Annual Survey of Laboratory Testing Practices for *C. difficile* Infection

CDC's Emerging Infections Program - Clostridioides difficile Infection Surveillance

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

Section 1: Laboratory Information

Public reporting burden of this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30329; ATTN: PRA (0920-0978).

Form Approved OMB No. 092-0978 Expires xx/xx/xxxx

How of	ten do you receive line lists from this lab?
\bigcirc	Daily
\bigcirc	Weekly
\bigcirc	Monthly
\bigcirc	Annually
\bigcirc	Never
\bigcirc	Other
	Specify:
How do	you receive line lists from this lab?
\bigcirc	Electronic laboratory reporting (e.g. HL7 messaging)
\bigcirc	Fax
\bigcirc	Email
\bigcirc	Mail
\bigcirc	Secure file transfer
\bigcirc	Other
	Specify:
Do you	receive specimens from this lab?
\bigcirc	Yes
\bigcirc	No
Was thi	is lab audited in 2018?
_	Yes, in person
_	Yes, not in person
_	No, not in catchment
\cup	No, not audited Specify reason:
	Specify reason.
Is this a	private, commercial lab (e.g. Quest or LabCorp)?
0	Yes
	No
Types o	of facilities in your catchment area served by this lab (select all that apply):
\bigcirc	Hospitals
\bigcirc	LTACHs
Ô	LTCFs
\bigcirc	Outpatient facilities

Form Approved OMB No. 092-0978 Expires xx/xx/xxxx

Section 2: Survey

To be completed by lab personnel

\sim	-		_			
1	111	ITA.	10	CTI	n	α
w		 ш		esti	ш	ᆮ

\bigcirc	
	Always (no onsite testing performed)
	LabID of Offsite Lab:
\bigcirc	Regularly, as part of standard testing algorithm
	LabID of Offsite Lab:
	Which tests are done offsite, and at which point in the testing algorithm?
\circ	Not regularly, but when a test ordered by a physician cannot be performed onsite Specify tests performed offsite:
\bigcirc	Never (All testing performed onsite)
_	Unknown
\bigcirc	Other
\circ	Specify:
	Specify
Testing	g Routine
2. Wha	t type and order of testing is routinely used by your laboratory in standard testing for C.difficile?
(Enter I	etter from choices below; choose only one option for each line of testing)
1 st li	ine of testing: 2 nd line of testing: 3rd line of testing:
	ine of testing: 2 nd line of testing: 3rd line of testing:
А	
A B	EIA Toxin A and B
A B C	EIA Toxin A and B . EIA for Toxin A only
A B C D	a. EIA Toxin A and B a. EIA for Toxin A only a. EIA for Toxin B only
A B C D	a. EIA Toxin A and B a. EIA for Toxin A only b. EIA for Toxin B only b. EIA Antigen (GDH)
A B C D	a. EIA Toxin A and B b. EIA for Toxin A only c. EIA for Toxin B only d. EIA Antigen (GDH) b. EIA Toxin A/B and Antigen (Simultaneous testing)
A B C D E F	a. EIA Toxin A and B b. EIA for Toxin A only c. EIA for Toxin B only b. EIA Antigen (GDH) c. EIA Toxin A/B and Antigen (Simultaneous testing) c. EIA Other
A B C D E F	a. EIA Toxin A and B b. EIA for Toxin A only c. EIA for Toxin B only b. EIA Antigen (GDH) c. EIA Toxin A/B and Antigen (Simultaneous testing) c. EIA Other Specify other EIA type:
A B C D E F G	a. EIA Toxin A and B b. EIA for Toxin A only c. EIA for Toxin B only c. EIA Antigen (GDH) b. EIA Toxin A/B and Antigen (Simultaneous testing) b. EIA Other becify other EIA type: b. Nucleic Acid Amplification (e.g. PCR, Illumigene, Luminex)
A B C D E F G H I.	a. EIA Toxin A and B b. EIA for Toxin A only c. EIA for Toxin B only b. EIA Antigen (GDH) c. EIA Toxin A/B and Antigen (Simultaneous testing) c. EIA Other begin{center} Specify other EIA type: c. Nucleic Acid Amplification (e.g. PCR, Illumigene, Luminex) b. Culture
A B C D E F G H I.	a. EIA Toxin A and B b. EIA for Toxin A only c. EIA for Toxin B only c. EIA Antigen (GDH) b. EIA Toxin A/B and Antigen (Simultaneous testing) c. EIA Other b. Specify other EIA type: b. Nucleic Acid Amplification (e.g. PCR, Illumigene, Luminex) c. Culture Cytotoxin Other
A B C D E F G H I.	a. EIA Toxin A and B b. EIA for Toxin A only c. EIA for Toxin B only b. EIA Antigen (GDH) c. EIA Toxin A/B and Antigen (Simultaneous testing) c. EIA Other Specify other EIA type: c. Nucleic Acid Amplification (e.g. PCR, Illumigene, Luminex) c. Culture Cytotoxin Other Specify other test type:
A B C D E F G H I.	I. EIA Toxin A and B I. EIA for Toxin A only I. EIA for Toxin B only I. EIA Antigen (GDH) I. EIA Toxin A/B and Antigen (Simultaneous testing) I. EIA Other Specify other EIA type: I. Nucleic Acid Amplification (e.g. PCR, Illumigene, Luminex) I. Culture Cytotoxin Other Specify other test type: I. No one routine test; clients can order from among several tests
A B C D E F G H I.	a. EIA Toxin A and B b. EIA for Toxin A only c. EIA for Toxin B only b. EIA Antigen (GDH) c. EIA Toxin A/B and Antigen (Simultaneous testing) c. EIA Other Specify other EIA type: c. Nucleic Acid Amplification (e.g. PCR, Illumigene, Luminex) c. Culture Cytotoxin Other Specify other test type:

