SURVEILLANCE CASE DEFINITION AND REPORTING CHANGES ASSOCIATED WITH SHIGA TOXIN-PRODUCING ESCHERICHIA COLI (STEC) INFECTIONS EFFECTIVE JANUARY 2018

FREQUENTLY ASKED QUESTIONS (FAQS)

The California Department of Public Health (CDPH) Infectious Diseases Branch (IDB) is pleased to present the following FAQs and answers to the recent changes in the reporting of cases of Shiga toxin-producing Escherichia coli (STEC) infections which are scheduled to take effect January 1, 2018. Additional questions not covered in this document may be addressed to Katherine Lamba (Katherine.Lamba@cdph.ca.gov) or Akiko Kimura (Akiko.Kimura@cdph.ca.gov) at 510-620-3434.

2018 Surveillance Case Definition Changes Associated with STEC Infections

• What are the major changes in the 2018 surveillance case definition compared to the previous definition?

The criteria for confirmed cases remain the same. The most substantial change to the case definition is the classification of probable cases. As of January 1, 2018, a clinically compatible illness in a person with a positive result from a culture-independent diagnostic test (CIDT), with negative or no culture confirmation, will be defined as a probable STEC case. This includes:

• A clinically compatible illness in a person with detection of Shiga toxin or Shiga toxin genes in a clinical specimen using a CIDT and no known isolation of Shigella from a clinical specimen, OR

• A clinically compatible illness in a person with detection of E. coli O157 or STEC/Enterohemorrhagic E. coli (EHEC) from a clinical specimen using a CIDT.

This definition applies regardless of the type of test (i.e., PCR or EIA) or performing laboratory (i.e., clinical laboratory or public health laboratory [PHL]).

These probable cases will be counted as part of the annual case count for STEC for California. Previously, CIDT positive specimens were considered to be suspect cases and were not counted as part of the annual STEC case count for California.

• How can I find out more about the new Council of State and Territorial Epidemiologists (CSTE) STEC case definition?

• What do you consider to be clinically compatible symptoms for STEC infection?

One or more of the following:

- diarrhea (defined as three or more loose stools within 24 hours)
- bloody diarrhea
- abdominal cramps
- hemolytic uremic syndrome (HUS)

• What do you consider to be a culture-independent diagnostic test (CIDT)-positive result?

A CIDT-positive result would include detection of Shiga toxin, Shiga toxin genes, *E. coli* O157, or Shiga toxin-producing *E. coli* (STEC)/ Enterohemorrhagic E. coli (EHEC) by a non-culture based laboratory test. This is usually a polymerase chain reaction (PCR) assay or enzyme immunoassay (EIA), but also Vero cell assay and lateral flow assay, without subsequent culture-confirmation.

• How should I classify a person with clinically compatible symptoms and a CIDT-positive (not culture-confirmed) result from a clinical lab if the specimen was not forwarded to a PHL for confirmation, or if the specimen tested CIDT-negative by a PHL?

As long as there is clinically compatible illness, any person with a CIDT-positive result (not culture-confirmed) should be reported as a **probable** STEC case. This is true regardless of the type of test (i.e., PCR or EIA) or performing laboratory (i.e., clinical laboratory or PHL).

• How should I classify a person who has no symptoms but has a CIDT-positive result without culture confirmation?

If there is no clinically compatible illness in a person with a CIDT-positive specimen (without culture confirmation), this should be reported as a **suspect** STEC case. This is true regardless of the type of test (i.e., PCR or EIA) or performing laboratory (i.e., clinical laboratory or PHL). Although suspect STEC cases are not counted for the purposes of an annual case count, they should still be reported to CDPH.

• How should I classify a person who has been lost to follow up, thus symptoms are unknown, and has a CIDT-positive result without culture confirmation?

If the clinical status of the person with a CIDT-positive specimen (without culture confirmation), is unknown, an attempt to contact the person’s healthcare provider to verify symptoms and contact information should be made. If this is not feasible, then this incident should be reported as a **suspect** STEC case. This is true regardless of
the type of test (i.e., PCR or EIA) or performing laboratory (i.e., clinical laboratory or PHL). Although suspect STEC cases are not counted for the purposes of an annual case count, they should still be reported to CDPH.

- **How should I classify a person who is an ill contact of someone who was CIDT-positive for STEC but without culture confirmation?**

An ill contact of a probable STEC case (i.e., CIDT-positive without culture confirmation) should be reported as probable STEC.

From the 2018 surveillance case definition for a probable case:

A clinically compatible illness in a person that is epidemiologically linked to a confirmed or probable case with laboratory evidence,

**OR**

A clinically compatible illness in a person that is a member of a risk group as defined by public health authorities during an outbreak.

- **When do these changes take place?**

The new case definition will apply to patients with an episode date (the earliest of the following dates in CalREDIE: Date of Onset, Lab Specimen Collection Date, Date of Diagnosis, Date of Death, and Date Received) of January 1, 2018 or later; this appears on the Case Investigation Tab under “Dates”. As a reminder, the Episode Date is calculated automatically in CalREDIE and is the last date listed on the “Case Investigation Tab”.

