: _____ **Were hospitalized:** _____

EXPOSURE INFORMATION

Place of Exposure: _____ **Address:** _____

City: _____ **County:** _____ **Phone: (_____) _____-_____**

Setting Type: ❑Day Care ❑Nursing Home ❑Workplace ❑Private Residence

❑Reception Hall ❑Restaurant ❑ School ❑ Other: _____

If a Catered Event:

Company: _____ **Address:** _____

City: _____ **County:** _____ **Phone: (_____) _____-_____**

Any other common activities during the 5 days before the first onset of illness?: ❑ Yes ❑ No

If yes: Where _____ Date: _____/_____/_____ Time: _____:_____ ❑ a.m. ❑ p.m.

Where _____ Date: _____/_____/_____ Time: _____:_____ ❑ a.m. ❑ p.m.

Any other shared meals, snacks, or drinks with the ill persons in your party: ❑ Yes ❑ No

If yes: Where _____ Date: _____/_____/_____ Time: _____:_____ ❑ a.m. ❑ p.m.

Where _____ Date: _____/_____/_____ Time: _____:_____ ❑ a.m. ❑ p.m.

LIST OF INDIVIDUALS AFFECTED

Name	Address	Phone	Contacted	Age	Sex	Ill	Stool Kit	Comments[†]
			☐ Yes ☐ No		☐ M ☐ F	☐ Yes ☐ No	☐ Mailed ☐ Picked Up ☐ Returned	
			☐ Yes ☐ No		☐ M ☐ F	☐ Yes ☐ No	☐ Mailed ☐ Picked Up ☐ Returned	
			☐ Yes ☐ No		☐ M ☐ F	☐ Yes ☐ No	☐ Mailed ☐ Picked Up ☐ Returned	
			☐ Yes ☐ No		☐ M ☐ F	☐ Yes ☐ No	☐ Mailed ☐ Picked Up ☐ Returned	
			☐ Yes ☐ No		☐ M ☐ F	☐ Yes ☐ No	☐ Mailed ☐ Picked Up ☐ Returned	
			☐ Yes ☐ No		☐ M ☐ F	☐ Yes ☐ No	☐ Mailed ☐ Picked Up ☐ Returned	
			☐ Yes ☐ No		☐ M ☐ F	☐ Yes ☐ No	☐ Mailed ☐ Picked Up ☐ Returned	
			☐ Yes ☐ No		☐ M ☐ F	☐ Yes ☐ No	☐ Mailed ☐ Picked Up ☐ Returned	
			☐ Yes ☐ No		☐ M ☐ F	☐ Yes ☐ No	☐ Mailed ☐ Picked Up ☐ Returned	
			☐ Yes ☐ No		☐ M ☐ F	☐ Yes ☐ No	☐ Mailed ☐ Picked Up ☐ Returned	

[†] Comments may include information about medical visits, hospitalization, date of illness onset, symptoms experienced, etc.

OTHER COMMENTS or NOTES:

____

____

____

____

____

Cancel Form

Enteric Disease Supplemental Form

Campylobacter, E. coli, Listeriosis, Salmonella, or Shigella Infection

Kansas Department of Health

Epidemiologic Case History

Condition

- ○ *Calicivirus/Norwalk-like virus (norovirus)*
- ○ *Campylobacter Infection (Campylobacter spp.)*
- ○ *Cryptosporidiosis (Cryptosporidium parvum)*
- ○ *Enterohemorrhagic Escherichia coli (EHEC)*
- ○ *Enterohemorrhagic Escherichia coli O157:H7*
- ○ *Enterohemorrhagic Escherichia coli shiga toxin positive (not serogrouped)*
- ○ *Enterohemorrhagic Escherichia coli shiga toxin positive (serogroup non-0157)*
- ○ *Giardiasis (Giardia lamblia)*
- ○ *Salmonellosis (Salmonella spp.)*
- ○ *Shigellosis (Shigella spp.)*
- ○ *Cyclosporiasis (Cyclospora cayetanensis)*
- ○ *Hepatitis A*
- ○ *Listeriosis (Listeria monocytogenes*

* indicates required fields

Case Type*
○ *Human Case* ○ *Non Human Case*

Classification*
○ *Confirmed* ○ *Not a Case* ○ *Probable* ○ *Suspect* ○ *Deleted* ○ *Unknown*

Supplemental Form Status
○ *Not Done* ○ *Form Complete* ○ *Form in Progress* ○ *Form Approved* ○ *Form Sent to CDC*

Report Date*
mm/dd/yyyy

Patient Demographic Information

* indicates required fields

Last Name*	First Name*	Middle Name	Name Type*	Age

Age Unit
○ *Days* ○ *Months* ○ *Unknown* ○ *Weeks* ○ *Years*

Date of Birth
mm/dd/yyyy

Race*
(Check all that apply)
☐ *American Indian or Alaska Native* ☐ *Asian* ☐ *Black or African American*
☐ *Native Hawaiian or Other Pacific Islander* ☐ *White* ☐ *Unknown*

Ethnicity*
○ *Hispanic or Latino* ○ *Not Hispanic or Latino* ○ *Unknown*

Sex*
○ *Failure to Report* ○ *Female* ○ *Male* ○ *Other* ○ *Transexual* ○ *Unknown*

Street Address

City	County	State	Zip

Evening Phone
###-###-####

Daytime Phone
###-###-####

Occupation

Patient Demographic Information cont.

High Risk Potential:
(Check all that apply)

- ☐ *Contact to a confirmed case*_____
- ☐ *Contact to a suspected case*_____
- ☐ *Daycare attendee*_____
- ☐ *Food handler*_____
- ☐ *Direct patient care worker*_____
- ☐ *Institutional resident or staff*_____
- ☐ *Daycare worker*_____
- ☐ *Animal handler*_____
- ☐ *Other*_____

If enrolled in day care, please complete the information below.

Name of Facility	**Evening Phone** ###-###-####
Street Address	**City**
County / **State** / **Zip**	

Person Providing Report

Name of Reporting Facility*

Clinical and Laboratory Data

Individual diagnosed with
○ *Hemolytic Uremic Syndrome (HUS)* ○ *Thrombotic Thrombocytopenic Purpura (TTP)*

Was a stool specimen collected?
○ *Yes* ○ *No*

Diarrhea?
○ *Yes* ○ *No* ○ *Unknown*

Number of Stools
○ *0 - 2* ○ *3 - 10* ○ *11 and above*

Blood in Stool?
○ *Yes* ○ *No* ○ *Unknown*

Vomiting?
○ *Yes* ○ *No* ○ *Unknown*

Nausea?
○ *Yes* ○ *No* ○ *Unknown*

Abdominal Cramps?
○ *Yes* ○ *No* ○ *Unknown*

Muscle Ache?
○ *Yes* ○ *No* ○ *Unknown*

Other Symptoms?
○ *other*_____

Fever?
○ *Yes* ○ *No* ○ *Unknown*

If Yes, specify highest temperature:

Scale:
○ *Fahrenheit* ○ *Celsius*

Was a physician consulted for this illness?
○ *Yes (please complete the information below)* ○ *No*

Physician Information

Name of physician:	**Evening Phone** ###-###-####
Street Address	**City**
County / **State** / **Zip**	

Clinical and Laboratory Data cont.

Antibiotic Information

Was case treated with antibiotics anytime in the 14 days prior to illness?	Type of treatment/antibiotic	Reason for taking	Date started
○ *Yes* ○ *No* ○ *Unknown*			mm/dd/yyyy

Date completed	Was case treated with antibiotics for this illness?	Type of treatment:	Date Started:
mm/dd/yyyy	○ *Yes* ○ *No* ○ *Unknown*		mm/dd/yyyy

Date completed:	Was organism resistant to antibiotics?	If yes, specify resistance pattern:
mm/dd/yyyy	○ *Yes* ○ *No* ○ *Unknown*	

Is the patient on any medication or receiving any treatment which may suppress their immune system (i.e. Corticosteroids or Cancer Chemotherapy)?	If yes please specify medication or treatment:	Did patient recover?
○ *Yes* ○ *No* ○ *Unknown*		○ *Yes* ○ *No* ○ *Unknown*

Recover Date	Recover Time
mm/dd/yyyy	

Exposure/Transmission

Did anyone else (in your family ..) recently have similar symptoms?

○ *Yes (please complete below)* ○ *No* ○ *Unknown*

Name	Age	Sex	Relationship to Case	Occupation	Symptoms	Date of Onset
						mm/dd/yyyy

Any restaurant, commercial food establishments, or group gatherings visited within the 7 days prior to onset of illness?

○ *Yes (please complete below)* ○ *No* ○ *Unknown*

Name of Establishment	City, County, State	Foods eaten	Date of Exposure
			mm/dd/yyyy

Travel History

Did the patient Travel prior to the onset of illness?

○ *Yes* ○ *No* ○ *Unknown*

If yes, please complete below:

Where:	Departure Date:	Return Date:
	mm/dd/yyyy	mm/dd/yyyy
Where:	**Departure Date:**	**Return Date:**
	mm/dd/yyyy	mm/dd/yyyy

Water Exposure

Possible water sources:
(Check all that apply)

☐ *Municipal Water System*_____ ☐ *Bottled Water*_____ ☐ *Private Well*_____
☐ *Rural Water System*_____ ☐ *Other (specify):*_____

Did patient drink water from other than a treated municipal system (i.e., stream, well)?

○ *Yes* ○ *No* ○ *Unknown*

Other Possible Exposure Information

Was there contact with pets or animals within 7 days prior to onset?

○ *Yes* ○ *No* ○ *Unknown*

If yes, please indicate below:
(Check all that apply)

☐ *Caged Birds* ☐ *Cats* ☐ *Cattle* ☐ *Chickens* ☐ *Dogs* ☐ *Ducks*
☐ *Frogs* ☐ *Goats* ☐ *Guinea Pigs* ☐ *Hamsters* ☐ *Horses* ☐ *Lizards*
☐ *Mice* ☐ *Parakeets* ☐ *Pigeons* ☐ *Pigs* ☐ *Poultry* ☐ *Rabbits*
☐ *Rats* ☐ *Sheep* ☐ *Snakes* ☐ *Turkeys* ☐ *Turtles* ☐ *Other*_____

Other Exposure Information

Other Birds?	**If yes, please specify**	**Other Reptiles?**	**If yes, please specify**
○ *Yes* ○ *No* ○ *Unknown*		○ *Yes* ○ *No* ○ *Unknown*	

Other Animals?	**If yes, please specify**
○ *Yes* ○ *No* ○ *Unknown*	

Were any of these animals ill near the time of onset

○ *Yes* ○ *No* ○ *Unknown*

If yes, please describe:

Where were the animals located?
(Check all that apply)

☐ *Home* ☐ *Farm* ☐ *School* ☐ *Pet Store* ☐ *Zoo* ☐ *Petting Zoo* ☐ *Other*_____

Within 7 days prior to onset of illness, did the patient participate in:

Activity	Participation	Date	Location
		mm/dd/yyyy	
Outdoor Activities			
Swimming			
Chlorinated Pool			
Wading Pool			
River/Lake/Pond			

Food History

Did case eat any of the following within 7 days prior to the onset of illness?

Food Product	Consumed	City, County, State	Variety or Brand(s)	Supplier	Supplier City
1. Chicken					
2. Hamburger					
3. Sausage					
4. Hot Dogs					
5. Lunch Meat					
6. Eggs					
7. Milk raw					
8. Milk past.					
8. Fresh juice					
10. Fresh berries					
11. Fresh melon					
12. Other fresh fruit					
13. Lettuce					
14. Alfalfa Sprouts					

Other fresh vegetables	Other Food Item 1	Other Food Item 2

At what store(s) do you regularly shop for groceries?

Cancel Form

KANSAS NOTIFIABLE DISEASE FORM

Today's Date: ____ / ____ /____

Patient's Name: _____
Last First Middle

Day Phone: _____ **Evening Phone:** _____

Residential Address: _____

City: _____ **Zip:** _____ **County:** _____

Ethnicity: Hispanic or Latino Not Hispanic or Latino Unknown

Race: ***(Circle all that apply)***

American Indian/Alaska Native Asian Black or African American

Native Hawaiian or Other Pacific Islander White Unknown

Sex: M F **Date of Birth:** _____ / _____ / _____ **Age if DOB unknown:** _____

Disease Name: _____

Symptoms: Onset: ___ / ___ /____ **List the 3 most prominent symptoms**:

Symptom 1: _____ Symptom 2:_____ Symptom 3:_____

Outbreak associated? Y N **Died?** Y N **Hospitalized?** Y N

Institutional Residence? None Nursing Home Correctional Residential Hospital Psych

Physician Name: _____ **Physician Phone:** _____

Laboratory Information:

Specimen Collection Date: _____ / _____ / _____ Date Reported To You: _____ / _____ / _____

Name of Test Performed: _____ Results of Test: _____

Name of Laboratory: _____ Laboratory Results Attached? Y N

Treatment Information:

Date of Treatment: _____ / _____ / _____ Treatment Type and Dosage: _____

Treatment Status: Complete On-going Discontinued

Name of person reporting: _____ **Phone:** _____

Comments: _____

Mail or fax reports to your local health department and/or to:
Bureau of Epidemiology & Disease Prevention - Disease Surveillance, 1000 SW Jackson, Suite 210, Topeka, KS 66612-1274
Fax: 1-877-427-7318 (toll-free)

(Revised 04/2006)

2006 REPORTABLE DISEASES IN KANSAS for health care providers, hospitals, and laboratories

(K.S.A. 65-118, 65-128, 65-6001 - 65-6007, K.A.R. 28-1-2, 28-1-4, and 28-1-18. Changes effective as of 4/28/06)

☏ **- Indicates that a telephone report is required by law within four hours of *suspect* or *confirmed* cases to KDHE toll-free at 1-877-427-7317**

ⓘ **- Indicates that an isolates must be sent to:** Division of Health and Environmental Laboratories
Forbes Field, Building #740, Topeka, KS 66620-0001
Phone: (785) 296-1636

Acquired Immune Deficiency Syndrome (AIDS)
Amebiasis
Anthrax ☏
Arboviral disease (including West Nile virus, Western Equine encephalitis (WEE) and St. Louis encephalitis (SLE)) - indicate virus whenever possible
Botulism ☏
Brucellosis
Campylobacter infections
Chancroid
Chlamydia trachomatis genital infection
Cholera ☏
Cryptosporidiosis
Cyclospora infection
Diphtheria
Ehrlichiosis
Escherichia coli O157:H7 (and other shiga-toxin producing E. coli, also known as STEC) ⓘ
Giardiasis
Gonorrhea
Haemophilus influenza , invasive disease
Hantavirus Pulmonary Syndrome
Hemolytic uremic syndrome, postdiarrheal
Hepatitis, viral (acute and chronic)
Hepatitis B during pregnancy
Human Immunodeficiency Virus (HIV) (includes Viral Load Tests)
Influenza deaths in children <18 years of age
Legionellosis
Leprosy (Hansen disease)
Listeriosis
Lyme disease
Malaria
Measles (rubeola) ☏
Meningitis, bacterial ☏
Meningococcemia ⓘ☏
Mumps ☏
Pertussis (whooping cough) ☏
Plague *(Yersinia pestis)* ☏
Poliomyelitis ☏
Psittacosis
Q Fever *(Coxiella burnetii)* ☏
Rabies, human and animal ☏
Rocky Mountain Spotted Fever
Rubella, including congenital rubella syndrome ☏
Salmonellosis, including typhoid fever ⓘ
Severe Acute Respiratory Syndrome (SARS) ⓘ☏
Shigellosis ⓘ
Smallpox ☏
Spongioform encephalopathy (STE) or prion disease (includes vCJD)
Streptococcal invasive, drug-resistant disease from Group A *Streptococcus* or *Streptococcus pneumoniae* ⓘ
Syphilis, including congenital syphilis
Tetanus
Toxic shock syndrome, streptococcal and staphylococcal
Trichinosis
Tuberculosis, active disease ⓘ☏
Tuberculosis, latent infection
Tularemia
Varicella (chickenpox)
Viral hemorrhagic fever ☏
Yellow fever

In addition, laboratories must report:

- Viral load results of reportable diseases
- ALL blood lead levels, as of 12/2002 (KCLPPP/ABLES)
- CD4+ T-lymphocyte count < 500/ µl or CD4+ T -lymphocytes <29% of total lymphocytes

Outbreaks, unusual occurrence of any disease, exotic or newly recognized diseases, and suspect acts of terrorism should be reported within 4 hours by telephone to the Epidemiology Hotline: 1-877-427-7317

Mail or fax reports to your local health department and/or to:
Bureau of Epidemiology & Disease Prevention - Disease Surveillance, 1000 SW Jackson, Suite 210, Topeka, KS 66612-1274
Fax: 1-877-427-7318 (toll-free)

Creating a Line Listing[1]

Line listings can be created by hand (paper copy) or on a computer. If a computer (electronic versions) is available commercial software programs such as Microsoft® Office Excel® or Microsoft® Office Access® can be used. One advantage of creating an electronic line listing is that frequency distributions and epidemic curves can be generated rapidly. The information that goes into a line listing is generally collected on a questionnaire. The important elements from the questionnaire are then used to create a line listing.

To set up a line listing, create a table in which each row represents a case and each column represents a variable of interest.

Variables

- Personal information
  - Name, address, phone number, and county of residence
- Demographic information
  - Age or date of birth, gender, race and occupation
- Illness Information
  - Date and time of onset, date and time of recovery, date of specimen collection, results of laboratory tests
  - Symptoms including diarrhea, bloody stools, vomiting, abdominal cramps, nausea, fever, and other symptoms
- Exposure Information
  - Meal location, date and time of meal, foods eaten, drinks
- Comments

It is helpful to have a comment variable on your line listing so that important information that might not be captured in any of the variables can be included. This is not an exhaustive list of variables that can be included on a line listing. The number and type of variables will change depending on the type of outbreak and the specific needs of the investigation.

After the line listing if created cases can be added and updated during the course of the investigation.

[1] Adapted from Torok, M., Focus on Field Epidemiology, Volume, 1 Issue 4

Creating an Epidemic Curve[2]

Epidemic (Epi) curves can be easily made by hand or with a software package such as Microsoft® Office Excel® or Microsoft® Office PowerPoint®. The structure of an epi curve is straight forward. Simply plot the number of cases reported during an outbreak on the y-axis and the onset date and/or time on the x-axis. One of the more difficult aspects of creating an epi curve is choosing the unit of time for the x-axis. The choice is usually based on the incubation period and the time interval of the outbreak. In general, a time unit that is ¼ of the incubation period is usually appropriate. For example, the mean incubation period for Shigellosis is 48 hours, so the unit of time for the x-axis would be 12 hours. If the incubation period for the outbreak is unknown, several time intervals for the x-axis can be plotted to see which one best represents the data. Because epi curves are histograms, there should be no spaces between the bars. The onset date and time that is shown on the x-axis should be prior to the start of the outbreak.

If Excel is used, the easiest way to set up the data is shown in Table 1. Then follow the following steps.