OMB No. 092-0978
Expires xx/xx/xxxx
 Negative by the 1st line of testing
Specimens with discordant results (e.g. EIA+/GDH- or GDH+/EIA-)
○ All specimens
On not use 2 nd line of testing (go to question 3a)
2b. Which specimens are used during your 3 rd line of testing? (Choose one)
2b. Which specimens are used during your 3 rd line of testing? (Choose one) One is a positive by the 2 nd line of testing
O Positive by the 2 nd line of testing
 Positive by the 2nd line of testing Negative by the 2nd line of testing

Form Approved

3a. Wl	nich 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. W	hich 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) Progastro CD
	Luminex xTAG GPP
	Other
	Specify other test:
	N/A (Do not use nucleic acid amplification)
Testin	g Codes
4. Wha	at are the testing codes associated with the tests your lab currently uses? Specify:
Labor	atory Algorithm
5. Has	your lab testing algorithm for <i>C. difficile</i> 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)

1st line of tes	ting:	2 nd line of testing:	3 rd line of testing: _	
A. EIA Toxi	n A and B			
B. EIA for T	Toxin A only			
C. EIA for T	Toxin B only			
D. EIA Anti	gen (GDH)			
E. EIA Toxi	n A/B and Antig	en (Simultaneous testir	g)	
F. EIA Othe	er .			
Specify of	other EIA type: ₋			
G. Nucleic	Acid Amplificati	on (e.g. PCR, Illumigene	e, Luminex)	
H. Culture				
I. Cytotoxii	n			
J. Other				
	• •			
	•	ents can order from am	ong several tests	
	ypes:			
L. None				
5h. Which specii	mens were used	l during your 2 nd line of	testing? (Choose one)	
•	by the 1 st line of		testing, (emosse one)	
•	by the 1 st line o	-		
	•	ent results (e.g. EIA +/G	DH- or GDH+/EIA-)	
○ All speci		,	, ,	
•		sting (go to question 6)		
5c. Which specir	nens were used	during your 3^{rd} line of	testing? (Choose one)	
•	by the 2 nd line o	-		
<u> </u>	e by the 2 nd line o	•		
		int results (e.g. EIA+/GI	DH- or GDH+/EIA-)	
All special				
O Do not u	se 3 rd line of tes	ting (go to question 6)		

Laboratory Policies

6. Does	s 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 <i>C. difficile</i> 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?
\circ	Yes
	What date did this change occur?//
	Specify changes:
\circ	No
For lab	os that changed testing practices in the past year

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

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