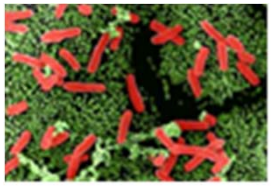
10X Essentials: Infectious Disease Diagnostics in the Geisinger Health System

Clostridium difficile Polymerase Chian Reaction (PCR) Testing FAQ

Clinical and Diagnostic Utility

GEISINGER
MEDICAL LABORATORIES

- **PCR is the preferred method to detect *C. difficile*** and its hypervirulent B1/NAP1 strains. Sensitivity and specificity are above 95%.
- **Do NOT submit multiple specimens for testing.** No improvement to yield (test positive predictive value) is achieved by testing multiple specimens.
- **Traditional testing methods, are of limited use.** Enzyme immunoassay (EIA), Glutamate dehydrogenase (GDH), and cytotoxicity assays (CT) range from 32-84% in sensitivity.
- **Do NOT attempt laboratory test of cure** for *C. difficile* infection (CDI).



C. difficile

Testing Criteria **New test code/name: CDIFP, *C. difficile*/Epi PCR; (old test code/test name: CDIF, *C. difficile* PCR)**

- **Limit testing to patients with risk factors for CDI and significant diarrhea (≥ 3 loose stools/day for ≥ 1 day).**
  - *False positive results can occur when testing patients without significant diarrhea, as the microbe can be present is some people's GI tract without causing disease, especially patients < 1-2 yrs. of age.*
- **Due to the high sensitivity of the PCR assay, we recommend only 1 specimen be tested during each 5 day period.**
  - *For special circumstances, call the Microbiology Laboratory for consultation or to request a policy waiver . When your patient shows signs of ileus in the absence of bowel movements, use clinical judgment for atypical disease presentation and empiric antibiotics as warranted.*

Specimens and Stability

- **Liquid/Unformed stool specimens (feces), minimum ≥ 0.5ml**, collected in a sterile cup or tube without preservatives
- **Transport/Stability: Transport to laboratory at 2-8 C, Stable for 5 days refrigerated at 2-8 C**.
- **Unacceptable:** Formed stool, rectal swabs, or stool preserved in 10% formalin, SAF, or PVA are NOT accepted.

dmw: cdiff
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ALERT: Institute "**Contact Precautions**" for *C. difficile* positive patients
For inpatient positive samples, request an Infectious Disease consult

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Background on hypervirulent *C. difficile* strains

- A rise in the incidence and the virulence of CDI links to the emergence of **hypervirulent strains, (most commonly B1/NAP1/027)**
- NAP1 strains have more **efficient sporulation** and production of **toxins**. The presence of binary toxin genes serve as a presumptive biomarker of this hypervirulent strain.
- NAP1 strains are associated with increased severity, need for surgery, mortality, and higher relapse and dissemination rates.
- An expanded repertoire of antibiotic resistance includes resistance to vancomycin, fidaxomicin, and fluoroquinolones, which offers a competitive advantage for transmission in healthcare settings and may require combination or alternate therapy
- Strains can cause disease in **non-traditional patient populations**, infecting young adults and pregnant women with no prior history of antibiotic use.

Cautions/Limitations to Testing

- The assay is inhibited by zinc oxide paste and Vagisil cream.
- Interpret results in conjunction with other laboratory and clinical data, e.g., radiologic and endoscopic abnormalities
- An assay positive result does not rule out the presence of other pathogens, which are rarely known to cause pseudomembranous colitis and antibiotic-induced diarrhea.
- The toxin A gene is not detected; however, it is becoming increasingly evident that toxin B plays a much more important role in disease than Toxin A. Toxin A positive, B negative strains are exceedingly rare and not yet encountered in the US.
- The *C. difficile* NAP1 strain identification is reported as presumptive because this assay only detects the most common marker. Other hypervirulent strains such as 078/NAP7/BK, which can also carry the binary toxin and are also known to infect patients. The 078 strains will be identified only as *C. difficile* by the PCR, without any NAP designation.

ALERT: Institute ***"Contact Precuations"*** for *C. difficile* positive patients