

**Change Request for Clostridium difficile (C. difficile) Laboratory Practice Survey (Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics- American Society for Microbiology; OMB Control # 0920-1096)**

Nonmaterial/ non-substantive changes are requested for the 2018 *Clostridium difficile* (*C. difficile*) *Laboratory Practice Survey* instrument, which is part of the OMB-approved information collection (Title: Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics- American Society for Microbiology. OMB Control # 0920-1096; Exp. Date 01/31/2019) and was submitted as Appendix M5: *Clostridium difficile* (*C. difficile*) *Laboratory Practice Survey* in the information collection request. Justification for the non-substantive change request are described below and detailed in the chart that follows. There are no requested changes in the purpose of the project, the scope of the study, the methodology, statistical methods, the interpretation of the results, or significant changes to the respondents, the information collection instrument, or burden.

All changes being requested to the survey instrument are minor ones including reformatting 8 questions editing/adding a response category to 7 questions, deleting 1 question, reordering 1 question, and adding a few questions. The reasons for these changes is that our results from another survey “Urine Collection, Storage and Preservation Laboratory Practice Survey” (also approved under OMB # 0920-1096) indicated that several questions needed additional clarity by refining the response options because answers to the same question in that survey revealed that the responses were not specific enough to identify the type of institutions respondents worked in. Therefore, similar questions have been edited for clarity and a “Do Not Know” option to all relevant response categories was included. Additional changes include the addition of new questions including asking about the newly published guideline “A Laboratory Medicine Best Practices Systematic Review and Meta-Analysis for the Laboratory Diagnosis of *Clostridium difficile*” which was not available when the current OMB approval was obtained.

The currently approved data collection instrument (Appendix M5) is attached along with the requested revised data collection instrument (pdf file).

<b>Form</b>	<b>Current Question/Item</b>	<b>Requested Change</b>
Clostridium difficile (C. difficile) Laboratory Practice Survey	Question 4: How did you learn about this survey? (6 choices)	<b>EDITING/ADDING RESPONSE CATEGORY TO QUESTION</b> <ul style="list-style-type: none"> <li>• Choice 4 changed from Clinical Microbiology Issues Update to Clinical and Public health Microbiology Newsletter</li> <li>• Choice 5 changed from <i>Microbe</i>, ASM’s monthly news magazine to <i>Microcosm</i>, ASM’s monthly news magazine</li> <li>• Added Choice 6: Laboratory Outreach Communication System (LOCS)</li> </ul>
		<b>ADDING NEW QUESTION 5</b> New Question 5: Were you aware of the ASM-CDC published guideline "A Laboratory Medicine Best Practices Systematic Review and Meta-Analysis for the Laboratory Diagnosis of <i>Clostridium difficile</i> " before receiving this survey? Yes or No

Question 6: Did you already complete this survey? Yes or No	<b>REFORMATTING QUESTION</b> Did someone from your laboratory complete the initial C. difficile survey in 2018? Yes, No, or Do not know
Question 7: Date MM/DD/YYYY	<b>REFORMATTING QUESTION</b> Today's Date MM/DD/YYYY
Question 8: Which of the following best describes your laboratory setting? (Select the best choice.) 8 choices	<b>EDITING/ADDING RESPONSE CATEGORY TO QUESTION</b> <ul style="list-style-type: none"> <li>• Choice 1 changed from University hospital/Academic medical center to University Hospital</li> <li>• Choice 2 added Academic/Teaching Medical Center (includes association with a medical school and residency training program)</li> <li>• Added Community Hospital/Health System (non-federal, short term general hospital)</li> <li>• Added Specialty Hospitals (e.g., women's, eye, heart, orthopaedic)</li> <li>• Independent laboratory changed to Independent Laboratory/Reference Laboratory</li> </ul>
Question 10: How many pathologists or other physicians are in your laboratory? (Do not include residents, fellows or trainees/medical students.)	<b>REFORMATTING QUESTION</b> How many pathologists or other physicians provide direct oversight in your laboratory? (Do not include residents, fellows or trainees/medical students.)
Question 13: What kind of patient population is at your institution? (Select all that apply) 4 choices	<b>RE-ORDERING QUESTION AND DELETING RESPONSE CATEGORY TO QUESTION</b> Moved as Question 15 and choices are now only three: Inpatient, Outpatient, and Other (please specify)
Question 14: How many hospital beds does the microbiology section serve? 5 choices	<b>EDITING/ADDING RESPONSE CATEGORY TO QUESTION</b> <ul style="list-style-type: none"> <li>• Added &gt;1,000 beds</li> <li>• Added 501-1,000 beds</li> </ul>
	<b>ADDING NEW QUESTION</b> New Question 16: What agency accredits your institution? (Select all that apply) 8 choices
Question 17: Do any of those members subscribe to (select all that apply)	<b>DELETING THIS QUESTION</b>
Question 18: Does the microbiology laboratory have a doctoral-level clinical scientist or consultant? (Yes or No)	<b>EDITING/ADDING RESPONSE CATEGORY TO QUESTION</b> Does the microbiology laboratory have a doctoral-level (e.g. Ph.D., M.D., D.O., etc) clinical scientist or consultant? Yes, No, Do not know
Question 19: What is their	<b>REFORMATTING AND EDITING/ADDING RESPONSE</b>

