

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

**Was this a new laboratory in 2023?**

- Yes  
 No

**Year added to surveillance:** \_\_\_\_\_

**Is this lab in another EIP site?**

- Yes

**What state?** \_\_\_\_\_

**LabID in other EIP site:** \_\_\_\_\_

- No

**Did this lab participate in surveillance in 2023?**

- Yes  
 No

**How often did you receive line lists from this lab in 2023?**

- Whenever there is a positive case  
 Daily  
 Weekly  
 Monthly  
 Annually  
 Never  
 Other

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

**How did you receive line lists from this lab in 2023?**

- Electronic laboratory reporting (e.g. HL7 messaging)
- Fax
- Email
- Mail
- Secure file transfer
- Other

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

**Did you receive specimens from this lab in 2023?**

- Yes
- No

**Was this lab audited in 2023?**

- 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 in 2023 (select all that apply):**

- Hospitals
- LTACHs
- LTCFs
- Outpatient facilities

## Section 2: Survey

To be completed by lab personnel

**Instructions: This survey is intended to capture testing practices at your laboratory between January 1, 2023 and December 31, 2023.**

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

- Laboratory Supervisor
- Microbiology Supervisor
- Other

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

### Offsite Testing

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**1. Did your laboratory ever send specimens off-site for *Clostridioides difficile* testing in 2023? (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 for CDI

**2a. Which testing method(s) for *Clostridioides difficile* (*C. difficile*) did your laboratory perform in 2023? (Choose all that apply. Include testing methods used for only part of the year or for only a specific subset of specimens, if applicable)**

	Did your laboratory use this testing method for <i>Clostridioides difficile</i> ( <i>C. difficile</i> ) in 2023?	Specify when you used this test (e.g. at provider request, for outpatients, for inpatients with a length of stay > 3 days, for every specimen received)	Did you use this testing method in this way for all of 2023?	What date did you change?	What test did you use in this situation before this date?
GDH and EIA for toxin simultaneously, followed by NAAT for discordant results	<input type="checkbox"/> Routinely <input type="checkbox"/> Sometimes <input type="checkbox"/> Never		<input type="checkbox"/> Yes <input type="checkbox"/> No		
NAAT, followed by EIA for toxin and GDH simultaneously if NAAT positive	<input type="checkbox"/> Routinely <input type="checkbox"/> Sometimes <input type="checkbox"/> Never		<input type="checkbox"/> Yes <input type="checkbox"/> No		
NAAT, followed by EIA for toxin if NAAT positive	<input type="checkbox"/> Routinely <input type="checkbox"/> Sometimes <input type="checkbox"/> Never		<input type="checkbox"/> Yes <input type="checkbox"/> No		
GDH, followed by NAAT if GDH positive	<input type="checkbox"/> Routinely <input type="checkbox"/> Sometimes <input type="checkbox"/> Never		<input type="checkbox"/> Yes <input type="checkbox"/> No		
GDH and EIA for toxin simultaneously, followed by cell cytotoxicity neutralization assay (cytotoxin)	<input type="checkbox"/> Routinely <input type="checkbox"/> Sometimes <input type="checkbox"/> Never		<input type="checkbox"/> Yes <input type="checkbox"/> No		

	Did your laboratory use this testing method for <i>Clostridioides difficile</i> (C. difficile) in 2023?	Specify when you used this test (e.g. at provider request, for outpatients, for inpatients with a length of stay > 3 days, for every specimen received)	Did you use this testing method in this way for all of 2023?	What date did you change?	What test did you use in this situation before this date?
GDH and EIA for toxin simultaneously	<input type="checkbox"/> Routinely <input type="checkbox"/> Sometimes <input type="checkbox"/> Never		<input type="checkbox"/> Yes <input type="checkbox"/> No		
EIA for toxin	<input type="checkbox"/> Routinely <input type="checkbox"/> Sometimes <input type="checkbox"/> Never		<input type="checkbox"/> Yes <input type="checkbox"/> No		
Cell cytotoxicity neutralization assay (cytotoxin)	<input type="checkbox"/> Routinely <input type="checkbox"/> Sometimes <input type="checkbox"/> Never		<input type="checkbox"/> Yes <input type="checkbox"/> No		
C. difficile-specific NAAT (e.g., PCR, LAMP)	<input type="checkbox"/> Routinely <input type="checkbox"/> Sometimes <input type="checkbox"/> Never		<input type="checkbox"/> Yes <input type="checkbox"/> No		
Multiplex GI panel NAAT	<input type="checkbox"/> Routinely <input type="checkbox"/> Sometimes <input type="checkbox"/> Never		<input type="checkbox"/> Yes <input type="checkbox"/> No		
Toxigenic culture (C. difficile culture followed by detection of toxins)	<input type="checkbox"/> Routinely <input type="checkbox"/> Sometimes <input type="checkbox"/> Never		<input type="checkbox"/> Yes <input type="checkbox"/> No		
Other (specify): _____ _____ _____ _____	<input type="checkbox"/> Routinely <input type="checkbox"/> Sometimes <input type="checkbox"/> Never		<input type="checkbox"/> Yes <input type="checkbox"/> No		

