

## 11-ID-14

**Committee:** Infectious Disease

**Title:** Update to Cryptosporidiosis Case Definition

### **I. Statement of the Problem:**

A position statement to revise the case definition of cryptosporidiosis, a disease under public health surveillance, was presented to CSTE at the 2010 Annual Conference. During the Infectious Disease Subcommittee review, an APHL representative and CSTE member raised concerns about the low positive predictive value (PPV) of immunochromatographic lateral-flow immunoassays, also known as “rapid cartridge assays” or “rapid immunochromatographic card tests” (Clin Infect Dis. 2010 Apr 15;50(8):e53-55) to diagnose cryptosporidiosis. Further revisions then ensued to assign a probable case classification to persons meeting clinical evidence of cryptosporidiosis with a positive laboratory test for cryptosporidiosis obtained by use of a commercial immunochromatographic card test. The resulting verbiage that was approved in the 2010 position statement has led to some confusion among state health department surveillance officers as to how to classify cases of cryptosporidiosis when the type of test being done is not included on the laboratory report, or how to classify epi-links to a case when the rapid immunochromatographic card test was used in diagnosing the index case. This proposed revision to the cryptosporidiosis case definition is needed to provide standardization among states in the case classification of cryptosporidiosis.

### **II. Background and Justification:**

Cryptosporidiosis is a diarrheal disease caused by microscopic parasites of the genus *Cryptosporidium*. Many species of *Cryptosporidium* exist that infect humans and a wide range of animals. An estimated 800,000 cases of cryptosporidiosis occur each year in the United States. *Cryptosporidium* is one of the most frequent causes of waterborne disease (drinking water and recreational water) among humans in the United States. International travelers and backpackers are at risk of contracting cryptosporidiosis. Outbreaks have occurred among children attending day care centers. Surveillance for cryptosporidiosis is necessary to identify and control outbreaks and to expand the scientific understanding of the role that each of the species play in human disease.

### **III. Statement of the desired action(s) to be taken:**

The national surveillance case definition for cryptosporidiosis should be revised. We propose to: 1) clarify the laboratory criteria language to standardize confirmed or probable case status based on the type of diagnostic test used; 2) assign a probable case status to persons meeting the clinical criteria and epidemiologically linked to a confirmed case (e.g., case-patient in the same household or other group setting, or with an identical exposure as the confirmed case); and 3) for epidemiologically-linked cases require clinical criteria of diarrhea, plus one or more symptoms of diarrhea of  $\geq 72$  hours duration, abdominal cramping, vomiting or anorexia.

### **IV. Goals of Surveillance:**

To provide information on the temporal, geographic, and demographic occurrence of cryptosporidiosis to facilitate its prevention and control. The goal of this change to the case

definition would be to remove confusion about the criteria for laboratory evidence of *Cryptosporidium* infection, and appropriately assign case classification for epidemiologically-linked cases.

## V. Methods for Surveillance:

Surveillance for cryptosporidiosis should use the following recommended sources of data and the extent of coverage listed in Table V.

**Table V.** Recommended sources of data for case identification and extent of coverage for ascertaining cases of cryptosporidiosis

Source of data for case identification	Coverage	
	Population-wide	Sentinel sites
Clinician reporting	x	
Laboratory reporting	x	
Reporting by other entities (e.g., hospitals, veterinarians, pharmacies)	x	
Death certificates	x	
Hospital discharge or outpatient records	x	
Extracts from electronic medical records	x	
Telephone survey		
School-based survey		
Other _____		

## VI. Criteria for Case Identification

### A. Narrative: A description of suggested criteria for case ascertainment:

Report any illness to public health authorities that meets any of the following criteria:

1. Any person who has a positive laboratory test for any *Cryptosporidium* species. These tests may include any of the following:
  - a) detection of *Cryptosporidium* organisms in stool, intestinal fluid, tissue samples or biopsy specimens,
  - b) detection of *Cryptosporidium* antigen by immunodiagnostic methods, or
  - c) detection of *Cryptosporidium*-specific nucleic acid in stool, intestinal fluid, tissue samples or biopsy specimens.
  
