Annual Survey of Laboratory Testing Practices for *C. difficile* Infection

CDC's Emerging Infections Program - Clostridioides difficile Infection Surveillance

Section 1: Laboratory Information To be completed by surveillance officer
LABID#:
Completed By:
Date survey was completed: /
Is this a new laboratory?
→ Yes → Y
◯ No
Year added to surveillance:
Is this lab in another EIP site?
○ Yes
What state?
LabID in other EIP site:
○ No
Is this lab participating in surveillance?
○ Yes
○ No
How often do you receive line lists from this lab?
O Daily
○ Weekly
Monthly
Annually
○ Never
○ Other

Specify:

Public reporting burden of this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30329; ATTN: PRA (0920-0978).

How do you receive line lists from this lab?
 Electronic laboratory reporting (e.g. HL7 messaging)
○ Fax
🔿 Email
🔿 Mail
○ Secure file transfer
○ Other
Specify:
Do you receive specimens from this lab?
○ Yes
○ No
Was this lab audited in 2019?
○ Yes, in person
Yes, not in person
O No, not in catchment
No, not audited
Specify reason:
Is this a private, commercial lab (e.g. Quest or LabCorp)?
⊖ Yes
○ No

Types of facilities in your catchment area served by this lab (select all that apply):

- ⊖ Hospitals
- C LTACHs
- O LTCFs
- Outpatient facilities

Section 2: Survey

To be completed by lab personnel

Position of the staff who responded to the survey:

- Laboratory Supervisor
- O Microbiology Supervisor
- \bigcirc Other

Specify: _____

Offsite Testing

- 1. Does your laboratory ever send specimens off-site for *Clostridioides difficile* testing? (Choose one)
 - Always (no onsite testing performed)
 LabID of Offsite Lab:
 - Regularly, as part of standard testing algorithm
 LabID of Offsite Lab: ______
 Which tests are done offsite, and at which point in the testing algorithm?

 - Never (All testing performed onsite)
 - 🔘 Unknown
 - \bigcirc Other

Specify: _____

2. What type and order of testing is routinely used by your laboratory in standard testing for C. difficile?

(Enter letter from choices below; choose only one option for each line of testing)

1 st line of testing:	2 nd line of testing:	3rd line of testing:
A. EIA Toxin A and B		
B. EIA for Toxin A only		
C. EIA for Toxin B only		
D. EIA Antigen (GDH)		
E. EIA Toxin A/B and Antig	en (Simultaneous testing)	
F. EIA Other		
Specify other EIA type:		_
G. Nucleic Acid Amplificat	ion (e.g. PCR, Illumigene, Lum	inex, Biofire)
H. Culture		
I. Cytotoxin		
J. Other		
Specify other test type:		
K. No one routine test; clie	ents can order from among se	veral tests
Specify types:		
L. None		

2a. Which specimens are used during your 2nd line of testing? (Choose one)

- O Positive by the 1st line of testing
- O Negative by the 1st line of testing
- Specimens with discordant results (e.g. EIA+/GDH- or GDH+/EIA-)
- All specimens
- Do not use 2nd line of testing

2b. Which specimens are used during your 3rd line of testing? (Choose one)

- \bigcirc Positive by the 2nd line of testing
- \bigcirc Negative by the 2nd line of testing
- Specimens with discordant results (e.g. EIA+/GDH- or GDH+/EIA-)
- All specimens
- \bigcirc Do not use 3rd line of testing

2c. Does your laboratory perform any onsite testing for C. difficile outside of your normal testing algorithm?

- No, all onsite testing is done according to the testing algorithm specified above
- Other

Specify: _____

Testing Kits for CDI

3a. Which EIA test kit is currently used by your laboratory? (Check all that apply)

- D Premier (Meridian) Toxins A & B
- D Premier (Meridian) Toxin A
- □ Remel ProSpecT Toxins A & B
- TechLab Toxins A & B
- □ Inverness Medical/Wampole Toxins A & B QuikCheck
- □ Inverness Medical/Wampole QuikCheck Complete (Toxins A & B and Antigen)
- □ N/A (Do not use EIA testing)

3b. Which Nucleic Acid Amplification test is currently used by your laboratory? (*Check all that apply*)

- D BD-GeneOhm C. difficile
- D BD MAX C. difficile
- Cepheid Xpert C. difficile
- Meridian Illumigene
- Prodesse (Gen-Probe) Progastro CD
- □ Luminex xTAG GPP
- Biofire Filmarray GI Panel
- Quidel AmpliVue C. difficile Assay
- Great Basin Portrait Toxigenic C. difficile Assay
- Nanosphere Verigene SP
- Other

Specify other test: _____

□ N/A (Do not use nucleic acid amplification)

Multiplex GI panels

4a. If your laboratory uses a multiplexed molecular diagnostic (e.g., Biofire Filmarray GI Panel, Luminex xTAG GPP) to test for several GI pathogens, does your laboratory suppress the C. diff result so that clinicians cannot see it?

