Form Approved
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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 2021?

- ◯ 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 2021?

- ◯ Yes
- ◯ No

How often did you receive line lists from this lab in 2021?

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

Specify: _____

How did you receive line lists from this lab in 2021?

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

Specify: _____

Did you receive specimens from this lab in 2021?

- ◯ Yes
- ◯ No

Was this lab audited in 2021?

- ◯ 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 2021 (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, 2021 and December 31, 2021.

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 2021? *(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: _____

2. What type and order of testing was routinely used by your laboratory in standard testing for *C. difficile* on December 31, 2021?
(Enter letter from choices below; choose only one option for each line of testing)

1st line of testing: _____ 2nd 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 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

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

◯ Positive by the 1st line of testing
◯ 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 were used during your 3rd line of testing? *(Choose one)*

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

2c. Did your laboratory perform any onsite testing for *C. difficile* outside of your normal testing algorithm in 2021?

◯ No, all onsite testing is done according to the testing algorithm specified above
◯ Yes, on physician request
Specify tests: _____

◯ Other

Specify: _____

Testing Kits for CDI

3a. Which EIA test kit was used by your laboratory in 2021? *(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 was used by your laboratory in 2021? *(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 2021, 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 2021 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 first line testing *followed* by a toxin EIA test (whenever NAAT result is positive) in 2021, 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 2021, 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

6. What are the LOINC or internal testing codes associated with the tests your lab used in 2021 (e.g. LOINC codes 13957-6, 34713-8, or 54067-4)?

Specify: _____

CDI Testing Shortage and Capacity

7a. In 2021, did your laboratory experience any shortages in supplies, reagents, and/or test kits for performing *C. difficile* testing (e.g., NAAT or EIA reagents, swabs)?

- □ Yes
  - ○ If yes, please specify the dates during which the supply shortage occurred (provide approximate dates if the exact dates are not known): _____
- □ No
- □ N/A (*C. difficile* testing was not routinely performed on onsite)

7b. If your laboratory experienced a supply shortage for *C. difficile* testing in 2021, how did the shortage affect your laboratory's ability to perform *C. difficile* testing? *(Check all that apply)*

- □ We had to decrease the frequency of *C. difficile* testing during the shortage
- □ We had to switch to an alternative method to test for *C. difficile* during the shortage
- □ We were not able to perform any type of *C. difficile* testing during the shortage
- □ We had to send all *C. difficile* testing offsite to another laboratory
- □ The shortage did not affect our ability to perform *C. difficile* testing
- □ Other, specify: _____
- □ N/A (*C. difficile* testing was not routinely performed onsite)

7c. In 2021, did your laboratory experience a high demand for COVID-19 testing that limited the availability of staff (e.g., reduced staffing or work time) or the use of equipment to perform *C. difficile* testing?

- □ Yes
- □ No
- □ N/A (*C. difficile* testing and/or COVID-19 testing was not routinely performed onsite)

Laboratory Algorithm Changes

8. Did your lab testing algorithm for *C. difficile* change between January 1, 2021 and December 31, 2021?

- ◯ Yes

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

◯ No

8a. *(If yes)* **What was the previous type and order of testing performed by your lab in 2021 before it changed its testing algorithm?**
(Enter letter from choices below; choose only one option for each line of testing)

1st line of testing: _____ 2nd 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 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

8b. Which specimens were used during your 2nd line of testing? *(Choose one)*

◯ Positive by the 1st line of testing
◯ 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 *(go to question 6)*

8c. Which specimens were used during your 3rd line of testing? *(Choose one)*

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

9. Did your lab have a policy to reject stool specimens for *C. difficile* testing in 2021? *(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: _____

9a. Did your rejection policy for stool specimens change between January 1, 2021 and December 31, 2021?

- ◯ Yes

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

  Specify changes: _____
- ◯ No

Testing Capacity

10. How many stool samples did you test for *C. difficile* each month in 2021?

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