2. Any person with diarrhea and/or one or more symptoms of abdominal cramping, diarrhea  $\geq$  72 hours duration, vomiting or anorexia, and who is either a contact of a confirmed case of cryptosporidiosis, or a member of a risk group as defined by the public health authorities during an outbreak.
  
3. A person whose healthcare record contains a diagnosis of cryptosporidiosis.

Other recommended reporting procedures:

- All cases of cryptosporidiosis should be reported.
- Reporting should be ongoing and routine.
- Frequency of reporting should follow the state health department's routine schedule.

**B. Table of criteria to determine whether a case should be reported to public health authorities:**

**Table VI-B.** Table of criteria to determine whether a case should be reported to public health authorities.

<b>Criterion</b>	<b>Disease or condition subtype</b>	
<i>Clinical Evidence</i>		
Diarrhea	O	
Abdominal cramps	O	
Vomiting	O	
Diarrhea of $\geq$ 72 hours duration	O	
Anorexia	O	
Healthcare record contains a diagnosis of cryptosporidiosis		S
<i>Laboratory evidence</i>		
<i>Cryptosporidium</i> organisms in stool, intestinal fluid, tissue samples or biopsy specimens		S
<i>Cryptosporidium</i> antigens in stool or intestinal fluid		S
<i>Cryptosporidium</i> -specific nucleic acid in stool, intestinal fluid, tissue samples or biopsy specimens		S
<i>Epidemiologic evidence</i>		
Contact of a confirmed case of cryptosporidiosis	O	
Member of a risk group as defined by the public health authorities during an outbreak	O	

Notes:

S = This criterion alone is Sufficient to identify a case for reporting.

O = At least one of these “O” (Optional) criteria in each category (e.g., clinical evidence and laboratory evidence) in the same column is required to identify a case for reporting.

**C. Disease-specific data elements:**

**Clinical Information**

HIV infection

Cancer chemotherapy

On treatment with immunosuppressive drugs

### **Laboratory Information**

Molecular characterization (e.g., species, genotype, or subtype designation), when available

### **Epidemiological Risk Factors**

Child care center attendee

Child care worker

International travel

Contact with recreational water

Contact with a confirmed case of cryptosporidiosis

## **VII. Case Definition for Case Classification**

### **A. Narrative description of criteria to determine whether a case should be classified as confirmed or probable:**

#### **Clinical criteria**

*Confirmed and Probable:* A gastrointestinal illness characterized by diarrhea and one or more of the following: diarrhea duration of 72 hours or more, abdominal cramping, vomiting, or anorexia.

#### **Laboratory criteria for surveillance case classification**

*Confirmed:* Evidence of *Cryptosporidium* organisms or DNA in stool, intestinal fluid, tissue samples, biopsy specimens, or other biological sample by certain laboratory methods with a high positive predictive value (PPV), e.g.,

- direct fluorescent antibody [DFA] test,
- polymerase chain reaction [PCR],
- enzyme immunoassay [EIA], or
- light microscopy of stained specimen.

*Probable:* The detection of *Cryptosporidium* antigen by a screening test method, such as immunochromatographic card/rapid card test; or a laboratory test of unknown method.

#### **Case classification**

*Confirmed:* A case that is diagnosed with *Cryptosporidium spp.* infection based on laboratory testing using a method listed in the confirmed criteria.

*Probable:* A case with supportive laboratory test results for *Cryptosporidia spp.* infection using a method listed in the probable laboratory criteria. When the diagnostic test method on a laboratory test result for cryptosporidiosis cannot be determined, the case can only be classified as probable.

### **OR**

A case that meets the clinical criteria and is epidemiologically linked to a confirmed case.

Comment: Persons who have a diarrheal illness and are epidemiologically linked to a probable case because that individual was only diagnosed with cryptosporidiosis by an immunochromatographic card/rapid test/ or unknown test method cannot be classified as probable cases. These epi-links can be considered suspect cases only.