### CDPH Reporting Changes

- **What are the new reporting categories for STEC?**

The good news is that the reporting categories have been simplified! Previously, there were seven different categories for STEC reporting. Now there are only three: “STEC without HUS”, “STEC with HUS”, and “HUS without evidence of STEC”. Please see table below.

<table>
<thead>
<tr>
<th>Previous Category</th>
<th>New Category as of January 1, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shiga toxin positive feces without HUS</td>
<td>STEC without HUS</td>
</tr>
<tr>
<td>Shiga toxin positive feces with HUS</td>
<td>STEC with HUS</td>
</tr>
<tr>
<td>STEC non-O157 without HUS</td>
<td>STEC without HUS</td>
</tr>
<tr>
<td>STEC non-O157 with HUS</td>
<td>STEC with HUS</td>
</tr>
<tr>
<td><em>E. coli</em> O157 without HUS</td>
<td>STEC without HUS</td>
</tr>
<tr>
<td>Previous Category</td>
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<tr>
<td>------------------------------------------------------------</td>
<td>--------------------------------------------------------</td>
</tr>
<tr>
<td><em>E. coli</em> O157 with HUS</td>
<td>STEC with HUS</td>
</tr>
<tr>
<td>Hemolytic Uremic Syndrome (HUS) without evidence of <em>E. coli</em> O157, other STEC, or Shiga toxin-positive feces</td>
<td>HUS without evidence of STEC</td>
</tr>
</tbody>
</table>

- **Will I still be able to access closed records from previous years?**

Yes. CalREDIE incidents created prior to the implementation of the revised clinical, lab, and epi information tabs in CalREDIE will remain available in CalREDIE under “HISTORICAL” conditions, and through downloads from the Data Distribution Portal (DDP).

- **What happens to the CalREDIE incidents that were created in 2017 but will not be closed until 2018? For example, the incident was created on November 8, 2017, and will be closed on January 10, 2018.**

CalREDIE incidents created in 2017 should be managed and closed out per usual protocols using the case definitions that were in place prior to January 1, 2018. If information on the “Laboratory Info” tab was entered into the “HISTORICAL DATA” sections which are now located at the bottom of the tab, please continue to enter lab information using those sections; otherwise, please enter laboratory data into the three new sections starting at the top of the tab.

- **How should I manage CalREDIE incidents that are created in 2018, but with an episode date of 2017? For example, I receive information on January 10, 2018 about a patient who had an illness onset date of September 5, 2017.**

CalREDIE incidents created in 2018 for cases with a 2017 episode date should be managed and closed out per usual protocols using the case definitions that were in place prior to January 1, 2018. Enter laboratory data into the three new sections starting at the top of the tab.

**CDPH STEC/HUS Form Updates**

- **How were the changes to the new case report form (CRF) made?**

The changes to the CRF were made on the basis of CSTE and Centers for Disease Control and Prevention (CDC) recommendations for the collection of specific risk factors, as well as to reflect the recent changes in the CSTE case definition to largely address the CIDT changes. Representatives from several California local health jurisdictions (LHJs) provided input into the form changes.
• **Why are there changes to the HUS section?**

The diagnosis of HUS can be challenging, especially in an adult. The checkboxes are now included to confirm that the diagnostic criteria have been met. Please include the medical records containing the diagnosis into the electronic filing cabinet whenever possible.

• **Why do I need to fill out the Microbial Disease Laboratory (MDL) laboratory results, when CDPH manages CalREDIE?**

Unfortunately, MDL does not have access to CalREDIE and therefore is unable to enter results directly into a patient record. Laboratory results including the results of Shiga toxin and O serogroup confirmation are reported to the laboratory (clinical or public health) which submitted the specimen. It is the responsibility of the LHJ of the patient’s county of residence to verify the final MDL or other PHL results and enter into the CalREDIE record.

• **Since the STEC O157 and non-O157 categories have been combined, why is it important to specify serogroup in the laboratory section?**

Currently, MDL performs molecular strain typing only for STEC O157, but not for the non-O157 STECs. Therefore, monitoring trends in the non-O157 serogroups becomes more important to detect increases which may reflect an outbreak.

• **Why have questions about antimicrobial resistance been added?**

The rise in antimicrobial resistance (AMR) is considered to be a serious public health threat. To better track changes in AMR, all updated forms for enteric pathogens will include questions about AMR.

• **What should I do if more than one serogroup has been identified from a specimen?**

Please enter in information about both serogroups in the MDL/PHL section under "stool cultures". Enter each serogroup in the stool culture section by clicking on the “add” button at the bottom of the section. Information about the specimen does not have to be repeated for each serogroup, but please be as complete as possible (i.e., include shiga toxin type and identified serogroup). Each serogroup is considered to be a separate case for the purposes of case counting.

• **What should I do if more than one reportable enteric pathogen has been isolated from a single specimen, for example, an STEC O26 and Salmonella?**

Please fill out the form for STEC and for salmonellosis. The clinical and risk factors do not need to be filled out for both forms, provided that 1) there is overlap in incubation period and risk factors and 2) the more detailed risk factor history is filled out. Please indicate the linked record in the CalREDIE notes.