Table 1 An Outbreak of Shigellosis

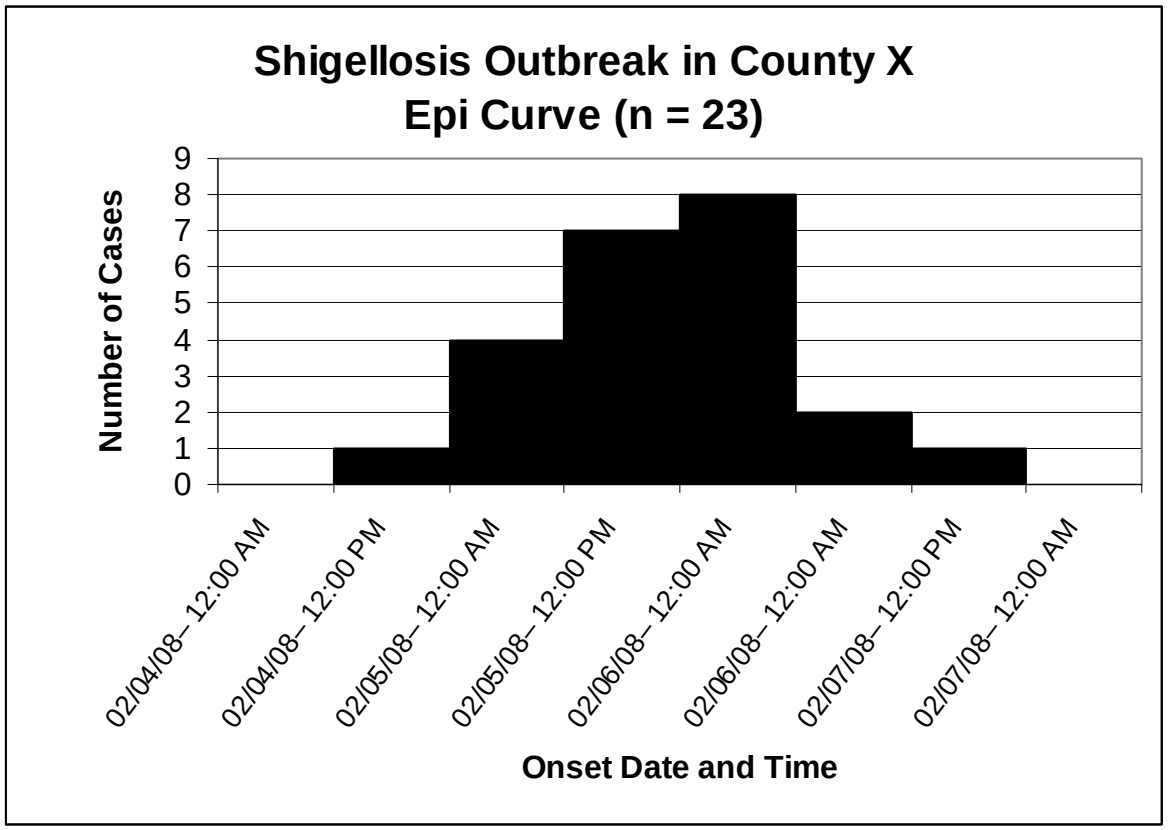
Onset Date and Time	Number of Cases
02/04/08– 12:00 AM	0
02/04/08– 12:00 PM	1
02/05/08– 12:00 AM	4
02/05/08– 12:00 PM	7
02/06/08– 12:00 AM	8
02/06/08– 12:00 AM	2
02/07/08– 12:00 PM	1
02/07/08– 12:00 AM	0

1. Click the “Chart Wizard” on the tool bar.
2. Choose “Column” as the chart type.
3. Click next and beside the Data Range” click the red arrow and select the two columns labeled Onset Date and Time and Number of Cases. Press enter
4. Make sure that beside “Series in” that “Columns” is marked.
5. Select next.
6. Under “Chart Title” include a descriptive title for the epi curve.
7. Label the x-axis and the y-axis.
8. Select next and then select finish.
9. At this point the bars on the graph won’t be touching as they should, so double click on one of the bars.
10. Under “Format Data Series” choose the “Options” tab and set the “Gap width” to 0.
11. If the y-axis scale is set to a number that is less than 1 (example: 0.5), double click on a number on the y-axis and under “Format Axis” select the “Scale” tab.

[2] Adapted from Torok, M., Focus on Field Epidemiology, Volume, 1 Issue 5

12. Beside the “Major unit” enter in 1 unless it is a large outbreak and then enter in an appropriate number. Example of an epi curve is shown in Figure 1.

Figure 1



Electronic
Foodborne
Outbreak
Reporting
System

Investigation of a Foodborne Outbreak

This form is used to report foodborne disease outbreak investigations to CDC. It is also used to report *Salmonella* Enteritidis and *E. coli* O157:H7 outbreak investigations involving any mode of transmission. A foodborne outbreak is defined as the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food in the United States. This form has 6 parts. Part 1 asks for the minimum or basic information needed and must be completed for the investigation to be counted in the CDC annual summary. Part 2 asks for additional information for any foodborne outbreak, while Parts 3 – 6 ask for information concerning specific vehicles or etiologies. Please complete as much of all parts as possible.

CDC Use Only
___-_____

State Use Only
_____

Part 1: Basic Information

1. Report Type

A.
□ Please check if this a final report

B.
□ Please check if data does not support a FOODBORNE outbreak

2. Number of Cases

Lab-confirmed cases_____(A)
Including _____ secondary cases

Probable cases_____(B)
Including _____ secondary cases

Estimated total ill_____
(If greater than sum A + B)

3. Dates

Please enter as many dates as possible

Date first case became ill __ __/__ __/__ __ __ __
Month Day Year

Date last case became ill __ __/__ __/__ __ __ __
Month Day Year

Date first known exposure __ __/__ __/__ __ ____
Month Day Year

Date last known exposure __ __/__ __/__ __ __ __
Month Day Year

4. Location of Exposure

Reporting state _____

If multiple states involved:
□ Exposure occurred in multiple states
□ Exposure occurred in single state, but cases resided in multiple states
Other states: _____
_____
_____

Reporting county_____

If multiple counties involved:
□ Exposure occurred in multiple counties
□ Exposure occurreded in one county, but cases resided in multiple counties
Other counties: _____
_____
_____

5. Approximate Percentage of Cases in Each Age Group

<1 year _____% 20-49 yrs _____%
1-4 yrs _____% ≥50 yrs _____%
5-19 yrs ____% Unknown _____%

6. Sex

(Estimated percent of the total cases)

Male_____%

Female_____%

7. Investigation Methods (Check all that apply)

□ Interviews of only cases
□ Food preparation review
□ Investigation at factory or production plant
□ Investigation at original source (farm, marine estuary, etc.)
□ Food product traceback
□ Environment / food sample cultures
□ Case-control study
□ Cohort study

8. Implicated Food(s): (Please provide known information)

Name of Food	Main Ingredient(s)	Contaminated Ingredient(s)	Reason(s) Suspected (See codes just below)	Method of Preparation (See attached codes)
e.g., Lasagna	e.g., Pasta, sauce, eggs, beef	e.g., Eggs	e.g., 4	e.g., M1
1)				
2)				
3)				

□ Food vehicle undetermined

Reason Suspected (List above all that apply)
1 - Statistical evidence from epidemiological investigation
2 - Laboratory evidence (e.g., identification of agent in food)
3 - Compelling supportive information
4 - Other data (e.g., same phage type found on farm that supplied eggs)
5 - Specific evidence lacking but prior experience makes it likely source

9. Etiology: (Name the bacteria, virus, parasite, or toxin. If available, include the serotype and other characteristics such as phage type, virulence factors, and metabolic profile. Confirmation criteria available at http//www.cdc.gov/ncidod/dbmd/outbreak/ or MMWR2000/Vol. 49/SS-1/App. B)

Etiology		Serotype	Other Characteristics (e.g., phage type)	Detected In (See codes just below)
1)	☐ Confirmed			
2)	☐ Confirmed			
3)	☐ Confirmed			

☐ Etiology undetermined

Detected In (List above all that apply)

1 - Patient Specimen(s) **3 -**Environment specimen(s)

2 - Food Specimen(s) **4 -** Food Worker specimen(s)

10. Isolate Subtype

State Lab ID	PFGE (PulseNet designation)	PFGE (PulseNet designation)	
1)			
2)			
3)			

11. Contributing Factors (Check all that apply. See attached codes and explanations)

☐ **Contributing factors unknown**

Contamination Factor

☐C1 ☐C2 ☐C3 ☐C4 ☐C5 ☐C6 ☐C7 ☐C8 ☐C9 ☐C10 ☐C11 ☐C12 ☐C13 ☐C14 ☐C15 (*describe in Comments)* ☐ N/A

Proliferation/Amplification Factor (bacterial outbreaks only)

☐P1 ☐P2 ☐P3 ☐P4 ☐P5 ☐P6 ☐P7 ☐P8 ☐P9 ☐P10 ☐P11 ☐P12 (*describe in Comments)* ☐ N/A

Survival Factor (microbial outbreaks only)

☐S1 ☐S2 ☐S3 ☐S4 ☐S5 (*describe in Comments)* ☐N/A

☐ **Was food-worker implicated as the source of contamination?** ☐ Yes ☐ No

If yes, please check **only one** of following

- ☐ laboratory *and* epidemiologic evidence
- ☐ epidemiologic evidence (w/o lab confirmation)
- ☐ lab evidence (w/o epidemiologic evidence)
- ☐ prior experience makes this the likely source (*please explain in Comments*)

Part 2: Additional Information

12. Symptoms, Signs and Outcomes

Feature	**Cases** with outcome/ feature	**Total cases** for whom you have information available
Healthcare provider visit		
Hospitalization		
Death		
Vomiting		
Diarrhea		
Bloody stools		
Fever		
Abdominal cramps		
HUS or TTP		
Asympomatic		
*		
*		
*		

13. Incubation Period

(Circle appropriate units)

Shortest_____(Hours, Days)
Longest_____(Hours, Days)
Median _____(Hours, Days)
□ Unknown

14. Duration of Illness

(Among those who recovered)
(Circle appropriate units)

Shortest_____(Hours, Days)
Longest_____(Hours, Days)
Median _____(Hours, Days)
□ Unknown

*** Use the following terms, if appropriate, to describe other common characteristics of cases**

Anaphylaxis	**Headache**	**Tachycardia**
Arthralgia	**Hypotension**	**Temperature reversal**
Bradycardia	**Itching**	**Thromobocytopenia**
Bullous skin lesions	**Jaundice**	**Urticaria**
Coma	**Lethargy**	**Wheezing**
Cough	**Myalgia**	
Descending paralysis	**Paresthesia**	
Diplopia	**Septicemia**	
Flushing	**Sore throat**	

15. If Cohort Investigation Conducted:

Attack rate* = _____ / _____ x 100 = _____%
Exposed and ill — Total number exposed for whom you have illness information

* The attack rate is applied to persons in a cohort who were exposed to the implicated vehicle. The numerator is the number of persons who were exposed and became ill; the denominator is the total number of persons exposed to the implicated vehicle. If the vehicle is unknown, then the attack rate should not be calculated.

16. Location Where Food Was Prepared

(Check all that apply)

□Restaurant or deli
□ Day care center
□ School
□ Office setting
□ Workplace cafeteria
□ Banquet Facility
□ Picnic
□ Caterer
□ Grocery Store
□ Nursing home
□ Prison, jail
□ Private home
□ Workplace, not cafeteria
□ Wedding reception
□ Church, temple, etc
□ Camp
□ Contaminated food imported into U.S.
□ Hospital
□ Fair, festival, other temporary/ mobile services
□ Commercial product, served without further preparation
□ Unknown or undetermined
□ Other (Describe) _____

17. Location of Exposure or Where Food Was Eaten

(Check all that apply)

□ Restaurant or deli
□ Day care center
□ School
□ Office Setting
□ Workplace cafeteria
□ Banquet Facility
□ Picnic
□ Grocery Store
□ Nursing Home
□ Prison, jail
□ Private home
□ Workplace, not cafeteria
□ Wedding Reception
□ Church, temple, etc.
□ Camp
□ Hospital
□ Fair, festival, temporary/ mobile service
□ Unknown or undetermined
□ Other (Describe) _____

18. Trace back

□ Please check if trace back conducted

Source to which trace back led:

Source (e.g., Chicken farm, Tomato processing plant)	**Location of Source** **State**	**Country**	**Comments**

19. Recall

☐ Please check if any food product recalled

Recall Comments

_____
_____
_____
_____
_____

20. Available Reports (Pease attach)

☐ Unpublished agency report

☐ Epi-Aid report

☐ Publication (please reference if not attached)

_____
_____

21. Agency reporting this outbreak

_____

Contact person:

Name _____

Title _____

Phone _____

Fax _____

E-mail _____

22. Remarks

Briefly describe important aspects of the outbreak not covered above (e.g., restaurant closure, immunoglobin administration, economic impact, etc)

_____
_____
_____
_____
_____

Part 3: School Questions

1. Did the outbreak involve a single or multiple schools?

☐ Single

☐ Multiple (*If yes*, number of schools____)

2. School characteristics (for all involved students in all involved schools)

a. Total approximate enrollment

_____ (number of students)

☐ Unknown or Undetermined

b. Grade level(s) (Please check all grades affected)

☐ Preschool

☐ Grade School (grades K-12)

Please check all grades affected: ☐K ☐1st ☐2nd ☐3rd ☐4th ☐5th ☐6th ☐7th ☐8th ☐9th ☐10th ☐11th ☐12th

☐ College/University/Technical School

☐ Unknown or Undetermined

c. Primary funding of involved school(s)

☐ Public ☐ Private ☐ Unknown or Undetermined

3. Describe the preparation of the implicated item:

☐ Heat and serve (item mostly prepared or cooked off-site, reheated on-site)

☐ Served a-la-carte

☐ Serve only (preheated or served cold)

☐ Cooked on site using primary ingredients

☐ Provided by a food service management company

☐ Provided by a fast food vendor

☐ Provided by a pre-plate company

☐ Part of a club/ fundraising event

☐ Made in the classroom

☐ Brought by a student/teacher/parent

☐ Other _____

☐ Unknown or Undetermined

4. How many times has the state, county or local health department inspected this school cafeteria or kitchen in the 12 months before the outbreak?*

☐ Once

☐ Twice

☐ More than two times

☐ Not inspected

☐ Unknown or Undetermined

5. Does the school have a HACCP plan in place for the school feeding program?*

☐ Yes

☐ No

☐ Unknown or Undetermined

*If there are multiple schools involved, please answer according to the most affected school

6. Was implicated food item provided to the school through the National School Lunch/Breakfast Program?

□ Yes
□ No
□ Unknown or Undetermined

***If Yes,* Was the implicated food item donated/purchased by :**

□ USDA through the Commodity Distribution Program
□ Purchased commercially by the state/school authority
□ Other_____
□ Unknown or Undetermined

Part 4: Ground Beef

1. What percentage of ill persons (for whom information is available) ate ground beef raw or undercooked? _____%

2. Was ground beef case ready? (Ground beef that comes from a manufacturer packaged for sale and not altered or repackaged by the retailer)

□ Yes
□ No
□ Unknown or Undetermined

3. Was the beef ground or reground by the retailer?

□ Yes
□ No
□ Unknown or Undetermined

If yes, was anything added to the beef during grinding (e.g., shop trim or any product to alter the fat content)_____

Part 5: Mode of Transmission

(Enterohemorrhagic *E. coli* or *Salmonella* Enteritidis only)

1. Mode of Transmission (for greater than 50% of cases)

Select one:

□ Food
□ Person to person
□ Swimming or recreational water
□ Drinking water
□ Contact with animals or their environment
□ Unknown or Undetermined

Part 6: Additional Egg Questions

1. Were Eggs: (Check all that apply)

□ in-shell, un-pasteurized?
□ in-shell, pasteurized?
□ liquid or dry egg product?
□ stored with inadequate refrigeration during or after sale?
□ consumed raw?
□ consumed undercooked?
□ pooled?

2. If eggs traced back to farm, was *Salmonella* Enteritidis found on the farm?

□ Yes
□ No
□ Unknown or Undetermined

Comment:_____
_____

Contamination Factors:[1]

C1 - Toxic substance part of tissue (e.g., ciguatera)
C2 - Poisonous substance intentionally added (e.g., cyanide or phenolphthalein added to cause illness)
C3 - Poisonous or physical substance accidentally/incidentally added (e.g., sanitizer or cleaning compound)
C4 - Addition of excessive quantities of ingredients that are toxic under these situations (e.g., niacin poisoning in bread)
C5 - Toxic container or pipelines (e.g., galvanized containers with acid food, copper pipe with carbonated beverages)
C6 - Raw product/ingredient contaminated by pathogens from animal or environment (e.g., *Salmonella* enteriditis in egg, Norwalk in shellfish, *E. coli* in sprouts)
C7 - Ingestion of contaminated raw products (e.g., raw shellfish, produce, eggs)
C8 - Obtaining foods from polluted sources (e.g., shellfish)
C9 - Cross-contamination from raw ingredient of animal origin (e.g., raw poultry on the cutting board)
C10 - Bare-handed contact by handler/worker/preparer (e.g., with ready-to-eat food)
C11 - Glove-handed contact by handler/worker/preparer (e.g., with ready-to-eat food)
C12 - Handling by an infected person or carrier of pathogen (e.g., *Staphylococcus*, *Salmonella*, Norwalk agent)
C13 - Inadequate cleaning of processing/preparation equipment/utensils B leads to contamination of vehicle (e.g., cutting boards)
C14 - Storage in contaminated environment B leads to contamination of vehicle (e.g., store room, refrigerator)
C15 - Other source of contamination (*please describe in Comments*)

Proliferation/Amplification Factors:[1]

P1 - Allowing foods to remain at room or warm outdoor temperature for several hours (e.g., during preparation or holding for service)
P2 - Slow cooling (e.g., deep containers or large roasts)
P3 - Inadequate cold-holding temperatures (e.g., refrigerator inadequate/not working, iced holding inadequate)
P4 - Preparing foods a half day or more before serving (e.g., banquet preparation a day in advance)
P5 - Prolonged cold storage for several weeks (e.g., permits slow growth of psychrophilic pathogens)
P6 - Insufficient time and/or temperature during hot holding (e.g., malfunctioning equipment, too large a mass of food)
P7 - Insufficient acidification (e.g., home canned foods)
P8 - Insufficiently low water activity (e.g., smoked/salted fish)
P9 - Inadequate thawing of frozen products (e.g., room thawing)
P10 - Anaerobic packaging/Modified atmosphere (e.g., vacuum packed fish, salad in gas flushed bag)
P11 - Inadequate fermentation (e.g., processed meat, cheese)
P12 - Other situations that promote or allow microbial growth or toxic production (*please describe in Comments*)

Survival Factors:[1]

S1 - Insufficient time and/or temperature during initial cooking/heat processing (e.g., roasted meats/poultry, canned foods, pasteurization)
S2 - Insufficient time and/or temperature during reheating (e.g., sauces, roasts)
S3 - Inadequate acidification (e.g., mayonnaise, tomatoes canned)
S4 - Insufficient thawing, followed by insufficient cooking (e.g., frozen turkey)
S5 - Other process failures that permit the agent to survive (*please describe in Comments*)

Method of Preparation:[2]

M1 - Foods eaten raw or lightly cooked (e.g., hard shell clams, sunny side up eggs)
M2 - Solid masses of potentially hazardous foods (e.g., casseroles, lasagna, stuffing)
M3 - Multiple foods (e.g., smorgasbord, buffet)
M4 - Cook/serve foods (e.g., steak, fish fillet)
M5 - Natural toxicant (e.g., poisonous mushrooms, paralytic shellfish poisoning)
M6 - Roasted meat/poultry (e.g., roast beef, roast turkey)
M7 - Salads prepared with one or more cooked ingredients (e.g., macaroni, potato, tuna)
M8 - Liquid or semi-solid mixtures of potentially hazardous foods (e.g., gravy, chili, sauce)
M9 - Chemical contamination (e.g., heavy metal, pesticide)
M10 - Baked goods (e.g., pies, eclairs)
M11 - Commercially processed foods (e.g., canned fruits and vegetables, ice cream)
M12 - Sandwiches (e.g., hot dog, hamburger, Monte Cristo)
M13 - Beverages (e.g., carbonated and non-carbonated, milk)
M14 - Salads with raw ingredients (e.g., green salad, fruit salad)
M15 - Other, does not fit into above categories *(please describe in Comments)*
M16 - Unknown, vehicle was not identified

[1] Frank L. Bryan, John J. Guzewich, and Ewen C. D. Todd. Surveillance of Foodborne Disease III. Summary and Presentation of Data on Vehicles and Contributory Factors; Their Value and Limitations. Journal of Food Protection, 60; 6:701-714, 1997.
[2] Weingold, S. E., Guzewich JJ, and Fudala JK. Use of foodborne disease data for HACCP risk assessment. Journal of Food Protection, 57; 9:820-830, 1994.

Guidelines for Completing the Form: "Investigation of a Foodborne Outbreak"
Foodborne and Diarrheal Diseases Branch
Centers for Disease Control and Prevention

I. *Report Type*
Indicate if this is a final report and if the data does not support a foodborne outbreak but you are nevertheless reporting this outbreak to CDC.

II. *Number of Cases*
Provide number of laboratory-confirmed cases and number of presumptive cases. If applicable, also provide an estimate of the total number of ill persons if you suspect that this number exceeds the sum of the laboratory-confirmed and presumptive cases.

III. *Dates*
Indicate dates that the first and last known case patients became ill, and the dates that the first and last known exposure took place. If available, please attach a copy of the epidemic curve along with this report form.

IV. *Location of Exposure*
Provide the two-letter state abbreviation and select the full name of the county in which exposure took place. If multiple states or counties were involved, list them in the "other states" or "other counties" section.

V. *Approximate Percentage of Cases in Each Age Group*
This item seeks to identify unique patterns of age distribution for the outbreak, as well as to identify age groups most affected. Indicate the approximate percentage of all cases (lab-confirmed and presumptive) in the various age groups listed.

