

## STEC (*Shiga toxin-producing E. coli*) Reporting Issues May 2008

Recent changes in laboratory technology and national disease reporting requirements have created substantial confusion regarding the reporting and case follow-up of Shiga toxin-producing *E. coli* (STEC) into CEDRS.

### Background

There are many different types of *Escherichia coli*, only some of which are pathogenic. In general, *E. coli* are characterized by their O antigens (cell wall) and H antigens (flagella). This O:H combination is called the serotype (eg O157:H7, O26:H11, O111:H8, O103:H2, and O113:H21). Even among the pathogenic types (such as enterotoxigenic, enteroinvasive, enteropathogenic, etc.), only enterohemorrhagic *E. coli* (EHEC) is reportable in Colorado as sporadic cases. EHEC possess a toxin called Shiga toxin, and is increasingly referred to as Shiga toxin-producing *E. coli* (STEC). In fact, CDC now wants states to report this group of organisms as “STEC.” The best-known STEC serotype is *E. coli* O157:H7.

*E. coli* O157 has unique biochemical properties compared to other *E. coli* (*E. coli* O157 is sorbitol negative, it does not ferment sorbitol). Because of this, screening methods using selective agar plating on Sorbitol MacConkey Agar or SMAC plates have been used to detect *E. coli* O157. Many labs that identify non-sorbitol fermenting colonies on SMAC plates report this as suspected *E. coli* O157 and send the isolate to the state lab for confirmation. Since this is a screening method, it is not surprising that isolates do not always turn out to be *E. coli* O157. Other labs do additional testing for O157 antigen and also send the isolate to the state lab. The unique properties and special culture methods have contributed to *E. coli* O157 being the best known and most commonly reported STEC.

In the past few years, enzyme immuno-assay tests (EIA) have become available (e.g. Meridian ImmunoCard Stat!, Oxoid *E. coli* ST EIA Kit, ProspecT STEC Microplate Assay), which allows the testing of stool specimens for the Shiga toxin itself, directly. This test, therefore, does not require the culturing of the *E. coli* organism – which also means that it does not lead to an isolate of *E. coli* that can be submitted to the state laboratory for confirmation, PFGE, etc. Since this EIA test has become widely available, some commercial labs no longer perform culture and isolation, creating a problem for further public health investigation. This method does have advantages, however, as there is now the potential to detect other STEC serotypes besides O157 that would not be detected using the SMAC screening method described above.

In Colorado, Quest, LabCorp, and Kaiser use EIA testing for Shiga toxin and do not perform stool culture for *E. coli*/STEC. Several other labs use Shiga toxin testing in conjunction with stool culture for *E. coli* O157.

Regardless of the testing methodology, the CDPHE lab requests that labs submit isolates or, for those labs that get a positive Shiga toxin test (i.e. by EIA), the original stool specimen (i.e. on Cary-Blair medium, in a broth, whole stool, etc.) to the state laboratory for confirmation. The state laboratory retests those specimens for Shiga toxin using PCR for Shiga toxin, performs a culture to isolate and identify the organism, identifies the O and H antigens, and performs PFGE. It can take the CDPHE lab significantly longer to confirm specimens in cases where only a Shiga toxin test was performed, because the lab is beginning with stool, not an isolate.

*E. coli* O157, any Shiga-toxin producing *E. coli* (STEC), or any specimen testing positive for Shiga toxin (i.e. by EIA) should be reported within 7 days of the positive test result.

Remember that “*E. coli*” with no other information is NOT reportable. This is a very common cause of urinary tract and other infections.

### **Instructions for STEC Case Reporting**

As with other reportable conditions, STEC cases are reported from a number of different sources, including hospital infection control practitioners, outpatient diagnostic laboratories, the state laboratory, and occasionally, individual clinicians.