	board certification? (Select all that apply.) 10 choices	<p><b>CATEGORY TO QUESTION</b></p> <p>What is their board certification (e.g. ABP, ABMM, HCLD, BCLD, ABB, etc.)? (Select all that apply.) 13 choices total. Choices were added, corrected, and edited.</p>
		<p><b>ADDING NEW QUESTIONS</b></p> <p>New Question 20: Do you provide instructions (written, verbal or computer) to your healthcare providers against sending stools for <i>C. difficile</i> testing if the patient is on laxatives? Yes, No, In the process of making changes based on the ASM-CDC guideline, Do not know</p> <p>New Question 23: Do you reject formed stools for <i>C. difficile</i> testing? Yes, No, In the process of making changes based on the ASM-CDC guideline, Do not know</p> <p>New Question 24: Does your laboratory have a policy to reject repeat stool specimens within seven days for <i>C. difficile</i> testing? Yes, No, In the process of making changes based on the ASM-CDC guideline, Do not know</p> <p>New Question 25: Does your laboratory have a policy to reject stool specimens for <i>C. difficile</i> “test of cure” testing? Yes, No, In the process of making changes based on the ASM-CDC guideline, Do not know</p> <p>New Question 26: Does your laboratory require a patient to have three liquid stools within 24 hours to be acceptable for <i>C. difficile</i> testing? Yes, No, In the process of making changes based on the ASM-CDC guideline, Do not know</p>
	<p>Question Header before Q23: For the following two questions, the abbreviations stand for --</p> <p>NAAT: Nucleic Acid Amplification Test</p> <p>GDH: Glutamate Dehydrogenase</p> <p>EIA: Enzyme Immunoassay</p>	<p><b>REFORMATTING QUESTION HEADER</b></p> <p>For the following two questions, the abbreviations stand for --</p> <p>NAAT: Nucleic Acid Amplification Test (such as PCR, LAMP and other amplification methods)</p> <p>EIA: Enzyme Immunoassay (including lateral flow)</p> <p>GDH: Glutamate Dehydrogenase EIA (including lateral flow)</p> <p>Toxin: Enzyme Immunoassay or lateral flow Assay</p> <p>--&gt; means followed by. i.e.: Test 1 followed by (--&gt;) Test 2 in a defined algorithm</p>
	Question 23: Which of the following is your primary	<p><b>EDITING/ADDING/ RESPONSE CATEGORY TO QUESTIONS</b></p>

testing strategy? 12 choices	13 choices (edited/updated current choices and added 1 new choice)
Question 24: Which of the following is your secondary testing strategy? 13 choices	<b>EDITING/ADDING RESPONSE CATEGORY TO QUESTIONS</b> 14 choices, added, edited, updated choices
Question 26: What is your average turn-around-time for the first result in your algorithm? (Text box)	<b>REFORMATTING QUESTION</b> Question 32: What is your average turn-around-time for the <i>initial</i> result in your algorithm? (Use whole numbers to represent hours from 1 hour to 96.) Changed to sliding scale.
Question 27: What is your average turn-around-time for the second result in your algorithm? (Enter N/A if a second test is not performed.)	<b>REFORMATTING QUESTION</b> Question 33: If you use more than one test in your algorithm, what is your average turn-around-time for the <i>second</i> result in your algorithm? (Enter "0" into the box on the right if a second test is not performed.) Changed to sliding scale.
	<b>ADDING NEW QUESTION</b> New Question 34: If you use more than two tests in your algorithm, what is your average turn-around-time for the <i>third</i> result in your algorithm? (Enter "0" into the box on the right if a third test is not performed.) Changed to sliding scale.  New Question 35: How many stool specimens do you test annually? 7 choices
Question 28: Do you know what percent of your tests are positive? Yes or No	<b>REFORMATTING QUESTION</b> Question 36: Do you know what percentage of your stool specimens are positive for <i>C. difficile</i> ? Yes or No
Question 29: What is the approximate percent? Text Box	<b>REFORMATTING QUESTION</b> Question 37: What percent of your stool specimens are positive for <i>C. difficile</i> ? Changed to sliding scale.
Question 30: Do any of your clients perform fecal transplants? Yes or No	<b>ADDING RESPONSE CATEGORY TO QUESTIONS</b> Added Do not Know as a choice.