VI. *Sex*
Estimate the percentage of males and females, using all cases (laboratory-confirmed and presumptive combined).

VII. *Investigation Methods*
Check off all boxes that describe the methods used to investigate this outbreak.

VIII. *Implicated Food(s)*
List the food item(s) implicated as a result of the investigation. Please be as specific as possible, and if known include main ingredient(s), contaminated ingredients, reasons suspected and method of preparation.

a. The name of the implicated food alone does not provide sufficient detail when one ingredient of many is the actual source of contamination. Identification of an implicated ingredient(s) provides a basis for identifying ingredients that may be involved in other outbreaks. The **contaminated ingredient(s)** is the ingredient that actually was contaminated with the agent, when such a distinction can be made.
b. **Reasons suspected** should be chosen from the list below the table.

c. **Method of preparation** refers to common food preparation processes. By identifying the food safety hazards associated with each method and the frequency with which they occur, appropriate interventions and priorities can be set for whole categories rather than just for a specific food. A list of codes to be used for the method of preparation is found on page 6 of the form.

IX. *Etiology*

a. Identify the bacterium, virus, parasite, or toxin responsible for the outbreak, using the criteria set forth in MMWR 1996 / Vol. 45 / ss-5 / Appendix B. The name should follow standard taxonomy. Give as much detail as you have about the organism or toxin.
b. If more than one etiology was identified, please include all of them in the "Etiology" section
c. Check off all boxes that correspond to the specimen(s) from which the etiologic agent was isolated or identified.

X. *Isolate Subtype*

If known, include the PFGE pattern designation for first and second enzyme as confirmed by PulseNet, CDC. The state laboratory assigns a unique identification number to each isolate and this number should go under the "State Lab ID" section.

XI. *Contributing Factors*

a. Factors that contribute to the occurrence of outbreaks are classified according to contamination, survival, and proliferation. A factor should be checked only if the investigator has strong evidence that it actually occurred in this outbreak; just because a factor has been cited in similar outbreaks in the past does not mean it was involved in this outbreak. **Contamination factors** relate to how the agent got onto or into the food vehicle. **Proliferation factors** relate to how microbial agents were able to increase in numbers and/or produce toxic products prior to the vehicle being ingested. **Survival factors** refer to processes or steps that should have eliminated or reduced the agent but did not because of one of these factors. Explanations and examples of the codes are provided on page 6 of the form. If the choice of "other" is made for any of the factors, please describe in the "Remarks" section.
b. If one or more **food workers** are implicated as the source of contamination, please indicate what evidence was used to support this conclusion. The choice of "prior experience makes this the likely source" is provided for situations when conclusive laboratory and epidemiologic evidence is absent, but other factors may prompt the investigator to suspect the food worker(s). If a food worker is implicated in the absence of laboratory and/or epidemiologic evidence, please explain in the "Remarks" section.

XII. *Symptoms, Signs and Outcomes*

For each outcome listed, provide the number of patients with the outcome, and the total number of patients for whom you have such outcome information available. If applicable, list other outcomes (and the relevant numbers) in the blank spaces provided.

A list of possible outcomes is provided to the right of the table.

XIII. *Incubation Period*
Indicate the shortest, median, and longest incubation period, and indicate whether each period is measured in hours or days.

XIV. *Duration of Illness*
Indicate the shortest, longest and median duration of illness among those who recovered. Indicate whether each period was measured in hours or days.

XV. *If a Cohort Investigation was Conducted*
Report the attack rate if a cohort investigation was conducted only when you have an implicated vehicle. This is the vehicle attack rate, not the event attack rate. The formula is provided to aid in keeping our definition of attack rates consistent across investigations.

XVI. *Location where Food was Prepared?*
Indicate where suspected/implicated food was prepared. Select all applicable options.

XVII. *Location of Exposure or where Food was Eaten?*
Indicate where suspected/implicated food was eaten. Select all applicable options.

XVIII. *Traceback*
Indicate whether a traceback investigation was conducted and include all available information.

XIX. *Recall*
Indicate whether there was a recall associated with this outbreak and include all available information.

XX. *Available Reports*
Indicate whether there are any additional reports and include them as an attachment. References should be cited for published papers.

XXI. *Agency Reporting this Outbreak*
Include the contact information for the agency reporting this outbreak.

XXII. *Remarks*
Describe other important aspects of the outbreak that may not have been reported elsewhere in the form.

Parts 3-6: Additional Sections
Fill in additional information in the appropriate section(s) if the outbreak was associated with a school, ground beef, Enterohemorrhagic *E. coli*, *Salmonella enterica* Enteritidis, or eggs.

Data Analyses

ANALYZING THE DATA COLLECTED

The following should be calculated to understand the data collected: frequencies and percentages, the incubation and recovery periods, the measures of association between exposure and disease, and appropriate tests of statistical significance.

EpiInfo™ Version 3.4.3 (released November 26, 2007) is a user-friendly, Windows-based software that is available for free by the CDC that may be used to conduct these specific analyses. Visit www.cdc.gov/epiinfo/ to download.

STEP 1. Calculate frequencies

COUNTS and **PERCENTAGES** should be calculated to define the outbreak. The following is a list of common calculations.

- For all individuals (retrospective cohort or case-control study)
  - Number and percentage of persons by sex
  - Median age and age range
  - Number and percentage of ill and not ill, for retrospective cohort studies
  - Number and percentage of cases and controls for case-control studies
  - Other characteristics may be recommended depending upon the outbreak, including race/ethnicity, occupation, county, state, zip code, school name, school grade, nursing home name, room number
- Total number of persons exposed (cohort study)
- For ill persons or cases (cohort or case-control study)
  - Number and percentage of each symptom experienced
    - Diarrhea (3 or more loose stools in a 24-hour period), bloody diarrhea, vomiting, nausea, abdominal cramping, fever, malaise, headache are common symptoms
  - Number of samples collected and submitted for testing
    - Stool, blood, urine
  - Number and percentage of laboratory-confirmed results
  - Number and percentage of persons hospitalized
  - Number and percentage of medical visits

STEP 2. Calculate the incubation period and recovery period

The **INCUBATION PERIOD** is the interval from the time an individual is infected (exposed) to the time when symptoms first appear. The incubation period may differ from person to person and from organism to organism.

Incubation period = onset time – time of exposure

EXAMPLE: Time of exposure = 8:00 P.M. on Saturday evening
Onset of symptoms = 2:00 A.M. on Monday morning

1. Determine how many hours there were per day.

   Hint: Time and days listed in military time or 24-hour increments will make calculations much easier for most analytic software.

   Saturday: 8:00 P.M. is equivalent to 20:00 in military time. So, 24:00 – 20:00 = 4 hours
   Sunday: All hours were of interest = 24 hours
   Monday: 2:00 A.M. is equivalent to 02:00 in military time = 2 hours

2. Add all the hours together for the days of interest.

   4 + 24 + 2 = 30 hours

   30 hours / 24 hours = 1.25 days

   Incubation period for ill person = 30 hours or 1.3 days

3. Calculate the incubation period for each ill person. Determine the **median** incubation period (the mid-point or middle value) and the **range** (the minimum and maximum numbers).

Person	Incubation Period		
# 1	14 hours	←	Minimum
# 2	18 hours		
# 3	23 hours		
# 4	30 hours	←	Median
# 5	36 hours		
# 6	45 hours		
# 7	47 hours	←	Maximum

Incubation period median = 30 hours

Incubation period range = 14 hours – 47 hours

The **RECOVERY PERIOD** is the period when symptoms decline and illness improves.

Recovery period = recovery time – onset time

EXAMPLE: Onset of symptoms = 2:00 A.M. on Monday morning
Recovery from illness = 11:00 P.M. on Tuesday evening

1. Determine how many hours there were per day.

Hint: Time and days listed in military time or 24-hour increments will make calculations much easier for most analytic software.

Monday: 2:00 A.M. is equivalent to 02:00 in military time. So, 24:00 – 2:00 = 22 hours
Tuesday: 11:00 P.M. is equivalent to 23:00 in military time. So the hours of interest on Tuesday = 23 hours

2. Add all the hours together for the days of interest.

22 + 23 = 45 hours

45 hours / 24 hours = 1.88 days

Recovery period for ill person = 45 hours or 1.9 days

3. Calculate the recovery period for each ill person. Determine the **median** recovery period (the mid-point or middle value) and the **range** (the minimum and maximum numbers).

Person	Recovery Period	
# 1	28 hours	← Minimum
# 2	29 hours	
# 3	33 hours	
# 4	37 hours	← Median
# 5	40 hours	
# 6	45 hours	
# 7	51 hours	← Maximum

Recovery period median = 37 hours

Recovery period range = 28 hours – 51 hours

STEP 3. Utilize the 2 x 2 table to calculate measures of association

A 2 x 2 contingency table can be used to compare the association between illness and exposure.

	Ill	Not Ill	
Exposed	**a**	**b**	**(a + b)**
Not Exposed	**c**	**d**	**(c + d)**
	(a + c)	**(b + d)**	**a + b + c + d**

Interpretation of the elements in the 2 x 2 table

a = the number of ill persons who were exposed to a specific risk factor
b = the number of persons who did not become ill, but were exposed to a specific risk factor
c = the number of ill persons who were not exposed to a specific risk factor
d = the number of persons who did not become ill and were not exposed to a specific risk factor

(a + b) = the total number of persons exposed
(c + d) = the total number of persons not exposed
(a + c) = the total number of ill persons
(b + d) = the total number of not-ill persons

a + b + c + d = the total number of persons

CALCULATIONS FOR RETROSPECTIVE COHORT STUDIES

Using a 2 x 2 table, attack rates, food-specific attack rates, and relative risk ratios may be calculated to describe the association between illness and exposure for retrospective cohort studies.

ATTACK RATES (includes food-specific attack rates)

An **attack rate** represents the occurrence of disease observed among a defined population over a limited period of time. Specifically, it is used to calculate (1) the percentage of illness among all individuals who were exposed to a specific risk factor and (2) the percentage of illness among all individuals who were not exposed to the specific risk factor.

$$\textbf{Attack rate for ill persons who were exposed} = \frac{a}{a+b} \quad \textbf{X 100}$$

$$\textbf{Attack rate for ill persons who were not exposed} = \frac{c}{c+d} \quad \textbf{X 100}$$

RELATIVE RISK

A **relative risk (RR)** is the measure of association between exposure and illness used for cohort studies. It is the ratio of the attack rate for ill persons who were exposed and the attack rate for ill persons who were not exposed.

$$\textbf{Relative risk ratio} = \frac{\textbf{Attack rate for ill persons who were exposed}}{\textbf{Attack rate for ill persons who were not exposed}} = \frac{a/a+b}{c/c+d}$$

Interpretation of Relative Risk (RR)[†]:

RR = 1: The risk of illness among exposed persons is the same as the risk of illness among those not exposed.

RR>1: The risk of illness among exposed persons is higher than the risk of illness among those not exposed.

RR<1: The risk of illness among exposed persons is lower than the risk of illness among those not exposed.

[†] "E. coli O157:H7 Infection in Michigan" Computer-based Case Study. www.phppo.cdc.gov/phtn/casestudies/computerbased.

EXAMPLE: One hundred fifty individuals attended a wedding reception. Several persons became ill with diarrhea and vomiting between 12 and 48 hours after eating food served at the reception. Calculate the attack rates for (1) ill persons who ate the food served at the reception and (2) ill persons who did not eat the food served at the reception. Also calculate the relative risk (RR) ratio and interpret the results.

	Ill	Not Ill	
Ate food at reception	72	63	135
Did not eat food at reception	2	13	15
	74	76	150

Attack rate for ill persons who ate food = $\frac{72}{135}$ **X 100 = 53.3%**

Attack rate for ill persons who did not eat food = $\frac{2}{15}$ **X 100 = 13.3%**

RR = $\frac{\text{Attack rate for ill persons who ate at the reception}}{\text{Attack rate for ill persons who did not eat at the reception}} = \frac{72/135}{2/15}$

$= \frac{.533}{.133} =$ **4.0**

Interpretation: About 53% of the persons who became ill had eaten the food served at the reception compared to 13% who became ill and had not eaten the food. The risk of illness among persons who ate food at the reception appears to be 4 times higher than the risk of illness among persons who did not eat food at the reception. In other words, persons who ate food at the reception were four times more likely to experience illness compared to person who did not eat food at the reception.

EXAMPLE: One hundred thirty-five individuals attended the wedding reception and ate the food served. Specific foods served included salad, dinner rolls, chicken, and cake. Calculate the food-specific attack rates for (1) ill persons who ate each of these items and (2) ill persons who did not eat each of these items. Also calculate the respective relative risk (RR) ratios and interpret the results.

EATING SALAD *vs.* BECOMING ILL

	Ill	**Not Ill**	
Ate salad	63	52	115
Did not eat salad	10	10	20
	72	63	135

Attack rate for ill persons who ate salad $= \frac{63}{115} \times 100 = 54.8\%$

Attack rate for ill persons who did not eat salad $= \frac{10}{20} \times 100 = 50\%$

$$\textbf{RR} = \frac{\textbf{Attack rate for ill persons who ate salad}}{\textbf{Attack rate for ill persons who did not eat salad}} = \frac{63/115}{10/20}$$

$$= \frac{.548}{.50} = 1.1$$

Interpretation: About 55% of the persons who became ill had eaten the salad served at the reception compared to 50% who became ill and had not eaten the salad. The risk of illness among persons who ate salad served at the reception was almost the same as the risk of illness among persons who did not eat the salad. In other words, persons who ate salad served at the reception were as likely to experience illness as persons who did not eat the salad.

EATING DINNER ROLLS *vs.* BECOMING ILL

	Ill	Not Ill	
Ate dinner rolls	57	40	97
Did not eat dinner rolls	15	23	38
	72	63	135

Attack rate for ill persons who ate rolls $= \frac{57}{97} \times 100 = 58.8\%$

Attack rate for ill persons who did not eat rolls $= \frac{15}{38} \times 100 = 39.5\%$

$$\textbf{RR} = \frac{\text{Attack rate for ill persons who ate rolls}}{\text{Attack rate for ill persons who did not eat rolls}} = \frac{57/97}{15/38}$$

$$= \frac{.588}{.395} = 1.49$$

Interpretation: About 59% of the persons who became ill had eaten the dinner rolls served at the reception compared to 40% who became ill and had not eaten the dinner rolls. The risk of illness among persons who ate the dinner rolls served at the reception was 1.5 times higher than the risk of illness among persons who did not eat the dinner rolls. In other words, persons who ate the dinner rolls served at the reception were 1.5 times more likely to experience illness compared to persons who did not eat the dinner rolls.

EATING CHICKEN *vs.* BECOMING ILL

	Ill	Not Ill	
Ate chicken	66	57	123
Did not eat chicken	6	6	12
	72	63	135

Attack rate for ill persons who ate chicken $= \frac{66}{123}$ **X 100 = 53.7%**

Attack rate for ill persons who did not eat chicken $= \frac{6}{12}$ **X 100 = 50%**

$$\textbf{RR} = \frac{\textbf{Attack rate for ill persons who ate chicken}}{\textbf{Attack rate for ill persons who did not eat chicken}} = \frac{66/123}{6/12}$$

$$= \frac{.537}{.50} = 1.1$$

Interpretation: About 54% of the persons who became ill had eaten the chicken served at the reception compared to 50% who became ill and had not eaten the chicken. The risk of illness among persons who ate chicken served at the reception was almost the same as the risk of illness among persons who did not eat the chicken. In other words, persons who ate chicken served at the reception were as likely to experience illness compared to those persons who did not eat the chicken.

EATING CAKE *vs.* BECOMING ILL

	Ill	Not Ill	
Ate cake	66	28	94
Did not eat cake	6	35	41
	72	63	135

Attack rate for ill persons who ate cake $= \frac{66}{94} \times 100 = 70.2\%$

Attack rate for ill persons who did not eat cake $= \frac{6}{41} \times 100 = 14.6\%$

$$\textbf{RR} = \frac{\text{Attack rate for ill persons who ate cake}}{\text{Attack rate for ill persons who did not eat cake}} = \frac{66/94}{6/41}$$

$$= \frac{.702}{.146} = 4.8$$

Interpretation: About 66% of the persons who became ill had eaten the cake served at the reception compared to 24% who became ill and had not eaten the cake. The risk of illness among persons who ate cake served at the reception was almost 5 times higher than the risk of illness among persons who did not eat cake. In other words, persons who ate cake served at the reception were almost five times more likely to experience illness compared to persons who did not eat cake.

OVERALL INTERPRETATION: Based on the attack rates and relative risk ratios for each food item served at the reception, cake appears to be the suspect food item.

CALCULATIONS FOR CASE-CONTROL STUDIES

The 2 x 2 table may also be used to calculate the odds ratio for case-control studies.

The **ODDS RATIO (OR)** measures whether a specific exposure is associated with a certain disease. In other words, it is the ratio of the odds that the cases were exposed to the odds that the controls were exposed. Odds ratios related to exposure to specific food items can also be calculated.

NOTE: The relative risk ratio cannot be used to measure the association between exposure and illness for case-control studies because the total population exposed is not well-defined.

	Ill	Not Ill	
Exposed	**a**	**b**	**(a + b)**
Not Exposed	**c**	**d**	**(c + d)**
	(a + c)	**(b + d)**	**a + b + c + d**

$$\textbf{Odds that the cases were exposed} = \frac{a}{b}$$

$$\textbf{Odds that the controls were exposed} = \frac{c}{d}$$

$$\textbf{OR} = \frac{\text{Odds that the cases were exposed}}{\text{Odds that the controls were exposed}} = \frac{a/b}{c/d} = \frac{ad}{bc}$$

Interpretation of Odds Ratio (OR)[†]:

OR = 1: The odds of exposure among cases is the same as the odds of exposure among controls.

OR>1: The odds of exposure among cases is higher than the odds of exposure among controls.

OR<1: The odds of exposure among cases is lower than the odds of exposure among controls.

[†] "E. coli O157:H7 Infection in Michigan" Computer-based Case Study. www.phppo.cdc.gov/phtn/casestudies/computerbased.

EXAMPLE: Five persons reported eating at Restaurant X and becoming ill. After conducting a case-control study, the following numbers were obtained. Calculate the odds ratio and interpret the results. Also calculate the odds of becoming ill from eating a beef dish served at Restaurant X.

ODDS OF BECOMING A CASE FROM EATING AT RESTAURANT X

	Case	Control	
Ate at Restaurant X	25	30	55
Did not eat at Restaurant X	10	40	50
	35	70	105

$$\textbf{OR} = \frac{\textbf{Odds that the cases ate at Restaurant}}{\textbf{Odds that the controls ate at Restaurant}} = \frac{\textbf{25 / 30}}{\textbf{10 / 40}} = \frac{\textbf{25(40)}}{\textbf{30(10)}} = \frac{\textbf{1000}}{\textbf{300}}$$

$$= \textbf{3.3}$$

Interpretation: The odds of exposure to Restaurant X was 3 times higher among cases than among controls. It can be concluded that eating at Restaurant X may have contributed to illness.

ODDS OF BECOMING A CASE FROM EATING BEEF AT RESTAURANT X

	Case	Control	
Ate beef at Restaurant X	30	13	43
Did not eat beef at Restaurant X	3	9	12
	33	22	55

$$\textbf{OR} = \frac{\textbf{Odds that the cases ate beef}}{\textbf{Odds that the controls ate beef}} = \frac{\textbf{30 / 13}}{\textbf{3 / 9}} = \frac{\textbf{30(9)}}{\textbf{13(3)}} = \frac{\textbf{270}}{\textbf{39}}$$

$$= \textbf{6.9}$$

Interpretation: The odds of exposure to beef at Restaurant X was almost 7 times higher among cases than among controls. It can be concluded that eating beef at Restaurant X may have contributed to illness.

SIGNIFICANCE TESTING OF THE RR AND THE OR

Tests of significance are calculated to determine if the association between exposure and illness occurred by chance alone. In other words, was the association observed between exposure and illness a random occurrence? The **95% confidence intervals** and the ***p*-values** may be calculated to determine the significance of the association between exposure and illness.

The 95% confidence intervals (C. I.) indicate how "confident" one can be that the RR or the OR observed actually lies within a range of numbers. In other words, the confidence interval is an estimated range of values within which the true RR or OR is likely to fall 95% of the time. In contrast, *p*-values represent the probability that the association observed between exposure and illness could have occurred by chance alone. Many statistical programs, like EpiInfo™, readily calculate these values. Refer to these statistical programs or statistical books for more information.

Final Epidemiology Report

FORMAT FOR WRITING AN OUTBREAK REPORT

The following is a standard format of a written outbreak report. The format may be modified depending on the complexity of the outbreak.