## Testing Kits for CDI

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**3a. Which EIA test kit was used by your laboratory in 2023?** (Check all that apply; see appendix for additional examples)

- 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 was used by your laboratory in 2023?** (Check all that apply)

- BD-GeneOhm *C. difficile*
- BD MAX *C. difficile*
- Cepheid Xpert *C. difficile*
- Meridian Illumigene
- Prodesse (Gen-Probe) Progestro 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

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**4a. If your laboratory used a multiplexed molecular diagnostic (e.g., Biofire Filmarray GI Panel, Luminex xTAG GPP) to test for several GI pathogens in 2023, did your laboratory suppress the *C. difficile* result so that clinicians could not see it?**

- Yes, *C. difficile* result is always suppressed
- Yes, *C. difficile* result is suppressed at clinician request
- Yes, *C. difficile* result is suppressed but laboratory will release the result upon clinician request
- Yes, *C. difficile* result is suppressed in certain situations  
**Specify:** \_\_\_\_\_
- No, clinicians always see *C. difficile* result
- N/A (Do not use multiplexed molecular diagnostic)

**4b. If your laboratory used a multiplexed diagnostic in 2023 and the result was suppressed, where does the suppression occur?**

- C. difficile* result is suppressed at the multiplexed molecular diagnostic instrument level (the result is not entered into the laboratory information management system (LIMS))
- C. difficile* result is suppressed at the laboratory information management system (LIMS) level
- C. difficile* result is suppressed somewhere else  
**Specify:** \_\_\_\_\_
- N/A (Do not use multiplexed molecular diagnostic or the result is never suppressed)

## Multistep Algorithm Testing for CDI

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**5a. If your laboratory used a nucleic acid amplification test (NAAT) (e.g., Cepheid Xpert *C. difficile*) as first line testing followed by a toxin EIA test (whenever NAAT result is positive) in 2023, did your laboratory suppress the positive NAAT result so that clinicians could not see it?**

- Yes, NAAT result is always suppressed when NAAT result is positive and confirmatory toxin EIA result is negative
- Yes, NAAT result is always suppressed but laboratory will release the positive NAAT result upon clinician request
- Yes, NAAT result is suppressed in certain situations  
**Specify:** \_\_\_\_\_
- No, clinicians always see the positive NAAT result
- N/A (Do not use this type of multistep algorithm testing)

**5b. If your laboratory used NAAT as first line testing followed by confirmatory toxin EIA testing in 2023, and both the NAAT and toxin EIA results were released to the clinician, did your laboratory provide any comments to help the clinician interpret the test results (e.g., NAAT-positive only result might represent colonization, etc.)?**

- Yes, laboratory provides comments to accompany the test results
  - If yes, please specify** the comments your laboratory uses to accompany the test results:  
\_\_\_\_\_
- No, laboratory does not provide comments to accompany the test results
- The laboratory provides comments to accompany the test results in certain situations

- If yes, please specify** the situations in which your laboratory provides comments and the comments your laboratory uses to accompany the test results: \_\_\_\_\_
- N/A (Do not use this type of multistep algorithm testing or NAAT test result is always suppressed)

## Testing Codes

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**6. What are the LOINC or internal testing codes associated with the tests your lab used in 2023 (e.g. LOINC codes 13957-6, 34713-8, or 54067-4)?**

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

## Laboratory Policies

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**7. Did your lab have a policy to reject stool specimens for *C. difficile* testing in 2023?** (Read all options. Check all that apply, even if it only applies sometimes)

- Yes, when stools are formed (formed stools are defined as stools that do NOT take the shape of the container)
- Yes, if there was a positive stool specimen recently (e.g. within 24 hours, within 7 days)
- Yes, if there was a negative stool specimen recently (e.g. within 24 hours, within 7 days)
- Yes, will not accept more than one stool specimen in a 24 hr period
- Yes, if patient is on a specific medication (e.g. laxatives)
- No rejection policy
- Other rejection policies

**Specify other rejection policy:** \_\_\_\_\_

**7a. Did your rejection policy for stool specimens change between January 1, 2023 and December 31, 2023?**

Yes

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

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

No



**8. How many stool samples did you test for *C. difficile* each month in 2023?**

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**

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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