**B. Classification Tables:**

**Table VII-B.** Criteria for defining cases of cryptosporidiosis

<b>Criterion</b>	<b>Confirmed</b>	<b>Probable</b>	
<i>Clinical Evidence</i>			
Diarrhea			N
Diarrhea of $\geq 72$ hours duration			O
Abdominal cramps			O
Vomiting			O
Anorexia			O
<i>Laboratory evidence</i>			
Detection of <i>Cryptosporidium</i> by direct fluorescent antibody [DFA] test	O		
Detection of <i>Cryptosporidium</i> -specific nucleic acid by polymerase chain reaction [PCR]	O		
Detection of <i>Cryptosporidium</i> by enzyme immunoassay [EIA]	O		
Demonstration of <i>Cryptosporidium</i> by microscopy and staining	O		
Immunochromatographic card/rapid card test		O	
Unknown laboratory test method/type		O	
<i>Epidemiologic evidence</i>			
Contact of a confirmed case of cryptosporidiosis			N

Notes:

N = All “N” criteria in the same column are Necessary to classify a case.

O = At least one of these “O” (Optional) criteria in each category (e.g., clinical evidence and laboratory evidence) in the same column—is required to classify a case.

**VIII. Period of Surveillance:**

Ongoing.

## IX. Data sharing/release and Print criteria:

- Notification to CDC of confirmed and probable cases is recommended.
- Data are reported to NNDSS and summarized weekly in the MMWR. Case counts of cryptosporidiosis are also published annually in the MMWR Summary of Notifiable Diseases and biennially in the MMWR Surveillance Summaries for cryptosporidiosis and giardiasis.
- State-specific data are published weekly in the MMWR and annually in the MMWR Summary of Notifiable Diseases. Data on cryptosporidiosis are also published biennially in the MMWR Surveillance Summaries for cryptosporidiosis and giardiasis.
- Summary data on cases of cryptosporidiosis are published biennially in the MMWR Surveillance Summaries and may be included in MMWR or journal articles.

## X. Revision History

Position Statement ID	Section of Document	Revision Description
11-ID-04	Statement of the Problem	“rapid immunocard tests” changed to “rapid immunochromatographic card tests” due to the trademarking of Immunocard™ by Meridian Bioscience, Inc.
11-ID-04	VII.A. Probable case classification	“immunocard/rapid test/or unknown test” changed to “immunochromatographic card/rapid test/or unknown test” due to the trademarking of Immunocard™ by Meridian Bioscience, Inc.
11-ID-04	X. Revision History	Added revision history and edited section numbering of References, Coordination, and Submitting Author sections.

## XI. References:

1. Council of State and Territorial Epidemiologists (CSTE). National Surveillance for Cryptosporidiosis. CSTE Position Statement 08-ID-08. Atlanta: CSTE. June 2008. Available from <http://www.cste.org>.
2. Council of State and Territorial Epidemiologists (CSTE). Continuation of Cryptosporidiosis Under National Surveillance. CSTE Position Statement 1998-ID-5. Atlanta: CSTE. June 1998. Available from <http://www.cste.org>.
3. Council of State and Territorial Epidemiologists (CSTE). National Surveillance for Cryptosporidiosis. CSTE Position Statement 1994-ID. Atlanta: CSTE. June 1994. Available from <http://www.cste.org>.
4. Robinson TJ, Cebelinski EA, Taylor C, and KE Smith. Evaluation of the Positive Predictive Value of Rapid Assays Used by Clinical Laboratories in Minnesota for the Diagnosis of Cryptosporidiosis. 2010;50:e53-e55.

## **XII. Coordination:**

### **Agencies for Response:**

- (1) Thomas R. Frieden, MD, MPH  
Director  
Centers for Disease Control and Prevention  
1600 Clifton Road, NE  
Atlanta GA 30333  
(404) 639-7000  
[txf2@cdc.gov](mailto:txf2@cdc.gov)

## **XIII. Submitting Author:**

- (1) Kristy Bradley, DVM, MPH  
State Epidemiologist & State Public Health Veterinarian  
Oklahoma State Department of Health  
1000 NE 10<sup>th</sup> St  
Oklahoma City, OK 73117-1299  
(405) 271-4060  
[kristyb@health.ok.gov](mailto:kristyb@health.ok.gov)
- (2) Robyn M Atkinson, Ph.D., HCLD(ABB)  
Director, Knoxville Regional Laboratory  
Deputy Director, State Laboratory  
TN Department of Health  
Division of Laboratory Services  
2101 Medical Center Way  
Knoxville TN 37920