INTRODUCTION
BACKGROUND
METHODS
- Epidemiologic Investigation
- Laboratory Analysis
- Environmental Assessment

RESULTS
- Epidemiologic Investigation
- Laboratory Analysis
- Environmental Assessment

DISCUSSION
RECOMMENDATIONS
ACKNOWLEDGEMENTS
SUPPORTING DOCUMENTS

The **INTRODUCTION** should include the following information:
- Who first reported the outbreak?
- When was the outbreak reported?
- What steps were taken to determine that an outbreak had occurred?
- What entities were involved with initiating the outbreak investigation?

The **BACKGROUND** should include the following information:
- What are the circumstances surrounding the outbreak?
- Where did the outbreak occur?
- What preliminary information was known?
    - Demographics of the affected group
    - Number of persons exposed
    - Number of persons ill
    - Severity and clinical picture of ill persons

The **METHODS** section should include epidemiologic, environmental, and laboratory or clinical information:
- Epidemiologic Investigation
    - What was the case definition?
    - What investigation tools were used to collect or organize the information?
        - Line list
        - Epidemic curves
        - Maps

        - Chart reviews
        - Communication with health care providers
        - Questionnaire
    - If a questionnaire was administered, how was it administered?
        - Self-administered?
        - By phone?
        - In person?
        - Electronically?
    - What type of study was conducted?
    - What statistical analyses were conducted?
    - What hypotheses were generated?
    - What prevention and control measures were implemented?
    - What entities were involved?
    - What specific tasks were conducted?
- Laboratory analysis
    - Were stool samples collected for testing?
    - Were food samples collected for testing?
    - What tests were conducted?
    - Where was testing performed?
- Environmental assessment
    - What kind of environmental assessment was conducted?
    - What was the physical layout of the outbreak?
    - Was a HACCP investigation performed?
    - Were there any tracebacks?

The **RESULTS** section should also include epidemiologic, environmental, and laboratory or clinical information:

- Epidemiologic Investigation
    - Total number of persons exposed (cohort study)
    - For all individuals (cohort or case-control study)
        - Number and percentage of persons by age group
        - Number and percentage of persons by sex
        - Number and percentage of other demographics collected
    - Number and percentage of ill and not-ill or of cases and controls
    - For ill persons or cases (cohort or case-control study)
        - Number and percentage of each symptom experienced
        - Number of samples collected
        - Number and percentage of positive results
        - Number and percentage of persons hospitalized
        - Number and percentage of medical visits
        - Incubation period (median and range)
        - Recovery period (median and range)
    - Overall attack rates and food-specific attack rates (cohort study)
    - Measures of association
        - Relative risk (cohort study)
        - Odds ratio (case-control study)

    - Any additional results
- Laboratory analysis
    - What were the results of the human samples submitted?
    - What were the results of any food samples tested?
- Environmental assessment
    - What were the results of the investigation or inspection, including any HACCP assessment?
    - What were the results of any food tracebacks, if done?
    - What were potential environmental factors that may have contributed to the outbreak?

The **DISCUSSION** section should make interpretations of all the information collected during the outbreak investigation.

- Taking into account all the information collected, what can be concluded about the outbreak?
- Did the results from the epidemiologic investigation, laboratory analysis, and environmental assessment support the hypotheses generated?
- Were there any important or interesting outcomes or findings?
- What were the strengths and limitations of the study conducted?

The **RECOMMENDATIONS** section should provide educational information to aid others in outbreak investigations.

- What can be learned from this outbreak?
- Were the prevention and control measures implemented successful?
- What measures would prevent future occurrences?

The **ACKNOWLEDGEMENTS** section should recognize personnel who assisted in the outbreak investigation.

The **SUPPORTING DOCUMENTS** section should include any relevant information. Important documentation includes the following:

- Copy of the questionnaire or survey tool used
- Tables, epidemic curves, or maps
- Inspection reports
- Fact sheets of the disease

APPENDIX C
Supplemental Documents for Laboratory Analysis

DIVISION OF HEALTH AND ENVIRONMENTAL LABORATORIES
DEPARTMENT OF HEALTH AND ENVIRONMENT
Forbes Field, Building 740
Topeka, Kansas 66620-0001

REQUISITION FOR LABORATORY SPECIMEN KITS

Please use the appropriate kit listed below to submit specimens to the Health and Environmental Laboratories. Each kit consists of a specimen container, an addressed mailing container, and a kit requisition form. Order the Universal Specimen Submission forms in the space below. If you have any questions about submitting specimens, please refer to the Manual of Laboratory Tests or call (785) 296-1623. Please enter the quantity needed on the line next to the item.

RUSH ORDERS: FAX to (785) 296-1641

Universal Specimen Submission Forms Only

_____ Specify number required

Serology

_____ Multi-tube bottle with mailing box (5 tube box)

_____ Blood Tubes (Yellow Top)

_____ Chlamydia/Gonorrhea Mailer

Viral Culture

_____ Virus VTM (HD and Influenza

_____ Flu VTM Surveillance Sites Only)

Parasite (O & P)

_____ Feces Mailer

_____ Pinworm (Health Departments Only)

Gonorrhea

_____ Culture Plates

_____ Mailer, for two specimens

_____ CO_2 Tablets

_____ Whirl-Pak Bag

Inorganic Chemistry

_____ Blood Lead Filter Paper Forms

_____ Blood Lead Confirmation Kits

_____ EDTA (Purple Top) Blood Tubes

Neonatal Screening

_____ Initial (Green) Collection Unit - ☐ Eng ☐ Span

_____ Repeat (Red) Collection Unit - ☐ Eng ☐ Span

Bacterial

_____ Enteric Mailer

_____ Miscellaneous Infectious Disease (IDS) Shipper

TB

_____ Sputum Mailer

Pertussis

_____ Pertussis Mailer

Other

_____ (Specify):_____

Contact Epidemiologic Services at (877) 427-7317 first for AIDS C/T test, Prenatal tests and WNV tests

Send to:
Facility ID No. : _____

Facility Name: _____

Attn: _____

Address: _____

City: _____ **, KS** _____

Phone: _____

LAB USE ONLY

Order Number: _____

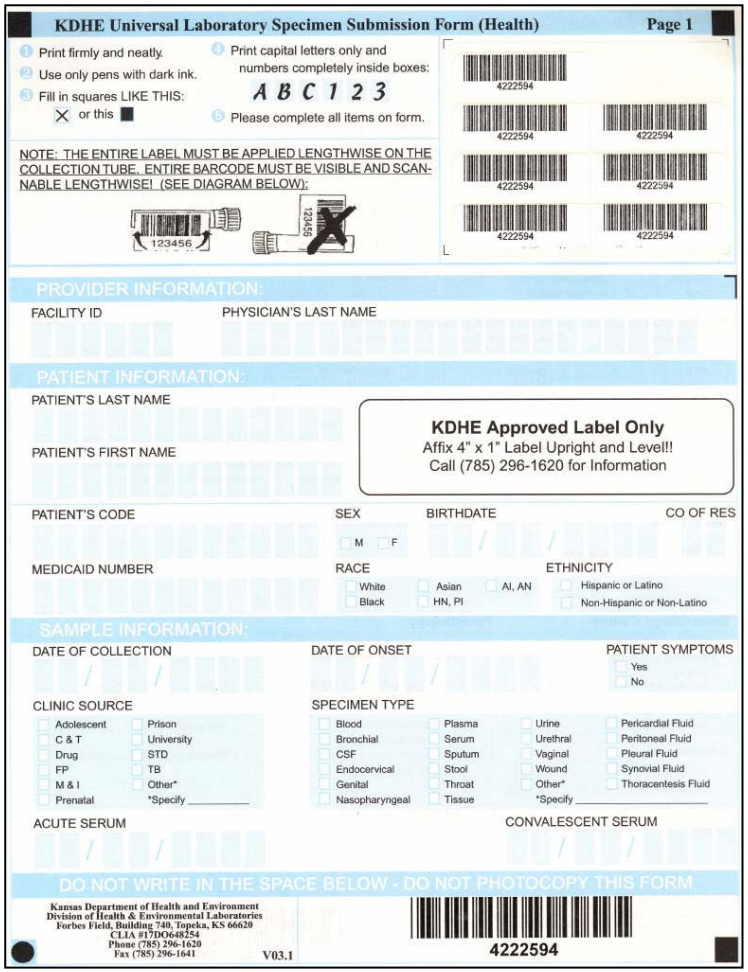
Date Received: _____

Date Shipped: _____

Shipped By: _____

KDHE Division of Laboratories – Universal Laboratory Specimen Submission Form (Test Requisition) Guide

Front Page



KDHE Universal Laboratory Specimen Submission Form (Health) Page 1

Print firmly and neatly.
Use only pens with dark ink.
Fill in squares LIKE THIS: ☒ or this ■
Print capital letters only and numbers completely inside boxes: A B C 1 2 3
Please complete all items on form.

NOTE: THE ENTIRE LABEL MUST BE APPLIED LENGTHWISE ON THE COLLECTION TUBE. ENTIRE BARCODE MUST BE VISIBLE AND SCANNABLE LENGTHWISE! (SEE DIAGRAM BELOW):

PROVIDER INFORMATION:
FACILITY ID
PHYSICIAN'S LAST NAME

PATIENT INFORMATION:
PATIENT'S LAST NAME
PATIENT'S FIRST NAME
PATIENT'S CODE
SEX M F
BIRTHDATE
CO OF RES
MEDICAID NUMBER
RACE White Black Asian HN, PI AI, AN
ETHNICITY Hispanic or Latino Non-Hispanic or Non-Latino

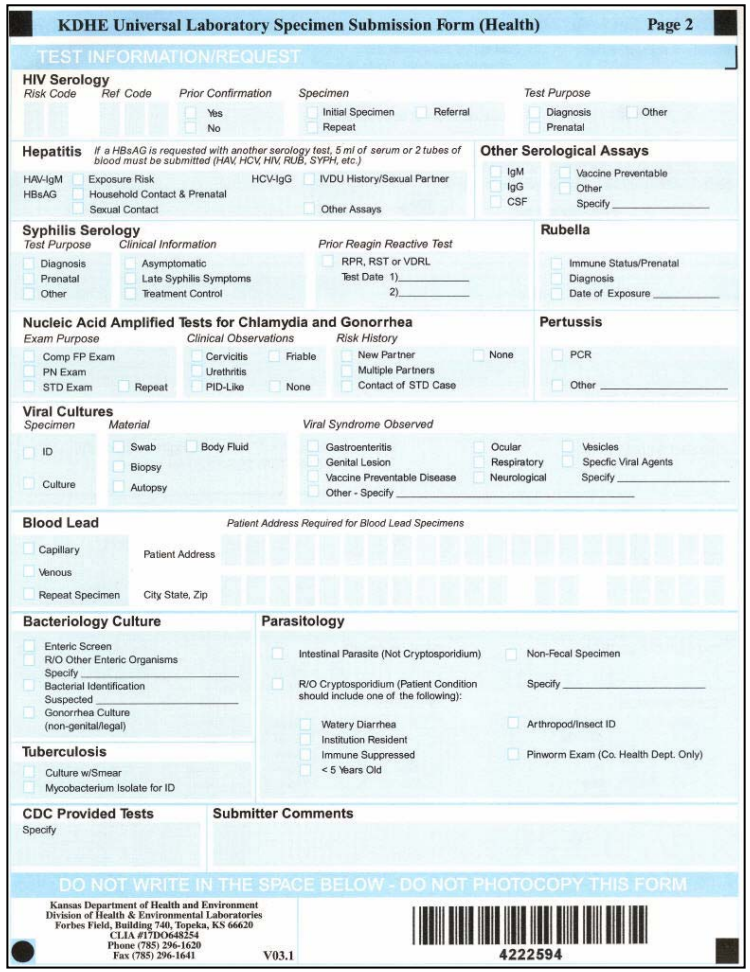
KDHE Approved Label Only
Affix 4" x 1" Label Upright and Level!!
Call (785) 296-1620 for Information

SAMPLE INFORMATION:
DATE OF COLLECTION
DATE OF ONSET
PATIENT SYMPTOMS Yes No
CLINIC SOURCE
Adolescent, C & T, Drug, FP, M & I, Prenatal, Prison, University, STD, TB, Other*, *Specify
SPECIMEN TYPE
Blood, Bronchial, CSF, Endocervical, Genital, Nasopharyngeal, Plasma, Serum, Sputum, Stool, Throat, Tissue, Urine, Urethral, Vaginal, Wound, Other*, *Specify, Pericardial Fluid, Peritoneal Fluid, Pleural Fluid, Synovial Fluid, Thoracentesis Fluid
ACUTE SERUM
CONVALESCENT SERUM

DO NOT WRITE IN THE SPACE BELOW - DO NOT PHOTOCOPY THIS FORM

Kansas Department of Health and Environment
Division of Health & Environmental Laboratories
Forbes Field, Building 740, Topeka, KS 66620
CLIA #17D0648254
Phone (785) 296-1620
Fax (785) 296-1641
V03.1
4222594

Back Page



KDHE Universal Laboratory Specimen Submission Form (Health) Page 2

TEST INFORMATION/REQUEST

HIV Serology
Risk Code | Ref Code | Prior Confirmation: Yes, No | Specimen: Initial Specimen, Repeat, Referral | Test Purpose: Diagnosis, Prenatal, Other

Hepatitis *If a HBsAG is requested with another serology test, 5 ml of serum or 2 tubes of blood must be submitted (HAV, HCV, HIV, RUB, SYPH, etc.)*
HAV-IgM, HBsAG, Exposure Risk, Household Contact & Prenatal, Sexual Contact, HCV-IgG, IVDU History/Sexual Partner, Other Assays

Other Serological Assays
IgM, IgG, CSF, Vaccine Preventable, Other, Specify

Syphilis Serology
Test Purpose: Diagnosis, Prenatal, Other
Clinical Information: Asymptomatic, Late Syphilis Symptoms, Treatment Control
Prior Reagin Reactive Test: RPR, RST or VDRL; Test Date 1)_____ 2)_____

Rubella
Immune Status/Prenatal, Diagnosis, Date of Exposure

Nucleic Acid Amplified Tests for Chlamydia and Gonorrhea
Exam Purpose: Comp FP Exam, PN Exam, STD Exam, Repeat
Clinical Observations: Cervicitis, Urethritis, PID-Like, Friable, None
Risk History: New Partner, Multiple Partners, Contact of STD Case, None

Pertussis
PCR, Other

Viral Cultures
Specimen: ID, Culture
Material: Swab, Biopsy, Autopsy, Body Fluid
Viral Syndrome Observed: Gastroenteritis, Genital Lesion, Vaccine Preventable Disease, Other - Specify, Ocular, Respiratory, Neurological, Vesicles, Specfic Viral Agents, Specify

Blood Lead *Patient Address Required for Blood Lead Specimens*
Capillary, Venous, Repeat Specimen
Patient Address
City State, Zip

Bacteriology Culture
Enteric Screen
R/O Other Enteric Organisms Specify
Bacterial Identification Suspected
Gonorrhea Culture (non-genital/legal)

Tuberculosis
Culture w/Smear
Mycobacterium Isolate for ID

Parasitology
Intestinal Parasite (Not Cryptosporidium)
R/O Cryptosporidium (Patient Condition should include one of the following):
Watery Diarrhea, Institution Resident, Immune Suppressed, < 5 Years Old
Non-Fecal Specimen
Specify
Arthropod/Insect ID
Pinworm Exam (Co. Health Dept. Only)

CDC Provided Tests
Specify

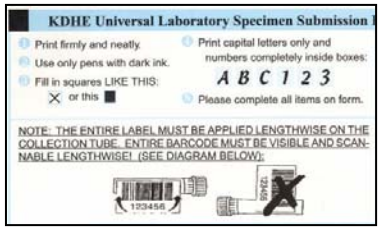
Submitter Comments

DO NOT WRITE IN THE SPACE BELOW - DO NOT PHOTOCOPY THIS FORM

Kansas Department of Health and Environment
Division of Health & Environmental Laboratories
Forbes Field, Building 740, Topeka, KS 66620
CLIA #17D0648254
Phone (785) 296-1620
Fax (785) 296-1641
V03.1
4222594

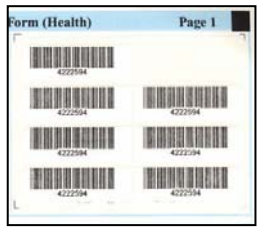
KDHE Division of Laboratories – Universal Laboratory Specimen Submission Form (Test Requisition) Guide

1



1) Carefully read and follow the instructions found on page 1 (front page), of the Universal Laboratory Specimen Submission Form (Universal Form).

2



2) Place a Barcode Sticker on your specimen(s) primary receptacle and keep one sticker for your records.

3

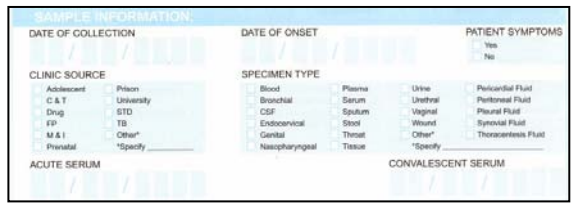
3) Fill in your DHEL Facility ID number and requesting Physician's last name in the Provider Information Section.

The Facility ID number determines where patient results will be sent. The number must be entered correctly.

4

4) Fill in the Patient's last name, first name, code (code is optional and is for the patients use, not for DHEL), Medicaid number, sex, DOB, county of residence, race, and ethnicity in the Patient Information Section.

5



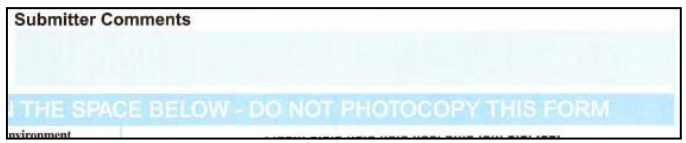
5) Fill in the date of collection, date of onset, patient symptoms, clinic source, and specimen type in the Sample Information Section. If applicable, fill in the Date of Onset, Acute or Convalescent serum sections.

6

6) Select the required tests on page 2 (back page) of the Universal Form.

Note: If selecting blood lead, patient address must be filled in.

7



7) If you have additional comments important to your specimen, write them in the Submitter Comments Section.

- Each form number is unique and assigned to you. **DO NOT** photocopy the Universal Form.
- Mark all applicable areas completely.
- If you do not know your facility ID, call the Lab at: (785) 296-1620.
- Place completed submission form inside fibreboard shipper **outside of secondary container.**
- Universal Forms checked out by your facility may only be used by your facility. Please do not share with other facilities.

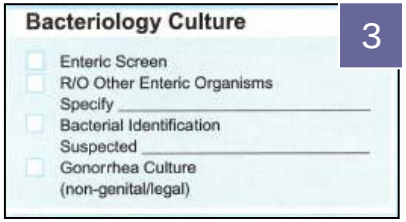
KDHE, Division of Laboratories –
Biological Substance, Category B Packaging and Shipping System Guide: Feces (Bacterial Culture)

- As of October 1, 2006, Federal law requires that the To, From, and **UN3373 Biological Substance, Category B** labels be attached to this fiberboard shipper; if it is not attached one should be attached by your facility.
- This guide is based upon a Triple Packaging system, the primary specimen container (Primary); the secondary red top 95 kPa polyethylene container (Secondary); cushioning material; and fiberboard shipper (Tertiary).
- The bubble wrap or other cushioning material should be wrapped around the primary container to ensure that the primary container does not break.

KDHE, Division of Laboratories –
Biological Substance, Category B Packaging and Shipping System Guide:
Feces (Bacterial Culture)

1) Fiberboard Shipper; Red-topped Secondary Container (95kPa container); Protective Bubble Wrap; absorbent pad; Primary Container.

2) Clinical Specimen Feces (Bacterial Culture) Label –This includes: To/From address blocks, kit expiration date, and sample type.



3) Complete Universal Laboratory Specimen Submission Form (Universal Form); marking the Enteric section on page 2 (back) of the form.

4) Place specimen in to the Primary Container with Modified Cary-Blair and fill in the patient information and date on the attached label.

5) Use the barcode sticker from the Universal Form to label the Primary Container and keep one for your records.

6) Place a barcode sticker from Universal Form on Primary C Container, in addition to the patient name & collection date; see note.

7) Place Primary Container in protective bubble wrap or other cushioning material.

8) Place the wrapped Primary Container into the Red-Topped Secondary Container.

NOTE: To prevent primary container from leaking, it is recommended that each specimen container be secured with ParaFilm or vinyl tape, such as electrical tape.