- □ Yes, always
- Yes, at clinician request
- Yes, but will release the result upon clinician request
- Yes, sometimes
 Specify: _____
- □ No, clinicians always see C. diff result
- □ N/A (Do not use multiplexed molecular diagnostic)

4b. If your laboratory uses a multiplexed diagnostic and the result is suppressed, where does the suppression occur?

- □ At the multiplexed molecular diagnostic instrument level (the result is not entered into the laboratory information management system (LIMS))
- □ At the laboratory information management system (LIMS) level

□ Other

Specify: _____

□ N/A (Do not use multiplexed molecular diagnostic or the result is never suppressed)

Testing Codes

5. What are the testing codes associated with the tests your lab currently uses?

Specify: _____

6. Has your lab testing algorithm for <i>C. difficile</i> changed since January 1, 2019?
○ Yes
What date did this change occur? / /
○ No
6a. (If yes) What was your previous type and order of testing?
(Enter letter from choices below; choose only one option for each line of testing)
1 st line of testing: 2 nd line of testing: 3 rd line of testing:
A. EIA Toxin A and B
B. EIA for Toxin A only
C. EIA for Toxin B only
D. EIA Antigen (GDH)
E. EIA Toxin A/B and Antigen (Simultaneous testing)
F. EIA Other
Specify other EIA type:
G. Nucleic Acid Amplification (e.g. PCR, Illumigene, Luminex, Biofire)
H. Culture
I. Cytotoxin
J. Other
Specify other test type:
K. No one routine test; clients can order from among several tests
Specify types:
L. None
6b. Which specimens were used during your 2 nd line of testing? (Choose one)
Positive by the 1 st line of testing
Negative by the 1 st line of testing
Specimens with discordant results (e.g. EIA +/GDH- or GDH+/EIA-)
 All specimens
O not use 2 nd line of testing (go to question 6)
6c. Which specimens were used during your 3 rd line of testing? (Choose one)
\bigcirc Positive by the 2 nd line of testing
\bigcirc Negative by the 2 nd line of testing
Specimens with discordant results (e.g. EIA+/GDH- or GDH+/EIA-)
○ All specimens

 \bigcirc Do not use 3rd line of testing (go to question 6)

7. Does your lab have a policy to reject stool specimens for *C. difficile* testing? (*Read all options. Check all that apply*)

- Yes, when stools are formed (formed stools are defined as stools that do NOT take the shape of the container)
- □ Yes, if there is a stool specimen already positive within 24 hrs of a new stool specimen
- □ Yes, if there is a stool specimen already positive within 48 hrs of a new stool specimen
- □ Yes, if there is a stool specimen that tested negative for *C. difficile* within 48 hours of a new stool specimen
- Yes, will not accept more than one stool specimen in a 24 hr period
- □ No rejection policy
- □ Other rejection policies
 - Specify other rejection policy: _____

7a. Has your rejection policy for stool specimens changed since January 1, 2019?

⊖ Yes

 What date did this change occur? _____ / _____

 Specify changes: _____

O No

8. How many stool samples did you test for C. diff each month in 2019?

Month	Stool samples tested	C. diff+ samples
January		
February		
March		
April		
May		
June		
July		
August		
September		
October		
November		
December		

Appendix: Common C. difficile Test Kit Names and Manufactures

EIA Toxin A & B

Wampole* Toxin A/B Quik Chek Techlab* *C. difficile* Toxin A/B II BioMerieux Vidas *C. difficile* Toxin A/B Meridian Immunocard Toxin A/B Meridian Premier Toxin A/B Remel Xpect *C. difficile* Toxin A/B Remel ProSpecT Toxin A/B

EIA Antigen (GDH)

Wampole* *C. difficile* Chek-60 Wampole* *C. difficile* Quik Chek Meridian Immunocard *C. difficile*

EIA Toxin A/B and Antigen (Simultaneous Testing)

Wampole* C. difficile Quik Chek Complete

Nucleic Acid Amplification

BD-GeneOhm *C. difficile* Cepheid Xpert *C. difficile* Great Basin Portrait Toxigenic *C. difficile* Assay Luminex xTAG Gastrointestinal Pathogen Panel (xTAG GPP) Meridian BioScience Illumigene Nanosphere Verigene SP Prodesse (Gen-Probe) Progastro CD Quidel AmpliVue *C. difficile* Assay

EIA for Toxin B Only

Alere* C. difficile Toxin B

*Techlab, Inverness Medical, Alere, Wampole may be used interchangeably for these test kits