Form Approved
OMB No. 0920-0978

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 2022?

- ◯ 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 2022?

- ◯ Yes
- ◯ No

How often did you receive line lists from this lab in 2022?

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

Specify: _____

How did you receive line lists from this lab in 2022?

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

Specify: _____

Did you receive specimens from this lab in 2022?

- ◯ Yes
- ◯ No

Was this lab audited in 2022?

- ◯ 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 2022 (select all that apply):

- ◯ Hospitals
- ◯ LTACHs
- ◯ LTCFs
- ◯ Outpatient facilities

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Section 2: Survey

To be completed by lab personnel

Instructions: This survey is intended to capture testing practices at your laboratory between January 1, 2022 and December 31, 2022.

Position of the staff who responded to the survey:

- ◯ Laboratory Supervisor
- ◯ Microbiology Supervisor
- ◯ Other
  Specify: _____

Offsite Testing

1. **Did your laboratory ever send specimens off-site for *Clostridioides difficile* testing in 2022?** *(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 2022? (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 Clostridioides difficile (C. difficile) in 2022?	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 2022?	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	☐ Routinely ☐ Sometimes ☐ Never		☐ Yes ☐ No		
NAAT, followed by EIA for toxin and GDH simultaneously if NAAT positive	☐ Routinely ☐ Sometimes ☐ Never		☐ Yes ☐ No		
NAAT, followed by EIA for toxin if NAAT positive	☐ Routinely ☐ Sometimes ☐ Never		☐ Yes ☐ No		
GDH, followed by NAAT if GDH positive	☐ Routinely ☐ Sometimes ☐ Never		☐ Yes ☐ No		
GDH and EIA for toxin simultaneously, followed by cell cytotoxicity neutralization assay (cytotoxin)	☐ Routinely ☐ Sometimes ☐ Never		☐ Yes ☐ No		

	Did your laboratory use this testing method for Clostridioides difficile (C. difficile) in 2022?	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 2022?	What date did you change?	What test did you use in this situation before this date?
GDH and EIA for toxin simultaneously	☐ Routinely ☐ Sometimes ☐ Never		☐ Yes ☐ No		
EIA for toxin	☐ Routinely ☐ Sometimes ☐ Never		☐ Yes ☐ No		
Cell cytotoxicity neutralization assay (cytotoxin)	☐ Routinely ☐ Sometimes ☐ Never		☐ Yes ☐ No		
C. difficile-specific NAAT (e.g., PCR, LAMP)	☐ Routinely ☐ Sometimes ☐ Never		☐ Yes ☐ No		
Multiplex GI panel NAAT	☐ Routinely ☐ Sometimes ☐ Never		☐ Yes ☐ No		
Toxigenic culture (C. difficile culture followed by detection of toxins)	☐ Routinely ☐ Sometimes ☐ Never		☐ Yes ☐ No		
Other (specify): _____ _____ _____ _____	☐ Routinely ☐ Sometimes ☐ Never		☐ Yes ☐ No		

3a. Which EIA test kit was used by your laboratory in 2022? *(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 2022? *(Check all that apply)*

- □ BD-GeneOhm C. difficile
- □ 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 used a multiplexed molecular diagnostic (e.g., Biofire Filmarray GI Panel, Luminex xTAG GPP) to test for several GI pathogens in 2022, 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 2022 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

5a. If your laboratory used a nucleic acid amplification test (NAAT) (e.g., Cepheid Xpert *C. difficile*) as <u>first line testing</u> *followed* by a toxin EIA test (whenever NAAT result is positive) in 2022, 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 2022, and <u>both</u> 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

6. What are the LOINC or internal testing codes associated with the tests your lab used in 2022 (e.g. LOINC codes 13957-6, 34713-8, or 54067-4)?

Specify: _____

Laboratory Policies

7. Did your lab have a policy to reject stool specimens for *C. difficile* testing in 2022? *(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, 2022 and December 31, 2022?

- ◯ Yes

  What date did this change occur? _____ / _____ / _____

  Specify changes: _____
- ◯ No

Testing Capacity

8. How many stool samples did you test for *C. difficile* each month in 2022?

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

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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