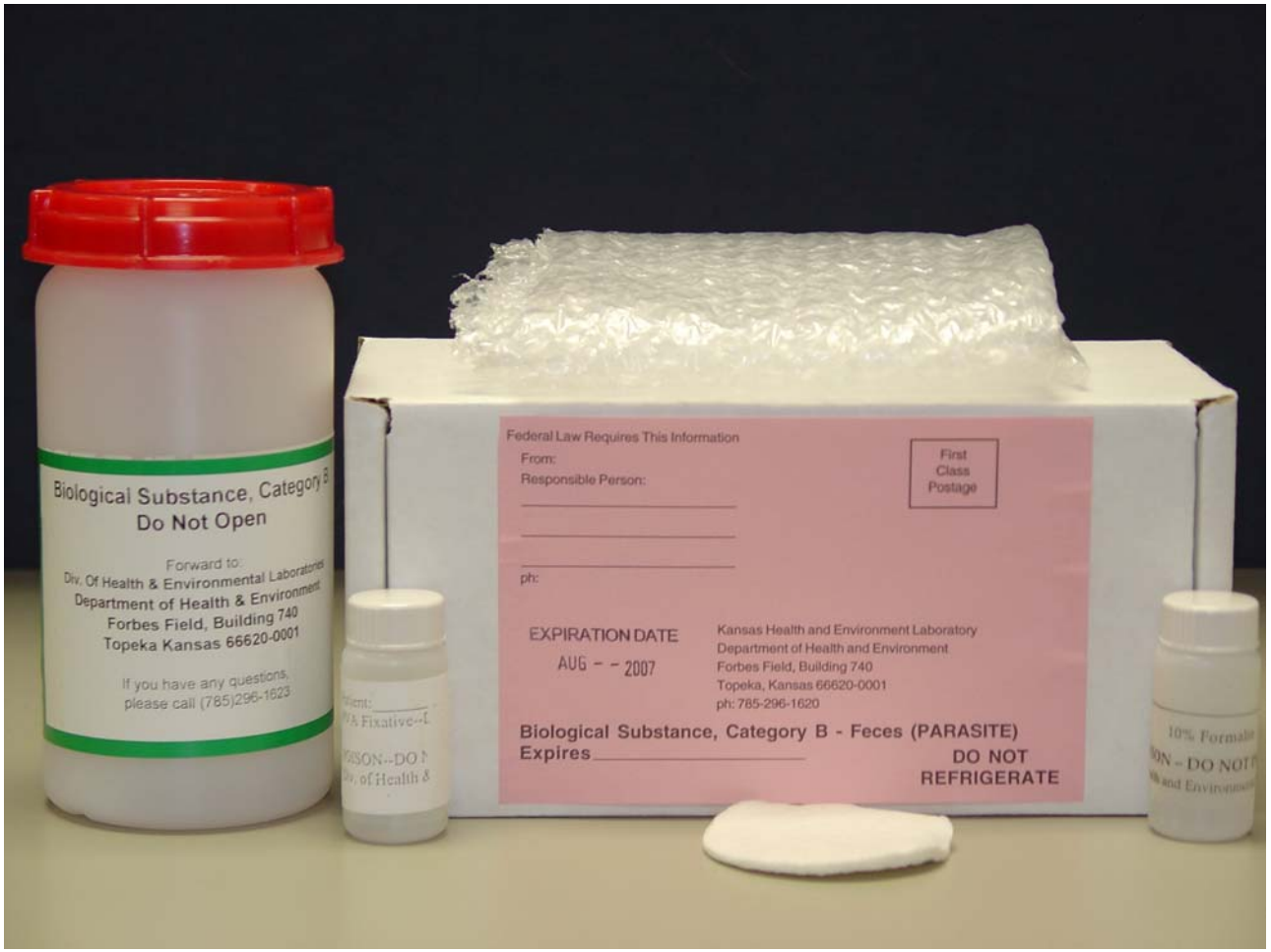
9) Secure top of Secondary Container firmly; **DO NOT** write on this container.

10) Place the Secondary Container into the Fiberboard Shipper.

11) Place cushioning material and the completed Universal Form inside Fiberboard Shipper OUTSIDE OF SECONDARY CONTAINER.

12) Secure Fiberboard Shipper with a strip of tape. Complete the return address label; **DO NOT** write on the box. This package is now ready for shipment to the DHEL.

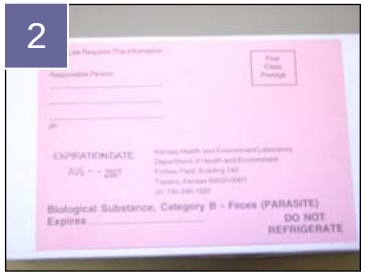
KDHE Division of Laboratories – Biological Substance, Category B Packaging and Shipping Guide: Feces (Parasitology)



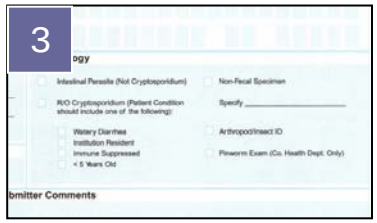
- As of October 1, 2006, Federal law requires that the To, From, and **UN3373 Biological Substance, Category B** labels be attached to this fiberboard shipper; if it is not attached one should be attached by your facility.
- This guide is based upon a Triple Packaging system, the primary specimen container (Primary); the secondary red top 95 kPa polyethylene container (Secondary); cushioning material; and fiberboard shipper (Tertiary).
- The bubble wrap or other cushioning material should be wrapped around the primary container to ensure that the primary container does not break.

KDHE Division of Laboratories –
Biological Substance, Category B Packaging and Shipping Guide:
Feces (Parasitology)

1) Fiberboard Shipper; Red-Topped Secondary Container (95kPa container); Protective Bubble Wrap; two primary containers (specimen bottles).



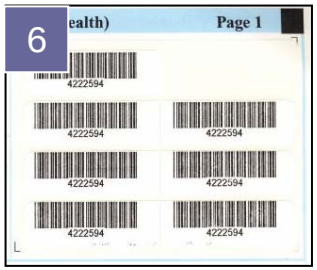
2) Feces (Parasite) Label - This includes: To/From address blocks; kit expiration date, and sample type.



3) Complete Universal Laboratory Specimen Submission Form (Universal Form); marking the Parasitology section on page 2 (back) of the form.

4) Specimen Container PVA Fixative (poison) DO NOT REFRIGERATE - space is provided on this label for patient information.

5) Specimen containing 10% Formalin (poison). Space is provided on this label for patient information.



6) Use the barcode sticker from the Universal Form to label the Primary Container and keep one for your records.

7) Place a barcode sticker from Universal Form on each Primary Container, in addition to the patient name & collection date; see Note.

8) Place the primary containers (10% Formalin bottle and PVA bottle) together into protective bubble wrap.

Note: To prevent primary container from leaking, it is recommended that each specimen container be secured with ParaFilm or vinyl tape, such as electrical tape.

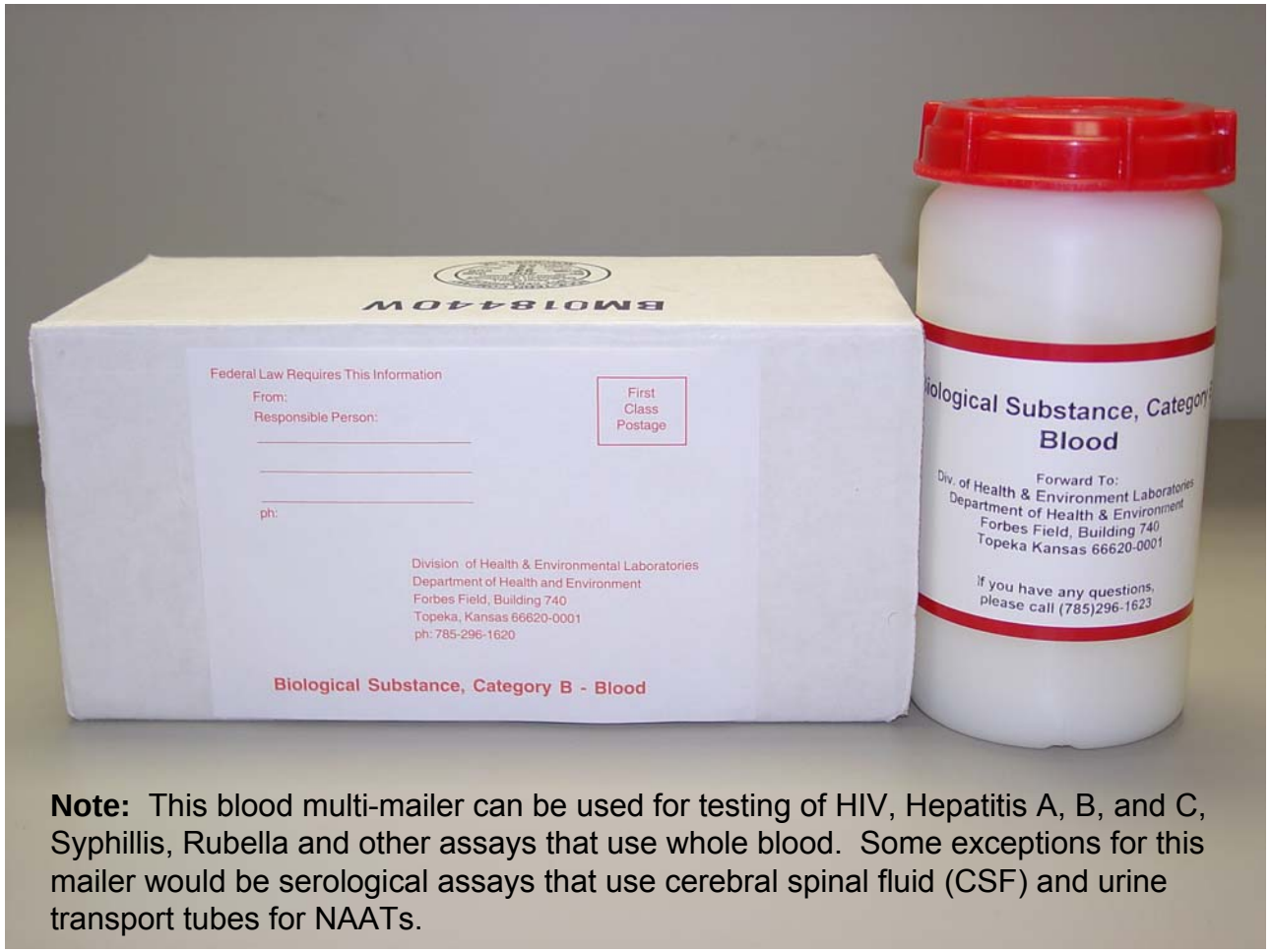
9) Place wrapped specimen containers inside the Secondary Container and firmly secure the top; **DO NOT** write on this container.

10) Place the Secondary Container into the Fiberboard Shipper.

11) Place cushioning material and the completed Universal Form inside Fiberboard Shipper OUTSIDE OF SECONDARY CONTAINER.

12) Secure Fiberboard Shipper with a strip of tape. Complete the return address label; **DO NOT** write on the box. This package is now ready for shipment to the DHEL.

KDHE Division of Laboratories – Biological Substance, Category B Packaging and Shipping System Guide: Blood Multi-mailer



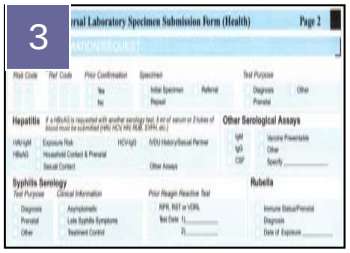
Note: This blood multi-mailer can be used for testing of HIV, Hepatitis A, B, and C, Syphillis, Rubella and other assays that use whole blood. Some exceptions for this mailer would be serological assays that use cerebral spinal fluid (CSF) and urine transport tubes for NAATs.

- As of October 1, 2006, Federal law requires that the To, From, and **UN3373 Biological Substance, Category B** labels be attached to this Fiberboard Shipper; if it is not attached one should be attached by your facility.
- This guide is based upon a Triple Packaging system, the primary specimen container (Primary); the secondary red top 95 kPa polyethylene container (Secondary); cushioning material; and Fiberboard Shipper (Tertiary).
- The bubble wrap or other cushioning material should be wrapped around the Primary Container to ensure that the Primary Container does not break.

KDHE Division of Laboratories –
Biological Substance, Category B Packaging and Shipping System Guide:
Blood Multi-mailer (e.g. HIV, Hepatitis A, B & C, Syphillis and Rubella)

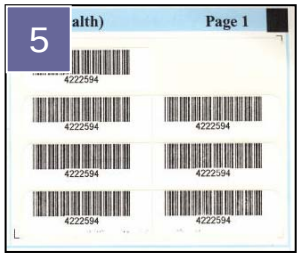
1) Fiberboard Shipper; Red-Topped Biohazard Secondary Container (95kPa container) with five-tube foam insert and topper.

2) Clinical Specimen Blood Label which includes: To/From address blocks, and sample type.



3) Complete Universal Laboratory Specimen Submission Form (Universal Form); marking the required blood test(s) on page 2 (back) of form.

4) Collect the specimen in the Vacutainer or other blood collection tube (Primary Container).

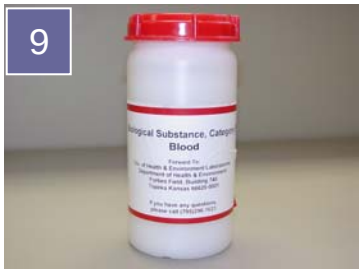


5) Use the barcode sticker from the Universal Form to label the Primary Container and keep one for your records.

6) Place a barcode sticker from Universal Form on Primary Container, in addition to the patient information and date.

7) Place Primary Container(s) in the five-tube foam insert inside the Secondary Container.

8) Place the foam topper insert on top of the blood tubes to secure them from shifting.



9) Secure top of Secondary Container firmly; **DO NOT** write on this container.

10) Place the Secondary Container into the Fiberboard Shipper.

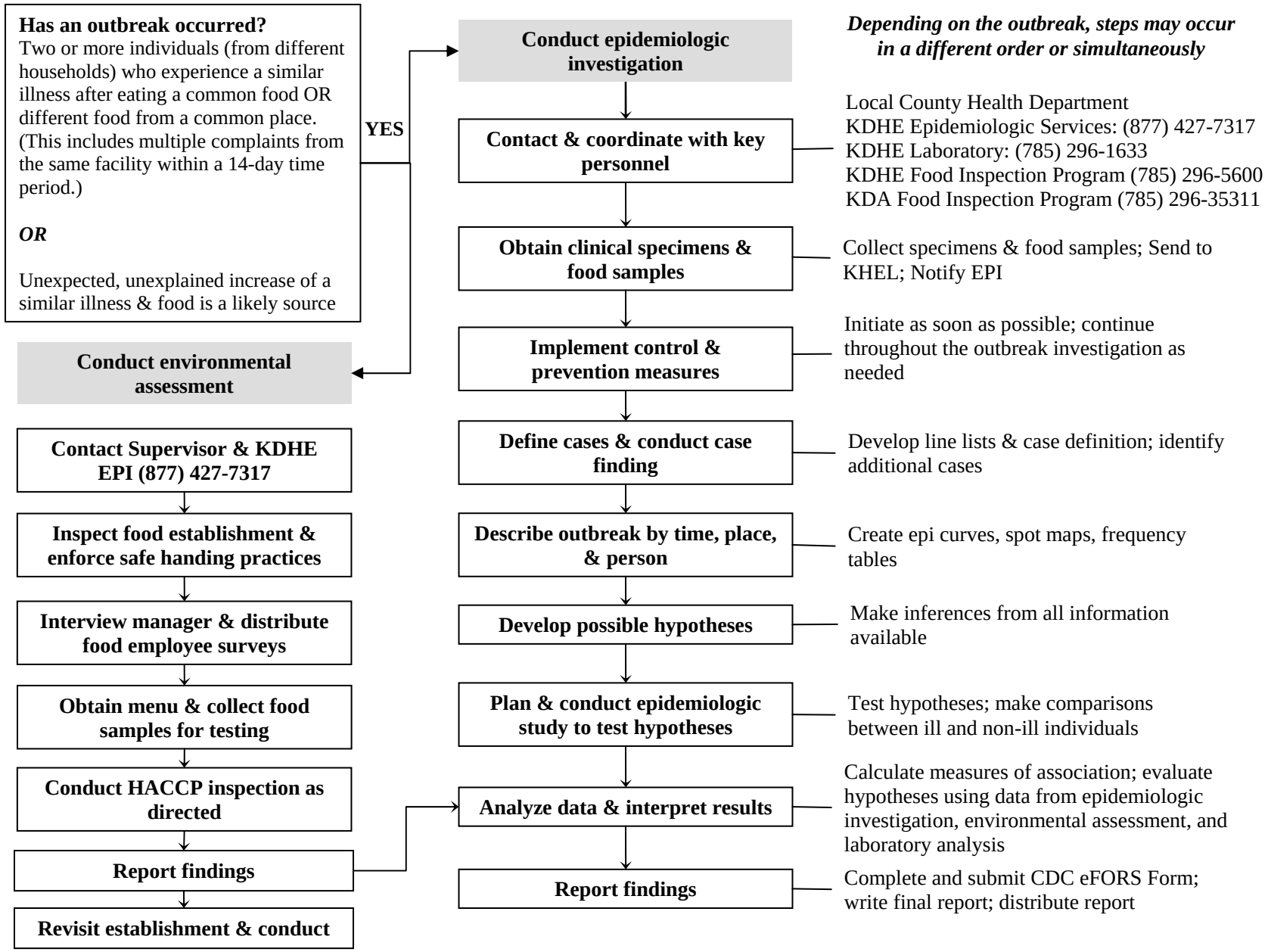
11) Place cushioning material and the completed Universal Form inside Fiberboard Shipper OUTSIDE OF SECONDARY CONTAINER.

12) Secure Fiberboard Shipper with tape. Complete the return address label; **DO NOT** write on the box itself. This package is now ready for shipment to the DHEL.

Note: Universal Forms and blood tubes need to be ordered separate from shipping system.

APPENDIX D
Supplemental Documents for Environment Assessments

FOODBORNE OUTBREAK INVESTIGATION FLOWCHART



Foodborne Disease Outbreak Checklist for Food Inspectors

The following checklist provides general steps that food inspectors or administrators should take during a foodborne disease outbreak investigation.

- ❑ Confirm that a foodborne disease outbreak has occurred. Does it meet the definition for a foodborne disease outbreak?

    - **Multiple foodborne illness complaints** – If there are two or more foodborne illness complaints from the same facility within a 14-day time period

      OR

    - **Two or more individuals became ill after consuming food from a common source AND they reside in at least two households**

- ❑ Call the complainant to collect preliminary information on illness, number ill, number of households involved, total number that attended the event or meal, and other common activities, meals, or drinks shared.

- ❑ Contact and coordinate with supervisor and KDHE Epidemiology at (877) 427-7317 for all outbreaks **prior** to the inspection.

- ❑ Contact and coordinate with local health department infection control nurse.

- ❑ Conduct the food inspection and implement corrective actions.

- ❑ Obtain a copy of the menu and provide it to KDHE Epidemiology so an outbreak questionnaire may be developed.

- ❑ Give the food employee surveys to the supervisor to hand out to **all** employees.

