

#### **IN THIS ISSUE**

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## Positive C. difficile Reflex to Toxin Assay

### Amy Leber, PhD, Senior Director, Clinical Laboratories, Director, Clinical Microbiology

Clostridioides difficile (formerly Clostridium difficile) is a Gram-positive spore forming organism that is a leading cause of health-care associated diarrhea. It can also cause community-associated diarrhea, a condition more common in children. The number of cases of C. difficile associated disease (CDAD) in children has been increasing, with an estimated 20,000 cases reported each year. Colonization with C difficile is also found in children and adults with organism detectable but not causing disease. It is estimated that upwards of 40% of children less than one year of age are colonized, with levels at 22% in toddlers 1-2 years of age before

Impact of
C. difficile Infection (CDI)
on Children

20 000
Children per year are affected by CDI in the US

75% of CDI cases in children are community-associated

No vaccines are currently available

New therapies are needed

Pediatrics. 2023;152(3). doi:10.1542/peds.2023-062307

declining to 1-3% by greater than 3 years of age, similar to adults.

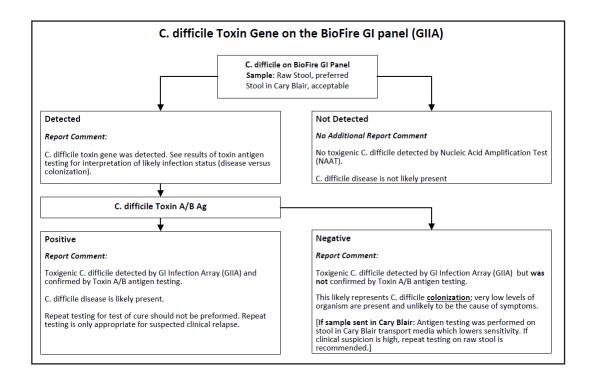
Testing for C *difficile* focuses on detection of toxin A and/or B. The methods have evolved significantly over the years. Cytotoxin

detection, a cell culture-based assay, has been used to test for functional toxin A/B in the stool. This method is labor-intensive, subjective, and lacks sensitivity. Antigen detection tests for toxin were introduced in the 1980s. These tests are faster and less labor intensive. However, there was also concern about low sensitivity. Nucleic acid amplification tests (NAAT) have been developed to detect the toxin genes of C. difficile and have increased sensitivity. However, this increase in sensitivity has led to decreased specificity with detection in cases of colonization. The Infectious Disease Society of American (IDSA) and The Society for Healthcare Epidemiology of America (SHEA) published guidelines recommending using a two-step algorithm for diagnosis of CDAD. This allows better discrimination of those with CDAD versus colonization and prevents overuse of antibiotics. Based on the recommendations above and in cooperation with NCH Infectious Diseases, we have adopted a twostep algorithm for the detection of C. difficile and C. difficile associated disease (CDAD). This algorithm will include a reflex for C. difficile toxin antigen testing on all C. difficile positive stool samples identified by molecular methods. The goal of this algorithm is to increase the specificity for the detection of CDAD versus possible C. difficile colonization. (See chart below)

#### References:

McDonald LC, Gerding DN, Johnson S, Bakken JS, Carroll KC, Coffin SE, Dubberke ER, Garey KW, Gould CV, Kelly C, Loo V, Shaklee Sammons J, Sandora TJ, Wilcox MH. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). Clin Infect Dis. 2018 Mar 19:66(7):e1-e48. doi: 10.1093/cid/cix1085. PMID: 29462280; PMCID: PMC6018983.

Shirley DA, Tornel W, Warren CA, Moonah S. Clostridioides difficile Infection in Children: Recent Updates on Epidemiology, Diagnosis, Therapy. Pediatrics. 2023 Sep 1;152(3):e2023062307. doi: 10.1542/peds.2023-062307. PMID: 37560802; PMCID: PMCI0471512.



#### Blood Drive: Urgent Need For Blood!

The Red Cross critically needs blood donors following a concerning trend over the past month – fewer donors rolling up a sleeve to give lifesaving



blood. In fact, about 20,000 fewer blood donations were collected over the past month than needed to maintain the Red Cross national blood supply.

To schedule an appointment, visit **RedCrossBlood.org/donate** and enter Sponsor Code: ForEveryChild, or call 1-800-RED-CROSS.



#### Spotlight on Client Services:

Kandi has been with NCH for eight years. She began her career with us by working in our offsite laboratories and then became a part of

our COVID response team with our drive up testing sites before transitioning into Client Services. Kandi received her phlebotomy certification while attending Columbus Technical Institute for Medical Assisting and retired from OSU Wexner Medical Center with 32 years of service prior to coming to NCH.

Kandi is a mother to 5 beautiful children has 15 amazing grandchildren and 2 incredibly adorable great-grandchildren. Kandi's hobbies outside of work include spending time with family and friends, hosting cookouts, holiday gatherings, playing board games, dancing, traveling and going to summer yard sales. When Kandi was asked to share advice to our clients, she advised clinicians to take a few extra minutes to ensure that all the pertinent information is filled out correctly on requisitions that you are sending with the patient sample. Having incomplete or wrong information can either delay testing or result in no testing being performed due to samples being delayed as we work to clarify or obtain missing information. Ex: (D.O.B., correct spelling of first and last name, the desired test name, collection time, etc.).



#### **Website Update**

Our Laboratory and Pathology website has received a face lift! The website has been updated with a simpler layout to assist with

finding information about our services. Visit our updated website at www.nationwidechildrens. org/lab.



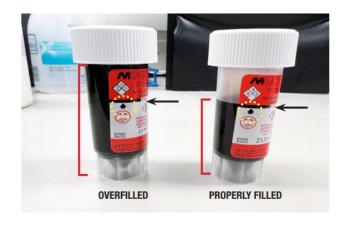
## Warm Weather Reminder

Summer is here and it is important that samples placed in a lockbox prior to transport be maintained at the appropriate temperature. If refrigerated samples are stored in the lockbox, then a refrigerated cold pack should also be placed in the lockbox to maintain the samples at the

appropriate temperature. The cold pack should not be frozen as this can cause whole blood samples to freeze. By following this lockbox practice, you will help insure the integrity of the samples and ultimately obtain reliable laboratory results.

# Total Fix Collection Vials for Ova and Parasite Collection ("O&P")

Recently we have received a number of stool samples submitted for "O&P" testing in Total Fix vials that had been grossly overfilled. The photo below has an over-filled vial (left) and a properly filled vial (right). Note the black line on the vial indicating the fill line. Overfilling the vial may result in the sample not being properly preserved, leading to degradation of the organism and a potential false negative result being reported.



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## How can Nationwide Children's Laboratory Services help your practice?

If you would like to become a client or learn more information about Nationwide Children's Laboratory Services, contact us at (800) 934-6575 or visit our website at NationwideChildrens.org/Lab. Would you like to receive the Nationwide Children's Laboratory Services Newsletter electronically? Please e-mail us at LaboratoryServices@NationwideChildrens.org and let us know!

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When your child needs a hospital, everything matters.