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

The California Department of Public Health (CDPH) Infectious Diseases Branch (IDB) wishes to alert local health jurisdictions to several changes in the reporting of cases of Shiga toxin-producing Escherichia coli (STEC) infections which are scheduled to take effect January 1, 2018. The chief changes to the surveillance case definition, reporting categories, and the CDPH STEC Case Report Form are detailed below.


These new surveillance case definitions will go into effect January 1, 2018. For the purposes of reporting to CDPH, these definitions will apply to cases with an Episode Date of January 1, 2018 or later. Episode Date is calculated in CalREDIE as the earliest of the following dates: Date of Onset, Lab Specimen Collection Date, Date of Diagnosis, Date of Death, and Date Received; 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”.

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.

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.

Note: A person who has a CIDT-positive specimen, but without clinically compatible symptoms will be classified as a suspect case. The other categories of probable STEC cases, such as an ill epi-linked contact who was not tested, will remain the same.
CDPH REPORTING CHANGES

As per Title 17, please continue to report Confirmed, Probable, and Suspect STEC and hemolytic uremic syndrome (HUS) cases to CDPH. However, due to the changes in the CSTE case classification, the reporting categories have changed. The E. coli O157 and STEC (non-O157) categories will be combined into one “STEC” category. Because persons with Shiga toxin-positive feces are now considered as probable or suspect STEC cases, Shiga toxin-positive feces have also been merged into the STEC category. As such, beginning January 1, 2018, there will be only three distinct reporting categories, a change from the seven previous categories (Table 1). The new reporting categories will be:

- Shiga toxin-producing E. coli (STEC) with HUS.
- Shiga toxin-producing E. coli (STEC) without HUS.
- Hemolytic uremic syndrome (HUS) without evidence of STEC.

Table 1: Categories for Reporting STEC and HUS to CDPH

<table>
<thead>
<tr>
<th>Previous categories</th>
<th>Beginning January 1, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>- E. coli O157 without HUS</td>
<td>- Shiga toxin-producing E. coli (STEC) without HUS</td>
</tr>
<tr>
<td>- E. coli O157 with HUS</td>
<td>- Shiga toxin-producing E. coli (STEC) with HUS</td>
</tr>
<tr>
<td>- STEC (non-O157) without HUS</td>
<td>- Hemolytic uremic syndrome (HUS) without evidence of STEC</td>
</tr>
<tr>
<td>- STEC (non-O157) with HUS</td>
<td></td>
</tr>
<tr>
<td>- Shiga toxin positive feces (without culture confirmation) without HUS</td>
<td></td>
</tr>
<tr>
<td>- Shiga toxin positive feces (without culture confirmation) with HUS</td>
<td></td>
</tr>
<tr>
<td>- Hemolytic Uremic Syndrome (HUS) without evidence of E. coli O157, other STEC, or Shiga toxinn positive feces</td>
<td></td>
</tr>
</tbody>
</table>

The surveillance case definition for HUS, post-diarrheal, has not changed, and was last updated in 1996 (https://wwwn.cdc.gov/nndss/conditions/hemolytic-uremic-syndrome-post-diarrheal/case-definition/1996/).

However, the CDPH reporting category name has been changed to “Hemolytic uremic syndrome (HUS) without evidence of STEC” to reflect the 2018 changes in STEC reporting categories.

Note: CalREDIE incidents that have been created before January 1, 2018, will remain available in CalREDIE and through the CalREDIE Data Distribution Portal. The current STEC conditions will be renamed to include “HISTORICAL” in the title; for example, the disease “E. coli O157 without HUS” will become “HISTORICAL - E. coli O157 without HUS”.
**CDPH STEC FORM UPDATES**

The 2018 CDPH STEC case report form (CRF) will go live on CalREDIE and a fillable version posted onto the [CDPH forms site](https://www.cdph.ca.gov/Programs/PSB/Pages/CommunicableDiseaseControl.aspx) on January 2, 2018:

https://www.cdph.ca.gov/Programs/PSB/Pages/CommunicableDiseaseControl.aspx.

The implementation of the 2018 CDPH STEC CRF will improve statewide surveillance of epidemiologic, clinical, and laboratory data of STEC cases in California, and allows for more consistent collection of data.

STEC infection is a CRF-required condition in California. However, the current form, last revised in 2011, did not incorporate risk factor assessment changes suggested by [the CSTE in 2013](http://c.ymcdn.com/sites/www.cste.org/resource/resmgr/PS/13-ID-01.pdf) In addition, the U.S. Centers for Disease Control and Prevention (CDC) is working on an STEC Initiative, similar to the Listeria Initiative, with the objective of collecting these risk factor assessments in a consistent manner across all states. Further, the previous version of the CDPH CRF did not reflect changes in diagnostic techniques and reporting adopted by the CDPH Microbial Diseases Laboratory (MDL) and other public health and clinical laboratories.

