Form Approved
OMB No. XXX-XXXX

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
- ◯ 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 2020?

- ◯ 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

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OMB No. XXX-XXXX

Section 2: Survey

To be completed by lab personnel

Position of the staff who responded to the survey:

- ◯ Laboratory Supervisor
- ◯ Microbiology Supervisor
- ◯ 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?
  _____
- ◯ 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 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)

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 are 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 are 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. 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
◯ Yes, on physician request
Specify tests: _____
◯ Other
Specify: _____

Testing Kits for CDI

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
- □ 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 LOINC or internal testing codes associated with the tests your lab currently uses (e.g. LOINC codes 13957-6, 34713-8, or 54067-4)?

Specify: _____

Laboratory Algorithm Changes

6. Has your lab testing algorithm for *C. difficile* changed since January 1, 2020?

- ◯ 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)

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

6b. 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)*

6c. 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)*

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, 2020?

- ◯ Yes

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

  Specify changes: _____
- ◯ No

Testing Capacity

8. How many stool samples did you test for C. diff each month in 2020?

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