When entering an STEC case it is important to select the correct test(s) performed. Most of the time the correct test is one of the first two in the list:

<u>Test name</u>	<u>Explanation</u>
Culture	“Culture” means that the lab actually grew the bacteria on an agar plate. Usually this is Sorbitol MacConkey Agar (or SMAC plates) that are specifically used to detect <i>E. coli</i> O157. Additional testing, such as an O157 test may or may not have been performed. The correct choices for culture results are: Positive, Negative and Presumptive. Most culture results for STEC should be “presumptive” when the case is first reported, pending O and H antigen testing.
Shiga toxin test (EIA) at outside lab	The lab performed a test to detect shiga toxin. This can be abbreviated in many ways, including “STEC” or “STX,” depending on the lab. Some tests yield only positive or negative results. Other test kits can determine if a specimen is positive for shiga toxin 1, shiga toxin 2, or both. Please report as much detail as you have using the following choices:  EIA positive for shiga toxin 1 EIA positive for shiga toxin 2 EIA positive for shiga toxin 1 and 2 EIA shiga toxin positive, undifferentiated type

<p>O antigen  H antigen  PCR Shiga toxin 1 at state lab  PCR Shiga toxin 2 at state lab  EIA shiga toxin at state lab  PFGE</p>	}	<p>These tests are usually performed at the state laboratory on isolates submitted by clinical labs. Results for these tests are generally entered by CDPHE staff.</p>
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**STEC Case investigation**

We recommend local public health agencies follow up on all STEC cases reported into CEDRS with “confirmed”, “probable” or “suspect” case status. This is especially true during the STEC season (during the warmer months) when STEC is more common. Cases with “unknown” case status are still in the process of verification, and it is OK to wait for more information before contacting these cases. When conducting a disease investigation with a person whose case is listed as “probable” or “suspect” in CEDRS, it is a good idea to let them know that additional testing is ongoing at the state lab.

Here is a guide to what the different case status designations should mean. You can also refer to the CDC website for complete case definition information at <http://www.cdc.gov/epo/dphsi/casedef/> .

- Confirmed: Case has been confirmed by the CDPHE state lab, another state’s public health lab, or in rare circumstances a clinical diagnostic lab. Isolate can be O157:H7, O157:non-motile, or another serotype such as O26:H11. It is possible to have a confirmed case without knowing the exact O and H antigens yet.
- Probable: Case is likely epi-linked to a confirmed case, *OR* Isolate is known to be O157 positive, but information about H antigen and/or Shiga toxin is not available
- Suspect: Case reported to be Shiga toxin positive by a lab that does Shiga toxin testing (e.g. Quest or LabCorp), pending further testing at state lab, *OR* Case was Shiga toxin positive at an outside lab and specimen never received at state lab for confirmation
- Unknown: CDPHE uses this category to indicate that the case status determination is pending. CDPHE is contacting the reporting lab to ascertain the type of testing performed that resulted in the case report.

As with other foodborne diseases, any positive laboratory test should be taken seriously, and be considered reliable in the absence of evidence to the contrary. For example, a person with consistent symptoms and a positive EIA for Shiga toxin should be considered to have STEC (e.g. *E. coli* O157) and investigated accordingly.

Some points to consider:

- Local public health agencies should investigate confirmed, probable, and suspect cases in CEDRS.
- A laboratory test does not need to be confirmed by the state laboratory in order to be “believed” or before action is taken. This is especially true during the STEC season, during the warmer months.
- When the case status is “unknown” this means that CDPHE staff are trying to obtain more lab information to determine case status. It is OK to delay case investigation until lab information is clarified (this should take no more than 1 day).
- When interviewing cases with probable or suspect case status, it is a good idea to let them know the specimen may not confirm at the state laboratory.
- CDC case definitions do not specify that a particular laboratory did the testing, nor do they require confirmation by the state laboratory.
- There are several tests in CEDRS that can be used to indicate results of Shiga toxin testing at an outside lab (Shiga toxin test [EIA] at outside lab) and Shiga toxin testing at the state lab (EIA shiga toxin at state lab, PCR shiga toxin 1, or PCR shiga toxin 2)
- Once the initial case is entered into CEDRS, CDPHE staff will update the lab data as results are available at the state lab or more information is obtained from the reporting lab.
- Sometimes an outside lab performs Shiga toxin testing using EIA and these results cannot be confirmed by the state laboratory. When this happens, the case will be deleted from CEDRS. The state laboratory performs PCR for Shiga toxin, so a negative at the state laboratory is considered the “gold standard” for Shiga toxin testing.
- CDC and FoodNet sites are currently evaluating the impact of Shiga toxin testing on STEC surveillance data and the prevalence of so-called “false positive” EIA test results for Shiga toxin, so it is possible that this guidance will change as more data become available.