The revised 2018 STEC CRF has undergone substantive changes to address these issues, including:

- Updates to the clinical information section;
- Complete revision of the laboratory section, including clear separation of clinical vs. public health laboratory results, removal of H antigen characterization, and incorporation of CIDT;
- Modification of the epidemiologic risk factors section as recommended by the 2013 CSTE position statement;
- Removal of unnecessary/unused fields.

Changes incorporated into the 2018 STEC CRF are detailed below:

**Clinical Information**

- The HUS section has been updated to clarify the diagnostic criteria for HUS (i.e., hemolytic anemia and renal injury);
- The question regarding antibiotic use prior to illness onset has been expanded from one week to 30 days;
- Questions about school and work absence, as well as gastrointestinal surgery as result of the illness have been removed.
**Laboratory Information**

The Laboratory Information section has been extensively revised.

The laboratory section has been reorganized into two main sections, titled: **Clinical Laboratory Results** and **CDPH Microbial Diseases Laboratory (MDL) or Other Reference Public Health Laboratory Results**. Per Title 17 of the California Code of Regulations, clinical laboratories are required to submit STEC isolates or Shiga toxin-positive (or other CIDT-positive) broths to a PHL for further identification and strain typing.

The **Clinical Laboratory Results** section includes:

- Details of CIDT results (including type of test done and results);
- Culture confirmation (if STEC were isolated from a clinical specimen);
- Antimicrobial susceptibility testing (AST) results:
  - Any AST results should be uploaded into the Electronic Filing Cabinet or attached to the 2018 STEC CRF when submitting to the Surveillance and Statistics Section (SSS) of CDPH.

The **CDPH Microbial Diseases Laboratory (MDL) or Other Reference Public Health Laboratory (PHL)** section includes:

- Details of Shiga toxin results performed by the PHL;
- Details of culture and serogroup confirmation by the PHL:
  - MDL tests only for the six most common O serogroups (O26, O103, O111, O121, O145, and O157). The remaining STECs are classified as “O-undetermined.” These choices are now reflected in the CRF. MDL does not test for H antigen identification.
  - MDL is not able to enter results into CalREDIE. Laboratory results including the results of Shiga toxin and O serogroup confirmation are reported to the laboratory (either clinical or PHL) that submitted the specimen. It is the responsibility of the local health jurisdiction of the patient’s county of residence to verify the final MDL or other PHL results and enter into the CalREDIE record.
  - If more than one STEC serogroup is identified from a single clinical specimen, please enter each serogroup in the stool culture section by clicking on the “add” button at the bottom of the section. Each serogroup is considered to be a separate case for the purposes of case counting.
- Fields to enter multiple locus variable-number tandem repeat analysis (MLVA) and whole genome sequencing (WGS) results.

Of note, old sub-sections (i.e., entry fields that were available in the previous versions of the form) have been moved to the bottom of the page and marked as “historical data.” Please do NOT enter data into these fields for any records with an episode date of January 1, 2018, or later. These fields will remain enabled for the 2017 cases until the 2017 closeout is complete.
sometime in spring 2018. For open records with an Episode Date prior to January 1, 2018, continue to use the old sections. All of the data will still be available through the Data Distribution Portal (DDP).

In addition, fields marked “For CEIP use only” only need to be completed by the California Emerging Infections Program for Alameda, Berkeley, Contra Costa, and San Francisco cases.

**Epidemiology Information**

The Epidemiology Information section has been updated to reflect CSTE recommendations. Changes include:

- Reordering of sections to begin with questions about travel, food eaten outside of the home, and grocery sources;
- Addition of food and other exposure details as recommended by CSTE;
- Addition of a section to track patient clearance information;
- The 2018 CSTE surveillance case definition replacing the 2014 case definition at the bottom of the tab.

Historical data will remain available through the CalREDIE DDP.

**Additional Resources**

- **Training materials regarding these changes will be posted to the CDPH CACDC website**, under “Resources and Documents” (https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/CACDC.aspx). Materials will include a frequently asked questions (FAQ) sheet which will be updated as needed depending on the questions that arise. These materials will be posted in the coming weeks.
- **These changes will also be reflected in the STEC chapter of the CDPH Communicable Disease Guidance** in early 2018 (https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/IDBGuidanceforManagingSelectCommunicableDiseases.aspx).
- **Questions may be directed to the Infectious Diseases Branch at 510-620-3434.**