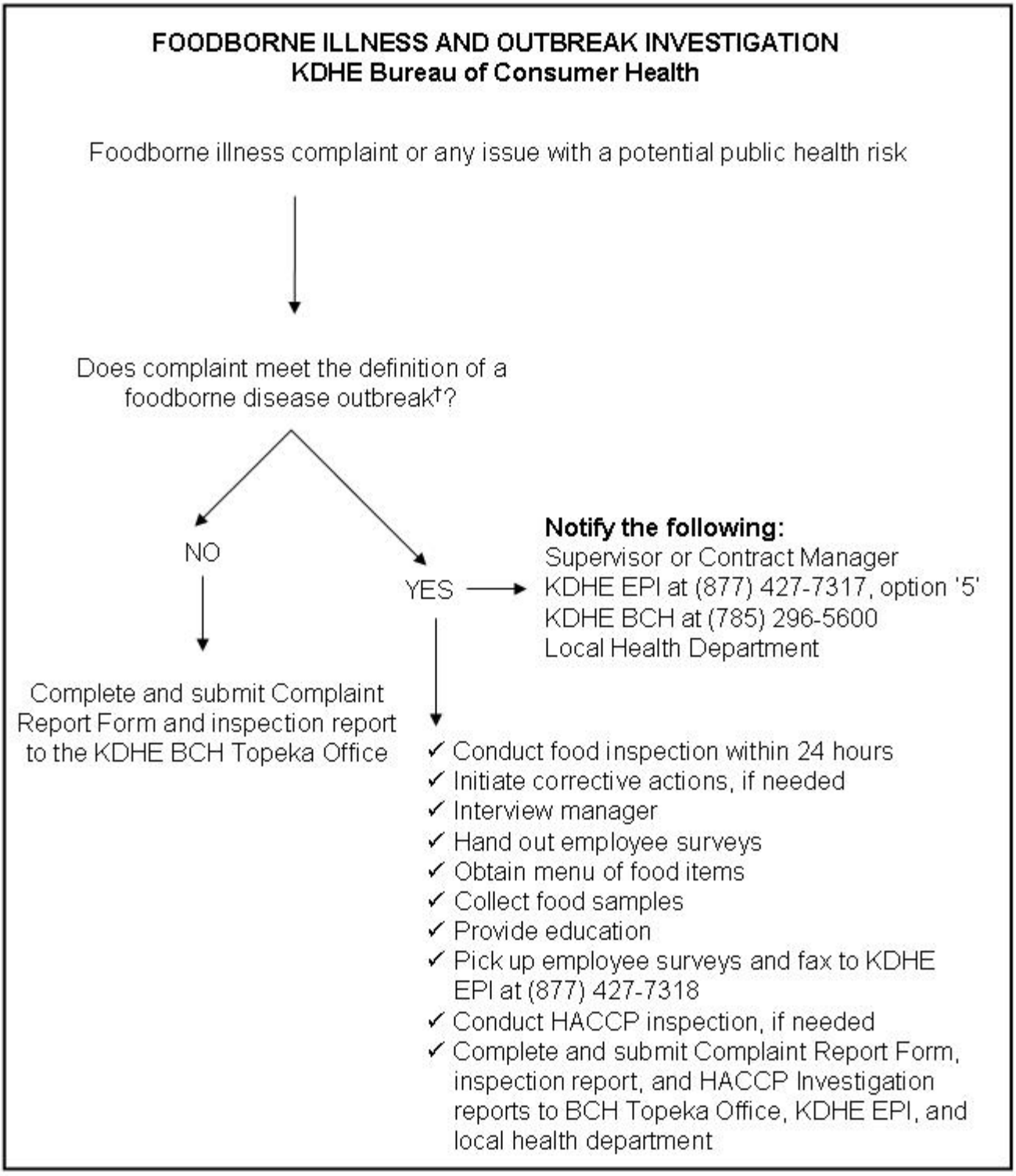
- ❑ Collect the employee surveys as soon as possible or within three days.

- ❑ Send surveys and inspection to KDHE Epidemiology by one of the following ways:
    - FAX: (877) 427-7318 **(preferred method)**
    - MAIL: KDHE- OSE, 1000 SW Jackson, Suite 210, Topeka, KS 66612
    - KDHE Courier

- ❑ As directed, contact a HACCP inspection of the food establishment.

- ❑ Reporting findings and provide reports to supervisor, KDHE Epidemiology, and the local health department

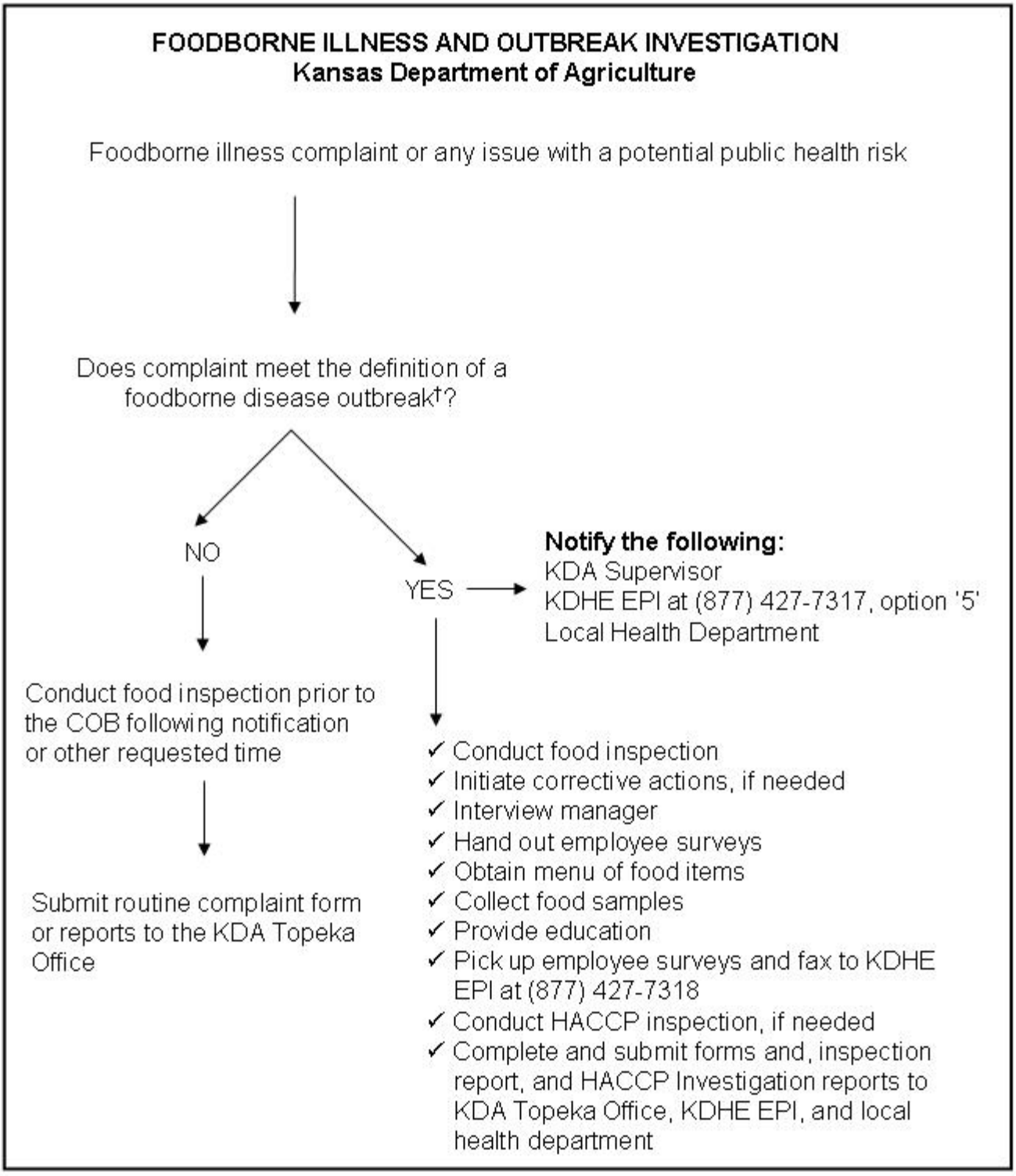
FOODBORNE ILLNESS AND OUTBREAK INVESTIGATION
KDHE Bureau of Consumer Health



† (1) Two or more individuals (from different households) who experience a similar illness after eating a common food or different food from a common place **OR** (2) Two or more foodborne illness complaints from the same facility within a 14-day time period **OR** (3) An unexplained, unexpected increase of a similar illness, and food is a likely source

Revised 03/2008

FOODBORNE ILLNESS AND OUTBREAK INVESTIGATION
Kansas Department of Agriculture



† (1) Two or more individuals (from different households) who experience a similar illness after eating a common food or different food from a common place **OR** (2) Two or more foodborne illness complaints from the same facility within a 14-day time period **OR** (3) An unexplained, unexpected increase of a similar illness, and food is a likely source

Revised 03/2008

COMPLAINT INVESTIGATION REPORT

KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT
BUREAU OF CONSUMER HEALTH
FOOD SAFETY & CONSUMER PROTECTION

Establishment Name: _____ Est ID #: _____ Type: _____

Date Received: _____ Received By: _____ Occurrence Date: _____ Occurrence Time: _____

Complainant: s _____ Phone: ( ) _____ Email: _____

Please check **one** major complaint type:

- ☐ 1 Alleged Foodborne Illness / Outbreak (see below)
- ☐ 2 Personal Health / Hygiene
- ☐ 3 Food Source (sound condition; spoilage; approved
- ☐ 4 Labeling / Expiration
- ☐ 5 Food Protection (temperatures)
- ☐ 6 Water / Plumbing Sewage
- ☐ 7 General Sanitation
- ☐ 8 Insect, Rodent, Animal
- ☐ 9 Other

COMPLAINANT'S CONCERN:

Alleged Foodborne Illness:

Symptoms (✓ All that Apply): ☐ Vomiting ☐ Diarrhea ☐ Nausea ☐ Abdominal Cramps ☐ Fever ☐ Other ____

Date of Illness Onset: _____ Time: _____ # Persons Ill: _____ # Persons Served: _____ # Households involved: _____

Doctor Visited?: Hospitalizations?: Stool sample taken?: Food samples available?:

Food/Beverage Eaten: _____

Any other commonalities/meals shared?: **N** If yes, which meal(s): _____

INSPECTOR COMMENTS:

Date Worked: _____ VALID: _____ INVALID: _____ UNDETERMINED: _____

Date Complainant Notified: _____ Via: Letter/email (copy attached)____ Phone____ Other____

ORIGINAL INSPECTION REPORT & COMPLAINT REPORT FORMS TO TOPEKA OFFICE

Gastroenteritis Surveillance Form for Employees

Name of the Facility _____

Instructions for Employees: Please complete this form as soon as possible and return to your supervisor before the end of the day or work shift.

Name:_____ Age:_____ Sex: ❑ Male ❑ Female

Title:_____ Phone:_____

Type of Work:_____

Do you work as a food service employee at another establishment? ❑ Yes ❑ No

If yes, where? _____

Have you developed any of the following symptoms since ___/___/____? ❑ Yes ❑ No

If yes, what date did the symptoms start? ___/___/____ what time? _____ ❑ a.m. ❑ p.m.

Symptom	Yes	No	Don't Know	
Diarrhea				How many times in a 24-hour period?____
Abdominal Cramps				
Vomiting				
Nausea				
Fever				How high?_____
Chills				
Headache				
Muscle Ache				
Loss of Appetite				
Bloody Stool				
Skin Infection				
Stool Specimen Submitted				Result? _____
Culture of skin infection				Result? _____

Did you completely recover? ❑ Yes ❑ No

If yes: Date: _____ Time _____ ❑ a.m. ❑ p.m.

Name:_____

Were you seen by a physician for the above symptoms? ❑ Yes ❑ No

If yes, Physician's Name and Phone_____

Do you know anyone else experiencing a similar illness? ❑ Yes ❑ No

Name _____ Phone(___)___-____

Name _____ Phone(___)___-____

Please list hours worked, **specific** duties during shift **including foods prepped or prepared**, and food items consumed at the facility on the menu for the following time period.

From ___/___/____through ___/___/____

Date	**Hours Worked**	**Specific Duties and Tasks**	**Foods and Drinks Consumed**

Other Comments:

_____

_____

_____

Procedure for distributing and collecting employee surveys during outbreak investigations

1. Notify KDHE Epidemiology prior to inspection
   If a foodborne illness complaint meets either of these definitions of a foodborne disease outbreak, call the EPI Hotline at (877) 427-7317, option '5', before conducting the inspection. If you are uncertain if a foodborne illness complaint meets the definition of an outbreak, please call the EPI Hotline.

   Definitions of a foodborne disease outbreak

   Multiple foodborne illness complaints – If there are two or more foodborne illness complaints from the same facility within a 14-day time period

   OR

   Two or more individuals became ill after consuming food from a common source AND they reside in at least two households

2. Determine the time period
   Give the epidemiologist on-call the details of the potential foodborne outbreak. The epidemiologist on-call will provide dates for the following lines on the form.

   Have you developed any of the following symptoms since ___/___/____?

   *Please list hours worked, **specific** duties during shift **including foods prepped or prepared**, and food items consumed at the facility on the menu for the following time period. From ___/___/____through* ___/___/____

   Write in these dates and the name of the establishment on the employee survey form.

3. Distribute forms at establishment
   Make as many copies as you think you will need for **all** the employees at the establishment. During the inspection give these forms to the supervisor to distribute to their employees and make arrangements to collect the forms within 3 days, if possible.

4. Send forms to KDHE Epidemiology
   After collecting the forms from the establishment, please send the forms to KDHE Epidemiology by one of the following ways:
   - FAX: (877) 427-7318
   - MAIL: KDHE- OSE, 1000 SW Jackson, Suite 210, Topeka, KS 66612
   - KDHE Courier

If you have questions, contact KDHE Epidemiology at (877) 427-7317, option ‘5’.

EXCLUSION AND RESTRICTION REQUIREMENTS FOR INFECTED FOODHANDLERS

Food handlers with specific diseases or health conditions should be excluded and restricted according to the following requirements. These requirements are based on the 2005 Kansas Food Code.

Health Status of Food handler	Facilities Serving Highly Susceptible Population[†]	Facilities Not Serving Highly Susceptible Population
Diagnosed with illness due to *Salmonella Typhi, Shigella spp.*, Shiga toxin-producing *Escherichia coli*, Hepatitis A virus, or Norovirus	EXCLUDE	EXCLUDE
Experiencing diarrhea, fever, vomiting, or jaundice	EXCLUDE	RESTRICT
Experiencing sore throat with fever or has a lesion containing pus such as a boil or infected wound that is open and draining that cannot be covered and kept dry.	RESTRICT	RESTRICT
Asymptomatic but stools positive for *S.* Typhi, or *E. coli* O157:H7	EXCLUDE	RESTRICT
Previous illness from *Salmonella* Typhi diagnosed within the last 3 months	EXCLUDE	NO RESTRICTIONS
Past illness from *Shigella spp*. or Shiga toxin producing *E. coli* within the last month	EXCLUDE	NO RESTRICTIONS
Onset of jaundice within the last 14 days	EXCLUDE	EXCLUDE
Onset of jaundice more than 14 days	EXCLUDE	RESTRICT
Consumed or prepared food implicated in a foodborne outbreak or consumed food in a setting that was prepared by a person infected or ill with Norovirus, Shiga toxin producing *E. coli*, *Shigella spp. Salmonella typhi*, or Hepatitis A	RESTRICT	NO RESTRICTIONS
Employee has a household contact that worked or attended a setting where there was a foodborne disease ourbreak or has been diagnosed with Norovirus, Shiga toxin producing *E. coli*, *Shigella spp. Salmonella typhi*, or Hepatitis A	RESTRICT	NO RESTRICTIONS

[†] A group of persons who are more likely than other populations to experience foodborne disease because they are immunocompromised or older adults and in a facility that provides health care or assisted living services, such as a hospital or nursing home; or preschool age children in a facility that provides custodial care, such as a day care center.

REMOVAL OF EXCLUSION AND RESTRICTION REQUIREMENTS FOR FOODHANDLERS

Infected food handlers who have been restricted or excluded may be removed from such requirements after the following criteria are met. These requirements are based on the 2005 Kansas Food Code.

Health Status of Food handler	Facilities Serving Highly Susceptible Population[†]	Facilities Not Serving Highly Susceptible Population
Diagnosed with illness due to *Salmonella Typhi*	▪ Reinstate with approval from regulatory authority AND ▪ Written medical documentation that person is free from *S. Typhi* infection	▪ Reinstate with approval from regulatory authority AND ▪ Written medical documentation that person is free from *S. Typhi* infection
Diagnosed with illness due to *Shigella spp.* or Shiga toxin-producing *Escherchia coli*	▪ Reinstate with approval from regulatory authority AND ▪ Written medical documentation of 2 consecutive negative stools taken 48 hours after discontinuance of antibiotics and 24 hours apart OR ▪ Person has been asymptomatic for 7 days	▪ Restrict once asymptomatic for 24 hours ▪ Reinstate with approval from regulatory authority. AND ▪ Written medical documentation of 2 consecutive negative stools taken 48 hours after discontinuance of antibiotics and 24 hours apart. OR ▪ Person has been asymptomatic for 7 days.
Diagnosed with illness due to hepatitis A virus	▪ Reinstate with approval from regulatory authority AND ▪ Person has been jaundiced for more than 7 days OR ▪ Person has had symptoms other than jaundice for more than 14 days OR ▪ Written medical documentation that person is free from Hepatitis A virus infection	▪ Reinstate with approval from regulatory authority. AND ▪ Person has been jaundiced for more than 7 days. OR ▪ Person has had symptoms other than jaundice for more than 14 days. OR ▪ Written medical documentation that person is free from Hepatitis A virus infection.
Diagnosed with illness due to Norovirus	▪ Reinstate with approval from regulatory authority. AND ▪ Written medical documentation that person is free from norovirus infection. OR ▪ Person has been asymptomatic for 48 hours.	▪ Restrict once asymptomatic for 24 hours. ▪ Reinstate with approval from regulatory authority. AND ▪ Written medical documentation that person is free from norovirus infection. OR ▪ Person has been asymptomatic for 48 hours.

[†] A group of persons who are more likely than other populations to experience foodborne disease because they are immunocompromised or older adults and in a facility that provides health care or assisted living services, such as a hospital or nursing home; or preschool age children in a facility that provides custodial care, such as a day care center.

REMOVAL OF EXCLUSION AND RESTRICTION REQUIREMENTS FOR FOODHANDLERS - CONTINUED		
Health Status of Food handler	**Facilities Serving Highly Susceptible Population[†]**	**Facilities Not Serving Highly Susceptible Population**
Experiencing diarrhea, fever, or vomiting but not diagnosed	▪ Reinstate once asymptomatic for 24 hours. OR ▪ Written medical documentation that the symptom is from a noninfectious condition.	▪ Reinstate once asymptomatic for 24 hours. OR ▪ Written medical documentation that the symptom is from a noninfectious condition.
Experiencing sore throat with fever	▪ Written medical documentation that person has been on antibiotics for 24 hours for *Streptococcus pyogenes*, has at least one negative throat culture for *Streptococcus pyogenes*, or is free of the infectious agent.	▪ Written medical documentation that person has been on antibiotics for 24 hours for *Streptococcus pyogenes*, has at least one negative throat culture for *Streptococcus pyogenes*, or is free of the infectious agent.

REMOVAL OF RESTRICTION REQUIREMENTS FOR FOODHANDLERS	
Health Status of Food handler	**Reinstate employee following Restriction**
Exposure to Norovirus	▪ 48 hours since employee was exposed or after household contact became asymptomatic.
Exposure to *Shigella spp*., Shiga toxin *E. coli*	▪ 3 days since employee was exposed or household contact became asymptomatic.
Exposure to *Salmonella Typhi*	▪ 14 days since employee was exposed or household contact became asymptomatic.
Exposure to Hepatitis A	▪ Employee is immune because of prior illness, vaccination, or IgG administration. OR ▪ 50 days since employee was exposed or since employee's household contact became jaundiced.

[†] A group of persons who are more likely than other populations to experience foodborne disease because they are immunocompromised or older adults and in a facility that provides health care or assisted living services, such as a hospital or nursing home; or preschool age children in a facility that provides custodial care, such as a day care center.

HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP)

Overview

Hazard Analysis and Critical Control Point, or HACCP (pronounced HAS-SIP), is a systematic, science-based approach of identifying, evaluating, and controlling food safety hazards[†]. Initially developed to keep food safe for astronauts within the space program, this approach was adopted by the Food and Drug Administration and the U.S. Department of Agriculture as a means of ensuring a safe food supply from harvest to consumption. Currently, the seafood industry, juice industry, and meat and poultry processing plants are required to follow a HACCP plan, or a written documentation of all food processing and handling procedures. A number of food companies in the U. S. have also adopted a HACCP plan in their manufacturing processes.

The following table lists the seven fundamental HACCP principles.

HACCP Principles[†]

1. Conduct a hazard analysis
2. Identify the critical control points (CCP)
3. Establish critical limits for each CCP
4. Establish monitoring procedures
5. Establish corrective actions
6. Establish recordkeeping procedures
7. Establish verification procedures

of common hazards include microorganisms naturally found in meat or poultry products (i.e. *Campylobacter*, *Salmonella*), chemicals that are unintentionally added to food (i.e. pesticides, cleaners), or foreign materials that are accidentally found in food (i.e. metal, plastic).

PRINCIPLE #2: Identify the critical control points (CCPs)

A critical control point (CCP) refers to a point, step, or procedure in the food process during which control measures may be applied to prevent, eliminate, or reduce hazards. An example of a CCP is the procedure of cooking poultry to 165º F to destroy microorganisms that may be present.

PRINCIPLE #3: Establish critical limits for each CCP

Critical limits are defined as the maximum or minimum value at which a biological, chemical, or physical hazard must be controlled at a given CCP to ensure food safety. An example of a critical limit includes holding temperatures, such as the minimum hot holding temperature of 140º F or the maximum cold holding temperature of 41º F.

[†] FDA. *HACCP: A State-of-the-Art Approach to Food Safety*. http://www.cfsan.fda.gov/~lrd/bghaccp.html

PRINCIPLE #4: Establish monitoring procedures
Monitoring procedures are those procedures that check, measure, and document the food process at a given CCP. An example of a monitoring procedure is the routine observation and recording of cooking times and temperatures.

