

# 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:** \_\_\_\_\_

**Position of the staff who responded to the survey:**

- Laboratory Supervisor
- Microbiology Supervisor
- Other

**Specify:** \_\_\_\_\_

**Date survey was completed:** \_\_\_\_ / \_\_\_\_ / \_\_\_\_

**Is this a new laboratory?**

- Yes
- 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?**

- Daily
- Weekly
- Monthly
- Annually
- Never
- Other

**Specify:** \_\_\_\_\_

**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 2018?**

- Yes, in person
- Yes, not in person
- 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
- LTACHs
- LTCFs
- Outpatient facilities

## Section 2: Survey

To be completed by lab personnel

### Offsite Testing

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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?

\_\_\_\_\_

Not regularly, but when a test ordered by a physician cannot be performed onsite

Specify tests performed offsite: \_\_\_\_\_

Never (All testing performed onsite)

Unknown

Other

Specify: \_\_\_\_\_

### Testing Routine

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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<sup>st</sup> line of testing: \_\_\_\_\_ 2<sup>nd</sup> line of testing: \_\_\_\_\_ 3<sup>rd</sup> 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)

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

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

Positive by the 1<sup>st</sup> line of testing

- Negative by the 1<sup>st</sup> line of testing
- Specimens with discordant results (e.g. EIA+/GDH- or GDH+/EIA-)
- All specimens
- Do not use 2<sup>nd</sup> line of testing (*go to question 3a*)

**2b. Which specimens are used during your 3<sup>rd</sup> line of testing? (Choose one)**

- Positive by the 2<sup>nd</sup> line of testing
- Negative by the 2<sup>nd</sup> line of testing
- Specimens with discordant results (e.g. EIA+/GDH- or GDH+/EIA-)
- All specimens
- Do not use 3<sup>rd</sup> line of testing (*go to question 3a*)

## Testing Kits

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

- Premier (Meridian) Toxins A & B
- 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)
- Antigen Testing

**Specify antigen testing kit name/manufacturer:** \_\_\_\_\_

- Other

**Specify other kit name/manufacturer:** \_\_\_\_\_

- N/A (Do not use EIA testing)

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

- BD-GeneOhm C. difficile
- Cepheid Xpert C. difficile
- Meridian Illumigene
- Prodesse (Gen-Probe) Progestro CD
- Luminex xTAG GPP
- Other

**Specify other test:** \_\_\_\_\_

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

## Testing Codes

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

**Specify:** \_\_\_\_\_

## Laboratory Algorithm

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**5. Has your lab testing algorithm for *C. difficile* changed since January 1, 2018?**

- Yes

**What date did this change occur?** \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

- No

\*\*\**(If Yes was checked, go on to 5a, but please do not forget to ask Q7 at the end of the survey)*\*\*\*

**5a. (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<sup>st</sup> line of testing:** \_\_\_\_\_ **2<sup>nd</sup> line of testing:** \_\_\_\_\_ **3<sup>rd</sup> 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)
- 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

**5b. Which specimens were used during your 2<sup>nd</sup> line of testing? (Choose one)**

- Positive by the 1<sup>st</sup> line of testing
- Negative by the 1<sup>st</sup> line of testing
- Specimens with discordant results (e.g. EIA +/GDH- or GDH+/EIA-)
- All specimens
- Do not use 2<sup>nd</sup> line of testing (*go to question 6*)

**5c. Which specimens were used during your 3<sup>rd</sup> line of testing? (Choose one)**

- Positive by the 2<sup>nd</sup> line of testing
- Negative by the 2<sup>nd</sup> line of testing
- Specimens with discordant results (e.g. EIA+/GDH- or GDH+/EIA-)
- All specimens
- Do not use 3<sup>rd</sup> line of testing (*go to question 6*)

Laboratory Policies

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**6. 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:** \_\_\_\_\_

**6a. Has your rejection policy for stool specimens changed since January 1, 2018?**

- Yes  
**What date did this change occur?** \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
**Specify changes:** \_\_\_\_\_
- No

For labs that changed testing practices in the past year

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**7. Since your laboratory changed its testing algorithm for CDI diagnosis in the past year and this may have had an impact in the number of positive specimens, it is very important for us to have information on the number of stool samples tested for *C. difficile* and the number of stool samples positive for *C. difficile* in the 3 months prior to and the 3 months following the change in testing methodology.**

	3 months prior (mm/yyyy)	2 months prior (mm/yyyy)	1 month prior (mm/yyyy)	1 month post (mm/yyyy)	2 months post (mm/yyyy)	3 months post (mm/yyyy)
Stool samples tested for <i>C.diff</i>						
Stool samples positive for <i>C.diff</i>						

If your lab phased in a new lab diagnostic test during a particular month and there is no specific date, please fill out the table below starting with the month prior to the switch (e.g. if switch was in July, fill out the pre period with data from months April through June and the post-period with data from August through October).

## Appendix: Common *C. difficile* Test Kit Names and Manufactures

### **EIA Toxin A & B**

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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)**

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

### **EIA Toxin A/B and Antigen (Simultaneous Testing)**

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Wampole\* *C. difficile* Quik Chek Complete

### **Nucleic Acid Amplification**

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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**

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Alere\* *C. difficile* Toxin B

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