PRINCIPLE #5: Establish corrective actions
When deviations or problems are identified through monitoring, corrective actions are initiated. An example of a corrective action is the disposing of food if the minimum cooking temperature is not met.

PRINCIPLE #6: Establish recordkeeping procedures
Recordkeeping is essential for the documentation of monitoring procedures, hazards identified, and actions taken to correct potential problems. Moreover, recordkeeping ensures that regulatory requirements are met.

PRINCIPLE #7: Establish verification procedures
Verification procedures are necessary to evaluate a HACCP system and determine if the system is working properly. Verification often involves the testing and reviewing of specific steps, quality control and assurance of equipment and procedures, and annual assessments.

Application of HACCP Principles during an Environmental Investigation

When a foodborne disease outbreak is identified in a food service establishment, food inspectors conduct an inspection that is based on the HACCP principles. Food inspectors follow the food process in the establishment, paying close attention to the preparation of suspect foods or foods implicated in the foodborne disease outbreak.

The following paragraphs describe the general procedures of a HACCP inspection during a foodborne disease outbreak investigation.

Introduction and purpose
Upon arrival at the food service establishment, the inspector should introduce himself to the person in charge and explain the purpose of the inspection.

Identification of ingredients and steps
The inspector should review the menu and identify the ingredients and steps involved in the receiving, storage, preparation and service of suspect food(s). The inspector should obtain recipes for all suspect food(s), identify the ingredients, and collect information about the source. The inspector should also pay close attention to potentially hazardous foods and high-risk preparation factors.

Identify critical control points

Based on the observations made, the inspector should identify critical control points and corrective actions to reduce potential hazards. Microbiological hazards account for the majority of foodborne illness; therefore, emphasis should be placed on contamination, survival, and growth/toxin production risks at these points.

Observe suspect food(s) through establishment

The inspector should observe the suspect food(s) and record the procedures conducted through the operation — from receipt of food from the delivery truck to consumption by the consumer. All risk factors should be observed, including the food source, cooking and holding procedures, potential contamination factors, and poor personal hygiene. Inspectors should have the proper equipment (e.g., thermometers) to assist with these observations. Written documentation on how food(s) were handled and what equipment was used should be completed. Observation and documentation of who handled the food(s) during each preparation step should also be done to help determine if a specific food handler or particular role may have contributed to illness. A flow chart should be developed as a visual tool of the process.

Monitoring and corrective action procedures

Monitoring procedures and corrective actions should be established. These should be discussed in a brief exit interview with the person in charge.

Submit paperwork

Inspectors should write and submit a HACCP inspection report, complete with flow charts, recommendations, and other appropriate paperwork to their supervisor and the epidemiology investigator. Following submission of the report, the inspector should return to the food service establishment to present the report and discuss recommendations with the person in charge.

APPENDIX E
Foodborne Illness and Etiology Tables

TABLE 1. Etiologic agents to consider for various manifestations of foodborne illness

Clinical presentation	Potential food-related agents to consider
Gastroenteritis (vomiting as primary symptom; fever and/or diarrhea also may be present)	Viral gastroenteritis, most commonly rotavirus in an infant or norovirus and other caliciviruses in an older child or adult; or food poisoning due to preformed toxins (eg, vomitoxin, *Staphylococcus aureus* toxin, *Bacillus cereus* toxin) and heavy metals.
Noninflammatory diarrhea (acute watery diarrhea without fever/dysentery; some patients may present with fever)*	Can be caused by virtually all enteric pathogens (bacterial, viral, parasitic) but is a classic symptom of Enterotoxigenic *Escherichia coli* *Giardia* *Vibrio cholerae* Enteric viruses (astroviruses, noroviruses and other caliciviruses, enteric adenovirus, rotavirus) *Cryptosporidium* *Cyclospora cayetanensis*
Inflammatory diarrhea (invasive gastroenteritis; grossly bloody stool and fever may be present)†	*Shigella* species *Campylobacter* species *Salmonella* species Enteroinvasive *E. coli* Enterohemorrhagic *E. coli* *E. coli* O157:H7 *Vibrio parahaemolyticus* *Yersinia enterocolitica* *Entamoeba histolytica*
Persistent diarrhea (lasting ≥14 days)	Prolonged illness should prompt examination for parasites, particularly in travelers to mountainous or other areas where untreated water is consumed. Consider *Cyclospora cayetanensis, Cryptosporidium, Entamoeba histolytica,* and *Giardia lamblia*.
Neurologic manifestations (eg, paresthesias, respiratory depression, bronchospasm, cranial nerve palsies)	Botulism (*Clostridium botulinum* toxin) Organophosphate pesticides Thallium poisoning Scombroid fish poisoning (histamine, saurine) Ciguatera fish poisoning (ciguatoxin) Tetradon fish poisoning (tetradotoxin) Neurotoxic shellfish poisoning (brevitoxin) Paralytic shellfish poisoning (saxitoxin) Amnesic shellfish poisoning (domoic acid) Mushroom poisoning Guillain-Barré syndrome (associated with infectious diarrhea due to *Campylobacter jejuni*)
Systemic illness (eg, fever, weakness, arthritis, jaundice)	*Listeria monocytogenes* *Brucella* species *Trichinella spiralis* *Toxoplasma gondii* *Vibrio vulnificus* Hepatitis A and E viruses *Salmonella* Typhi and *Salmonella* Paratyphi Amebic liver abscess

* Noninflammatory diarrhea is characterized by mucosal hypersecretion or decreased absorption without mucosal destruction and generally involves the small intestine. Some affected patients may be dehydrated because of severe watery diarrhea and may appear seriously ill. This is more common in the young and the elderly. Most patients experience minimal dehydration and appear mildly ill with scant physical findings. Illness typically occurs with abrupt onset and brief duration. Fever and systemic symptoms usually are absent (except for symptoms related directly to intestinal fluid loss).

† Inflammatory diarrhea is characterized by mucosal invasion with resulting inflammation and is caused by invasive or cytotoxigenic microbial pathogens. The diarrheal illness usually involves the large intestine and may be associated with fever, abdominal pain and tenderness, headache, nausea, vomiting, malaise, and myalgia. Stools may be bloody and may contain many fecal leukocytes.

Foodborne Illnesses (Bacterial)

Etiology	Incubation Period	Signs and Symptoms	Duration of Illness	Associated Foods	Laboratory Testing	Treatment
Bacillus anthracis	2 days to weeks	Nausea, vomiting, malaise, bloody diarrhea, acute abdominal pain.	Weeks	Insufficiently cooked contaminated meat.	Blood.	Penicillin is first choice for naturally acquired gastrointestinal anthrax. Ciprofloxacin is second option.
Bacillus cereus (preformed enterotoxin)	1–6 hrs	Sudden onset of severe nausea and vomiting. Diarrhea may be present.	24 hrs	Improperly refrigerated cooked or fried rice, meats.	Normally a clinical diagnosis. Clinical laboratories do not routinely identify this organism. If indicated, send stool and food specimens to reference laboratory for culture and toxin identification.	Supportive care.
Bacillus cereus (diarrheal toxin)	10–16 hours	Abdominal cramps, watery diarrhea, nausea.	24–48 hours	Meats, stews, gravies, vanilla sauce.	Testing not necessary, self-limiting (consider testing food and stool for toxin in outbreaks).	Supportive care.
Brucella abortus, B. melitensis, and *B. suis*	7–21 days	Fever, chills, sweating, weakness, headache, muscle and joint pain, diarrhea, bloody stools during acute phase.	Weeks	Raw milk, goat cheese made from unpasteurized milk, contaminated meats.	Blood culture and positive serology.	*Acute:* Rifampin and doxycycline daily for ≥6 weeks. Infections with complications require combination therapy with rifampin, tetracycline, and an aminoglycoside.
Campylobacter jejuni	2–5 days	Diarrhea, cramps, fever, and vomiting; diarrhea may be bloody.	2–10 days	Raw and undercooked poultry, unpasturized milk, contaminated water.	Routine stool culture; *Campylobacter* requires special media and incubation at 42°C to grow.	Supportive care. For severe cases, antibiotics such as erythromycin and quinolones may be indicated early in the diarrheal disease. Guillain-Barré syndrome can be a sequela.
Clostridium botulinum—children and adults (preformed toxin)	12–72 hrs	Vomiting, diarrhea, blurred vision, diplopia, dysphagia, and descending muscle weakness.	Variable (from days to months). Can be complicated by respiratory failure and death.	Home-canned foods with a low acid content, improperly canned commercial foods, home-canned or fermented fish, herb-infused oils, baked potatoes in aluminium foil, cheese sauce, bottled garlic, foods held warm for extended periods of time (eg, in a warm oven).	Stool, serum, and food can be tested for toxin. Stool and food can also be cultured for the organism. These tests can be performed at some state health department laboratories and CDC.	Supportive care. Botulinum antitoxin is helpful if given early in the course of the illness. Contact the state health department. The 24-hour number for state health departments to call is (770) 488-7100.
Clostridium botulinum—infants	3–30 days	In infants <12 months, lethargy, weakness, poor feeding, constipation, hypotonia, poor head control, poor gag and sucking reflex.	Variable	Honey, home-canned vegetables and fruits, corn syrup.	Stool, serum, and food can be tested for toxin. Stool and food can also be cultured for the organism. These tests can be performed at some state health department laboratories and CDC.	Supportive care. Botulism immune globulin can be obtained from the Infant Botulism Prevention Program, Health and Human Services, California (510-540-2646). Botulinum antitoxin is generally not recommended for infants.
Clostridium perfringens toxin	8–16 hrs	Watery diarrhea, nausea, abdominal cramps; fever is rare.	24–48 hrs	Meats, poultry, gravy, dried or precooked foods, time- and/or temperature-abused food.	Stools can be tested for enterotoxin and cultured for organism. Because *Clostridium perfringens* can normally be found in stool, quantitative cultures must be done.	Supportive care. Antibiotics not indicated.
Enterohemorrhagic *E. coli* (EHEC) including *E. coli* O157:H7 and other Shiga toxin-producing *E. coli* (STEC)	1–8 days	Severe diarrhea that is often bloody, abdominal pain and vomiting. Usually, little or no fever is present. More common in children <4 years.	5–10 days	Undercooked beef especially hamburger, unpasteurized milk and juice, raw fruits and vegetables (eg. sprouts), salami (rarely), and contaminated water.	Stool culture; *E. coli* O157:H7 requires special media to grow. If *E. coli* O157:H7 is suspected, specific testing must be requested. Shiga toxin testing may be done using commercial kits; positive isolates should be forwarded to public health laboratories for confirmation and serotyping.	Supportive care, monitor renal function, hemoglobin, and platelets closely. *E. coli* O157:H7 infection is also associated with hemolytic uremic syndrome (HUS), which can cause lifelong complications. Studies indicate that antibiotics may promote the development of HUS.

Foodborne Illnesses (Bacterial) (*Continued*)

Etiology	Incubation Period	Signs and Symptoms	Duration of Illness	Associated Foods	Laboratory Testing	Treatment
Enterotoxigenic *E. coli* (ETEC)	1–3 days	Watery diarrhea, abdominal cramps, some vomiting.	3 to >7 days	Water or food contaminated with human feces.	Stool culture. ETEC requires special laboratory techniques for identification. If suspected, must request specific testing.	Supportive care. Antibiotics are rarely needed except in severe cases. Recommended antibiotics include TMP-SMX and quinolones.
Listeria monocytogenes	9–48 hrs for gastrointestinal symptoms, 2–6 weeks for invasive disease	Fever, muscle aches, and nausea or diarrhea. Pregnant women may have mild flu-like illness, and infection can lead to premature delivery or stillbirth. Elderly or immunocompromised patients may have bacteremia or meningitis.	Variable	Fresh soft cheeses, unpasteurized milk, inadequately pasteurized milk, ready-to-eat deli meats, hot dogs.	Blood or cerebrospinal fluid cultures. Asymptomatic fecal carriage occurs; therefore, stool culture usually not helpful. Antibody to listerolysin O may be helpful to identify outbreak retrospectively.	Supportive care and antibiotics; Intravenous ampicillin, penicillin, or TMP-SMX are recommended for invasive disease.
	At birth and infancy	Infants infected from mother at risk for sepsis or meningitis.				
Salmonella spp.	1–3 days	Diarrhea, fever, abdominal cramps, vomiting. *S.* Typhi and *S.* Paratyphi produce typhoid with insidious onset characterized by fever, headache, constipation, malaise, chills, and myalgia; diarrhea is uncommon, and vomiting is not usually severe.	4–7 days	Contaminated eggs, poultry, unpasteurized milk or juice, cheese, contaminated raw fruits and vegetables (alfalfa sprouts, melons). *S.* Typhi epidemics are often related to fecal contamination of water supplies or street-vended foods.	Routine stool cultures.	Supportive care. Other than for *S.* Typhi and *S.* Paratyphi, antibiotics are not indicated unless there is extra-intestinal spread, or the risk of extra-intestinal spread, of the infection. Consider ampicillin, gentamicin, TMP-SMX, or quinolones if indicated. A vaccine exists for *S.* Typhi.
Shigella spp.	24–48 hrs	Abdominal cramps, fever, and diarrhea. Stools may contain blood and mucus.	4–7 days	Food or water contaminated with human fecal material. Usually person-to-person spread, fecal–oral transmission. Ready-to-eat foods touched by infected food workers, eg, raw vegetables, salads, sandwiches.	Routine stool cultures.	Supportive care. TMP-SMX recommended in the US if organism is susceptible; nalidixic acid or other quinolones may be indicated if organism is resistant, especially in developing countries.
Staphylococcus aureus (preformed enterotoxin)	1–6 hrs	Sudden onset of severe nausea and vomiting. Abdominal cramps. Diarrhea and fever may be present.	24–48 hrs	Unrefrigerated or improperly refrigerated meats, potato and egg salads, cream pastries.	Normally a clinical diagnosis. Stool, vomitus, and food can be tested for toxin and cultured if indicated.	Supportive care.
Vibrio cholerae (toxin)	24–72 hrs	Profuse watery diarrhea and vomiting, which can lead to severe dehydration and death within hours.	3–7 days. Causes life-threatening dehydration.	Contaminated water, fish, shellfish, street-vended food typically from Latin America or Asia.	Stool culture; *Vibrio cholerae* requires special media to grow. If *V. cholerae* is suspected, must request specific testing.	Supportive care with aggressive oral and intravenous rehydration. In cases of confirmed cholera, tetracycline or doxycycline is recommended for adults, and TMP-SMX for children (<8 years).
Vibrio parahaemolyticus	2–48 hrs	Watery diarrhea, abdominal cramps, nausea, vomiting.	2–5 days	Undercooked or raw seafood, such as fish, shellfish.	Stool cultures. *Vibrio parahaemolyticus* requires special media to grow. If *V. parahaemolyticus* is suspected, must request specific testing.	Supportive care. Antibiotics are recommended in severe cases: tetracycline, doxycycline, gentamicin, and cefotaxime.
Vibrio vulnificus	1–7 days	Vomiting, diarrhea, abdominal pain, bacteremia, and wound infections. More common in the immunocompromised, or in patients with chronic liver disease (presenting with bullous skin lesions). Can be fatal in patients with liver disease and the immunocompromised.	2–8 days	Undercooked or raw shellfish, especially oysters, other contaminated seafood, and open wounds exposed to sea water.	Stool, wound, or blood cultures. *Vibrio vulnificus* requires special media to grow. If *V. vulnificus* is suspected, must request specific testing.	Supportive care and antibiotics; tetracycline, doxycycline, and ceftazidime are recommended.

Foodborne Illnesses (Bacterial) (*Continued*)

Etiology	Incubation Period	Signs and Symptoms	Duration of Illness	Associated Foods	Laboratory Testing	Treatment
Yersinia enterocolytica and *Y. pseudotuberculosis*	24–48 hrs	Appendicitis-like symptoms (diarrhea and vomiting, fever, and abdominal pain) occur primarily in older children and young adults. May have a scarlitiniform rash with *Y. pseudotuberculosis.*	1–3 weeks, usually self-limiting	Undercooked pork, unpasteurized milk, tofu, contaminated water. Infection has occurred in infants whose caregivers handled chitterlings.	Stool, vomitus, or blood culture. *Yersinia* requires special media to grow. If suspected, must request specific testing. Serology is available in research and reference laboratories.	Supportive care. If septicemia or other invasive disease occurs, antibiotic therapy with gentamicin or cefotaxime (doxycycline and ciprofloxacin also effective).

Foodborne Illnesses (Viral)

Etiology	Incubation Period	Signs and Symptoms	Duration of Illness	Associated Foods	Laboratory Testing	Treatment
Hepatitis A	28 days average (15–50 days)	Diarrhea, dark urine, jaundice, and flu-like symptoms, i.e., fever, headache, nausea, and abdominal pain.	Variable, 2 weeks – 3 months	Shellfish harvested from contaminated waters, raw produce, contaminated drinking water, uncooked foods and cooked foods that are not reheated after contact with infected food handler.	Increase in ALT, bilirubin. Positive IgM and anti-hepatitis A antibodies.	Supportive care. Prevention with immunization.
Noroviruses (and other caliciviruses)	12–48 hrs	Nausea, vomiting, abdominal cramping, diarrhea, fever, myalgia, and some headache. Diarrhea is more prevalent in adults and vomiting is more prevalent in children.	12–60 hrs	Shellfish, fecally contaminated foods, ready-to-eat foods touched by infected food workers (salads, sandwiches, ice, cookies, fruit).	Routine RT-PCR and EM on fresh unpreserved stool samples. Clinical diagnosis, negative bacterial cultures. Stool is negative for WBCs.	Supportive care such as rehydration. Good hygiene.
Rotavirus	1–3 days	Vomiting, watery diarrhea, low-grade fever. Temporary lactose intolerance may occur. Infants and children, elderly, and immunocompromised are especially vulnerable.	4–8 days	Fecally contaminated foods. Ready-to-eat foods touched by infected food workers (salads, fruits).	Identification of virus in stool via immunoassay.	Supportive care. Severe diarrhea may require fluid and electrolyte replacement.
Other viral agents (astroviruses, adenoviruses, parvoviruses)	10–70 hrs	Nausea, vomiting, diarrhea, malaise, abdominal pain, headache, fever.	2–9 days	Fecally contaminated foods. Ready-to-eat foods touched by infected food workers. Some shellfish.	Identification of the virus in early acute stool samples. Serology. Commercial ELISA kits are now available for adenoviruses and astroviruses.	Supportive care, usually mild, self-limiting. Good hygiene.

Foodborne Illnesses (Parasitic)

Etiology	Incubation Period	Signs and Symptoms	Duration of Illness	Associated Foods	Laboratory Testing	Treatment
Angiostrongylus cantonensis	1 week to ≥1 month	Severe headaches, nausea, vomiting, neck stiffness, paresthesias, hyperesthesias, seizures, and other neurologic abnormalities.	Several weeks to several months	Raw or undercooked intermediate hosts (eg, snails or slugs), infected paratenic (transport) hosts (eg, crabs, fresh water shrimp), fresh produce contaminated with intermediate or transport hosts.	Examination of CSF for elevated pressure, protein, leukocytes, and eosinophils; serologic testing using ELISA to detect antibodies to *Angiostrongylus cantonensis.*	Supportive care. Repeat lumbar punctures and use of corticosteroid therapy may be used for more severely ill patients.
Cryptosporidium	2–10 days	Diarrhea (usually watery), stomach cramps, upset stomach, slight fever.	May be remitting and relapsing over weeks to months	Any uncooked food or food contaminated by an ill food handler after cooking, drinking water.	Request specific examination of the stool for *Cryptosporidium.* May need to examine water or food.	Supportive care, self-limited. If severe consider paromomycin for 7 days. For children aged 1–11 years, consider nitazoxanide for 3 days.
Cyclospora cayetanensis	1–14 days, usually at least 1 week	Diarrhea (usually watery), loss of appetite, substantial loss of weight, stomach cramps, nausea, vomiting, fatigue.	May be remitting and relapsing over weeks to months	Various types of fresh produce (imported berries, lettuce).	Request specific examination of the stool for *Cyclospora.* May need to examine water or food.	TMP-SMX for 7 days.

Foodborne Illnesses (Parasitic) (*Continued*)

Etiology	Incubation Period	Signs and Symptoms	Duration of Illness	Associated Foods	Laboratory Testing	Treatment
Entamoeba histolytica	2–3 days to 1–4 weeks	Diarrhea (often bloody), frequent bowel movements, lower abdominal pain.	May be protracted (several weeks to several months)	Any uncooked food or food contaminated by an ill food handler after cooking, drinking water.	Examination of stool for cysts and parasites—may need at least 3 samples. Serology for long-term infections.	Metronidazole and a luminal agent (iodoquinol or paromomycin).
Giardia lamblia	1–2 weeks	Diarrhea, stomach cramps, gas.	Days to weeks	Any uncooked food or food contaminated by an ill food handler after cooking, drinking water.	Examination of stool for ova and parasites — may need at least 3 samples.	Metronidazole.
Toxoplasma gondii	5–23 days	Generally asymptomatic, 20% may develop cervical lymphadenopathy and/or a flu-like illness. In immunocompromised patients: central nervous system (CNS) disease, myocarditis, or pneumonitis is often seen.	Months	Accidental ingestion of contaminated substances (eg, soil contaminated with cat feces on fruits and vegetables), raw or partly cooked meat (especially pork, lamb, or venison).	Isolation of parasites from blood or other body fluids; observation of parasites in patient specimens via microscopy or histology. Detection of organisms is rare; serology (reference laboratory needed) can be a useful adjunct in diagnosing toxoplasmosis. However, IgM antibodies may persist for 6–18 months and thus may not necessarily indicate recent infection. PCR of bodily fluids. For congenital infection: isolation of *T. gondii* from placenta, umbilical cord, or infant blood. PCR of white blood cells, CSF, or amniotic fluid, or IgM and IgA serology, performed by a reference laboratory.	Asymptomatic healthy, but infected, persons do not require treatment. Spiramycin or pyrimethamine plus sulfadiazine may be used for pregnant women. Pyrimethamine plus sulfadiazine may be used for immunocompromised persons, in specific cases. Pyrimethamine plus sulfadiazine (with or without steroids) may be given for ocular disease when indicated. Folinic acid is given with pyrimethamine plus sulfadiazine to counteract bone marrow suppression.
Toxoplasma gondii (congenital infection)	In infants at birth	Treatment of the mother may reduce severity and/or incidence of congenital infection. Most infected infants have few symptoms at birth. Later, they will generally develop signs of congenital toxoplasmosis (mental retardation, severely impaired eyesight, cerebral palsy, seizures), unless the infection is treated.	Months	Passed from mother (who acquired acute infection during pregnancy) to child.		
Trichinella spiralis	1–2 days for initial symptoms; others begin 2–8 weeks after infection	Acute: nausea, diarrhea, vomiting, fatigue, fever, abdominal discomfort followed by muscle soreness, weakness, and occasional cardiac and neurologic complications.	Months	Raw or undercooked contaminated meat, usually pork or wild game meat (eg, bear or moose).	Positive serology or demonstration of larvae via muscle biopsy. Increase in eosinophils.	Supportive care plus mebendazole or albendazole.

Foodborne Illnesses (Noninfectious)

Etiology	Incubation Period	Signs and Symptoms	Duration of Illness	Associated Foods	Laboratory Testing	Treatment
Antimony	5 min – 8 hrs. usually <1 hr	Vomiting, metallic taste.	Usually self-limited	Metallic container.	Identification of metal in beverage or food.	Supportive care.
Arsenic	Few hrs	Vomiting, colic, diarrhea.	Several days	Contaminated food.	Urine. May cause eosinophilia.	Gastric lavage, BAL (dimercaprol).
Cadmium	5 min – 8 hrs. usually <1 hr	Nausea, vomiting, myalgia, increase in salivation, stomach pain.	Usually self-limited	Seafood, oysters, clams, lobster, grains, peanuts.	Identification of metal in food.	Supportive care.
Ciguatera fish poisoning (ciguatera toxin)	2–6 hrs 3 hrs 2–5 days	GI: abdominal pain, nausea, vomiting, diarrhea. Neurologic: paresthesias, reversal of hot or cold, pain, weakness. Cardiovascular: bradycardia, hypotension, increase in T wave abnormalities.	Days to weeks to months	A variety of large reef fish. Grouper, red snapper, amberjack, and barracuda (most common).	Radioassay for toxin in fish or a consistent history.	Supportive care, IV mannitol. Children more vulnerable.
Copper	5 min – 8 hrs. usually <1 hr	Nausea, vomiting, blue or green vomitus.	Usually self-limited	Metallic container.	Identification of metal in beverage or food.	Supportive care.
Mercury	1 week or longer	Numbness, weakness of legs, spastic paralysis, impaired vision, blindness, coma. Pregnant women and the developing fetus are especially vulnerable.	May be protracted	Fish exposed to organic mercury, grains treated with mercury fungicides.	Analysis of blood, hair.	Supportive care.
Mushroom toxins, short-acting (muscinol, muscarine, psilocybin, coprius artemetaris, ibotenic acid)	<2 hrs	Vomiting, diarrhea, confusion, visual disturbance, salivation, diaphoresis, hallucinations, disulfiram-like reaction, confusion, visual disturbance.	Self-limited	Wild mushrooms (cooking may not destroy these toxins).	Typical syndrome and mushroom identified or demonstration of the toxin.	Supportive care.
Mushroom toxin, long-acting (amanitin)	4–8 hrs diarrhea; 24–48 hrs liver failure	Diarrhea, abdominal cramps, leading to hepatic and renal failure.	Often fatal	Mushrooms.	Typical syndrome and mushroom identified and/or demonstration of the toxin.	Supportive care, life-threatening, may need life support.
Nitrite poisoning	1–2 hrs	Nausea, vomiting, cyanosis, headache, dizziness, weakness, loss of consciousness, chocolate-brown colored blood.	Usually self-limited	Cured meats, any contaminated foods, spinach exposed to excessive nitrification.	Analysis of the food, blood.	Supportive care, methylene blue.
Pesticides (organophosphates or carbamates)	Few min to few hrs	Nausea, vomiting, abdominal cramps, diarrhea, headache, nervousness, blurred vision, twitching, convulsions, salivation and meiosis.	Usually self-limited	Any contaminated food.	Analysis of the food, blood.	Atropine; 2-PAM (Pralidoxime) is used when atropine is not able to control symptoms and is rarely necessary in carbamate poisoning.
Puffer fish (tetrodotoxin)	<30 min	Parasthesias, vomiting, diarrhea, abdominal pain, ascending paralysis, respiratory failure.	Death usually in 4–6 hours	Puffer fish.	Detection of tetrodotoxin in fish.	Life-threatening, may need respiratory support.
Scombroid (histamine)	1 min – 3 hrs	Flushing, rash, burning sensation of skin, mouth and throat, dizziness, uriticaria, parasthesias.	3–6 hrs	Fish: bluefin, tuna, skipjack, mackerel, marlin, escolar, and mahi mahi.	Demonstration of histamine in food or clinical diagnosis.	Supportive care, antihistamines.

Foodborne Illnesses (Noninfectious) (*Continued*)

Etiology	Incubation Period	Signs and Symptoms	Duration of Illness	Associated Foods	Laboratory Testing	Treatment
Shellfish toxins (diarrheic, neurotoxic, amnesic)	Diarrheic shellfish poisoning (DSP) — 30 min to 2 hrs	Nausea, vomiting, diarrhea, and abdominal pain accompanied by chills, headache, and fever.	Hrs to 2–3 days	A variety of shellfish, primarily mussels, oysters, scallops, and shellfish from the Florida coast and the Gulf of Mexico.	Detection of the toxin in shellfish; high-pressure liquid chromatography.	Supportive care, generally self-limiting. Elderly are especially sensitive to ASP.
	Neurotoxic shellfish poisoning (NSP) — few min to hours	Tingling and numbness of lips, tongue, and throat, muscular aches, dizziness, reversal of the sensations of hot and cold, diarrhea, and vomiting.				
	Amnesic shellfish poisoning (ASP) — 24–48 hrs	Vomiting, diarrhea, abdominal pain and neurologic problems such as confusion, memory loss, disorientation, seizure, coma.				
Shellfish toxins (paralytic shellfish poisoning)	30 min – 3 hrs	Diarrhea, nausea, vomiting leading to parasthesias of mouth, lips, weakness, dysphasia, dysphonia, respiratory paralysis.	Days	Scallops, mussels, clams, cockles.	Detection of toxin in food or water where fish are located; high-pressure liquid chromatography.	Life-threatening, may need respiratory support.
Sodium fluoride	Few min to 2 hrs	Salty or soapy taste, numbness of mouth, vomiting, diarrhea, dilated pupils, spasms, pallor, shock, collapse.	Usually self-limited	Dry foods (eg, dry milk, flour, baking powder, cake mixes) contaminated with sodium fluoride–containing insecticides and rodenticides.	Testing of vomitus or gastric washings. Analysis of the food.	Supportive care.
Thallium	Few hrs	Nausea, vomiting, diarrhea, painful parathesias, motor polyneuropathy, hair loss.	Several days	Contaminated food.	Urine, hair.	Supportive care.
Tin	5 min – 8 hrs. usually <1 hr	Nausea, vomiting, diarrhea.	Usually self-limited	Metallic container.	Analysis of the food.	Supportive care.
Vomitoxin	Few min to 3 hrs	Nausea, headache, abdominal pain, vomiting.	Usually self-limited	Grains such as wheat, corn, barley.	Analysis of the food.	Supportive care.
Zinc	Few hrs	Stomach cramps, nausea, vomiting, diarrhea, myalgias.	Usually self-limited	Metallic container.	Analysis of the food, blood and feces, saliva or urine.	Supportive care.

Etiologic agent	Incubation period	Clinical syndrome	Confirmation
Bacterial			
1. *Bacillus cereus*			
a. Vomiting toxin	1–6 hrs	Vomiting; some patients with diarrhea; fever uncommon	Isolation of organism from stool of two or more ill persons and not from stool of control patients OR Isolation of 10^5 organisms/g from epidemiologically implicated food, provided specimen is properly handled
b. Diarrheal toxin	6–24 hrs	Diarrhea, abdominal cramps, and vomiting in some patients; fever uncommon	Isolation of organism from stool of two or more ill persons and not from stool of control patients OR Isolation of 10^5 organisms/g from epidemiologically implicated food, provided specimen is properly handled
2. *Brucella*	Several days to several mos; usually >30 days	Weakness, fever, headache, sweats, chills, arthralgia, weight loss, splenomegaly	Two or more ill persons and isolation of organism in culture of blood or bone marrow; greater than fourfold increase in standard agglutination titer (SAT) over several wks, or single SAT 1:160 in person who has compatible clinical symptoms and history of exposure
3. *Campylobacter jejuni/coli*	2–10 days; usually 2–5 days	Diarrhea (often bloody), abdominal pain, fever	Isolation of organism from clinical specimens from two or more ill persons OR Isolation of organism from epidemiologically implicated food

Etiologic agent	Incubation period	Clinical syndrome	Confirmation
4. *Clostridium botulinum*	2 hrs–8 days; usually 12–48 hrs	Illness of variable severity; common symptoms are diplopia, blurred vision, and bulbar weakness; paralysis, which is usually descending and bilateral, might progress rapidly	Detection of botulinal toxin in serum, stool, gastric contents, or implicated food OR Isolation or organism from stool or intestine
5. *Clostridium perfringens*	6–24 hrs	Diarrhea, abdominal cramps; vomiting and fever uncommon	Isolation of 10^5 organisms/g from stool of two or more ill persons, provided specimen is properly handled. OR Demonstration of enterotoxin in the stool of two or more ill persons OR Isolation of 10^5 organisms/g from epidemiologically implicated food, provided specimen is properly handled
6. *Escherichia coli*			
a. Enterohemorrhagic (*E. coli* O157:H7 and others)	1–10 days; usually 3–4 days	Diarrhea (often bloody), abdominal cramps (often severe), little or no fever	Isolation of *E. coli* O157:H7 or other Shiga-like toxin-producing *E. coli* from clinical specimen from two or more ill persons OR Isolation of *E. coli* O157:H7 or other Shiga-like toxin-producing *E. coli* from epidemiologically implicated food
b. Enterotoxigenic (ETEC)	6–48 hrs	Diarrhea, abdominal cramps, nausea; vomiting and fever less common	Isolation of organism of same serotype, demonstrated to produce heat-stable (ST) and/or heat-labile (LT) enterotoxin, from stool of two or more ill persons
c. Enteropathogenic (EPEC)	Variable	Diarrhea, fever, abdominal cramps	Isolation of organism of same enteropathogenic serotype from stool of two or more ill persons

Etiologic agent	Incubation period	Clinical syndrome	Confirmation
d. Enteroinvasive (EIEC)	Variable	Diarrhea (might be bloody), fever, abdominal cramps	Isolation of same enteroinvasive serotype from stool of two or more ill persons
7. *Listeria monocytogenes*			
a. Invasive disease	2–6 wks	Meningitis, neonatal sepsis, fever	Isolation of organism from normally sterile site
b. Diarrheal disease	Unknown	Diarrhea, abdominal cramps, fever	Isolation of organism of same serotype from stool of two or more ill persons exposed to food that is epidemiologically implicated or from which organism of same serotype has been isolated
8. Nontyphoidal *Salmonella*	6 hrs–10 days; usually 6–48 hrs	Diarrhea, often with fever and abdominal cramps	Isolation of organism of same serotype from clinical specimens from two or more ill persons OR Isolation of organism from epidemiologically implicated food
9. *Salmonella* Typhi	3–60 days; usually 7–14 days	Fever, anorexia, malaise, headache, and myalgia; sometimes diarrhea or constipation	Isolation of organism from clinical specimens from two or more ill persons OR Isolation of organism from epidemiologically implicated food
10. *Shigella* spp.	12 hrs–6 days; usually 2–4 days	Diarrhea (often bloody), often accompanied by fever and abdominal cramps	Isolation of organism of same serotype from clinical specimens from two or more ill persons OR Isolation of organism from epidemiologically implicated food

Etiologic agent	Incubation period	Clinical syndrome	Confirmation
11. *Staphylococcus aureus*	30 min–8 hrs; usually 2–4 hrs	Vomiting, diarrhea	Isolation of organism of same phage type from stool or vomitus of two or more ill persons OR Detection of enterotoxin in epidemiologically implicated food OR Isolation of 10^5 organisms/g from epidemiologically implicated food, provided specimen is properly handled
12. *Streptococcus,* group A	1–4 days	Fever, pharyngitis, scarlet fever, upper respiratory infection	Isolation of organism of same M- or T-type from throats of two or more ill persons OR Isolation of organism of same M- or T-type from epidemiologically implicated food
13. *Vibrio cholerae*			
a. O1 or O139	1–5 days	Watery diarrhea, often accompanied by vomiting	Isolation of toxigenic organism from stool or vomitus of two or more ill persons OR Significant rise in vibriocidal, bacterial-agglutinating, or antitoxin antibodies in acute- and early convalescent-phase sera among persons not recently immunized OR Isolation of toxigenic organism from epidemiologically implicated food
b. non-O1 and non-O139	1–5 days	Watery diarrhea	Isolation of organism of same serotype from stool of two or more ill persons

Etiologic agent	Incubation period	Clinical syndrome	Confirmation
14. *Vibrio parahaemolyticus*	4–30 hrs	Diarrhea	Isolation of Kanagawa-positive organism from stool of two or more ill persons OR Isolation of 10^5 Kanagawa-positive organisms/g from epidemiologically implicated food, provided specimen is properly handled
15. *Yersinia enterocolitica*	1–10 days; usually 4–6 days	Diarrhea, abdominal pain (often severe)	Isolation of organism from clinical specimen from two or more ill persons OR Isolation of pathogenic strain of organism from epidemiologically implicated food
Chemical			
1. Marine toxins			
a. Ciguatoxin	1–48 hrs; usually 2–8 hrs	Usually gastrointestinal symptoms followed by neurologic symptoms (including paresthesia of lips, tongue, throat, or extremities) and reversal of hot and cold sensation	Demonstration of ciguatoxin in epidemiologically implicated fish OR Clinical syndrome among persons who have eaten a type of fish previously associated with ciguatera fish poisoning (e.g., snapper, grouper, or barracuda)
b. Scombroid toxin (histamine)	1 min–3 hrs; usually <1 hr	Flushing, dizziness, burning of mouth and throat, headache, gastrointestinal symptoms, urticaria, and generalized pruritis	Demonstration of histamine in epidemiologically implicated fish OR Clinical syndrome among persons who have eaten a type of fish previously associated with histamine fish poisoning (e.g., mahi-mahi or fish of order Scomboidei)

Etiologic agent	Incubation period	Clinical syndrome	Confirmation
c. Paralytic or neurotoxic shellfish	30 min–3 hrs	Paresthesia of lips, mouth or face, and extremities; intestinal symptoms or weakness, including respiratory difficulty	Detection of toxin in epidemiologically implicated food OR Detection of large numbers of shellfish-poisoning–associated species of dinoflagellates in water from which epidemiologically implicated mollusks are gathered
d. Puffer fish, tetrodotoxin	10 min–3 hrs; usually 10–45 min	Paresthesia of lips, tongue, face, or extremities, often following numbness; loss of proprioception or floating sensations	Demonstration of tetrodotoxin in epidemiologically implicated fish OR Clinical syndrome among persons who have eaten puffer fish
2. Heavy metals • Antimony • Cadmium • Copper • Iron • Tin • Zinc	5 min–8 hrs; usually <1 hr	Vomiting, often metallic taste	Demonstration of high concentration of metal in epidemiologically implicated food
3. Monosodium glutamate (MSG)	3 min–2 hrs; usually <1 hr	Burning sensation in chest, neck, abdomen, or extremities; sensation of lightness and pressure over face or heavy feeling in chest	Clinical syndrome among persons who have eaten food containing MSG (e.g., usually 1.5 g MSG)
4. Mushroom toxins			
a. Shorter-acting toxins	2 hrs	Usually vomiting and diarrhea, other symptoms differ with toxin	Clinical syndrome among persons who have eaten mushroom identified as toxic type OR Demonstration of toxin in epidemiologically implicated mushroom or food containing mushroom
• Muscimol		• Confusion, visual disturbance	
• Muscarine		• Salivation, diaphoresis	
• Psilocybin		• Hallucinations	
• *Coprinus artrementaris*		• Disulfiram-like reaction	
• Ibotenic acid		• Confusion, visual disturbance	

Etiologic agent	Incubation period	Clinical syndrome	Confirmation
b. Longer-acting toxins (e.g., *Amanita* spp.)	6–24 hrs	Diarrhea and abdominal cramps for 24 hrs followed by hepatic and renal failure	Clinical syndrome among persons who have eaten mushroom identified as toxic type OR Demonstration of toxin in epidemiologically implicated mushroom or food containing mushrooms
Parasitic			
1. *Cryptosporidium parvum*	2–28 days; median: 7 days	Diarrhea, nausea, vomiting; fever	Demonstration of organism or antigen in stool or in small-bowel biopsy of two or more ill persons OR Demonstration of toxin in epidemiologically implicated food
2. *Cyclospora cayetanensus*	1–11 days; median: 7 days	Fatigue, protracted diarrhea, often relapsing	Demonstration of organism in stool of two or more ill persons
3. *Giardia lamblia*	3–25 days; median: 7 days	Diarrhea, gas, cramps, nausea, fatigue	Two or more ill persons and detection of antigen in stool or demonstration of organism in stool, duodenal contents, or small-bowel biopsy specimen
4. *Trichinella* spp.	1–2 days for intestinal phase; 2–4 wks for systemic phase	Fever, myalgia, periorbital edema, high eosinophil count	Two or more ill persons and positive serologic test or demonstration of larvae in muscle biopsy OR Demonstration of larvae in epidemiologically implicated meat

Etiologic agent	Incubation period	Clinical syndrome	Confirmation
Viral			
1. Hepatitis A	15–50 days; median: 28 days	Jaundice, dark urine, fatigue, anorexia, nausea	Detection of immunoglobulin M anti-hepatitis A virus in serum from two or more persons who consumed epidemiologically implicated food
2. Norwalk family of viruses, small round-structured viruses (SRSV)	15–77 hrs; usually 24–48 hrs	Vomiting, cramps, diarrhea, headache	More than fourfold rise in antibody titer to Norwalk virus or Norwalk-like virus in acute and convalescent sera in most serum pairs OR Visualization of small, round-structured viruses that react with patient's convalescent sera but not acute sera — by immune-electron microsopy (assays based on molecular diagnostics [e.g., polymerase-chain reaction, probes, or assays for antigen and antibodies from expressed antigen] are available in reference laboratories)
3. Astrovirus, calicivirus, others	15–77 hrs; usually 24–48 hrs	Vomiting, cramps, diarrhea, headache	Visualization of small, round-structured viruses that react with patient's convalescent sera but not acute sera — by immune-electron microsopy (assays based on molecular diagnostics [e.g., polymerase-chain reaction, probes, or assays for antigen and antibodies from expressed antigen] are available in reference laboratories)