C. DIFF QUIK CHEK COMPLETE®

Clostridium difficile is present in 13 of every 1000 hospital inpatients.[1] Rapid, accurate, and sensitive methods of screening for C. difficile are necessary to maintain good infection control measures and improve patient outcomes.

Advancements in *C. difficile* Testing

- Guidelines now recommend GDH screening in combination with toxin testing to improve sensitivity.[2] The *C. DIFF QUIK CHEK COMPLETE®* test is the only device that simultaneously detects both GDH antigen and Toxins A & B.
- Algorithm testing provides a more complete diagnostic picture than molecular testing alone. The *C. DIFF QUIK CHEK COMPLETE®* test detects actual antigen and toxins present. Molecular assays indicate if a gene is present, but not if toxins are being produced or causing disease.

Increased Sensitivity with Algorithm Testing

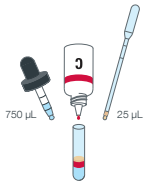
- Sensitivity and Negative Predictive Value (NPV) of GDH are equivalent to PCR when compared to cytotoxicity or toxigenic culture.[3-5]
- **99.8%** NPV gives you confidence that negative results are accurate.[6] Repeat testing is no longer recommended for Positive Ag/Positive Tox & Negative Ag/Negative Tox results.
- Approximately **90%** of samples can be reported in **< 30 min**. using the *C. DIFF QUIK CHEK COMPLETE®* test, improving workflow and effective management of C. difficile infections.[6]

To learn more about cost-effective, sensitive, rapid detection of ***C. difficile,*** contact your local Alere Representative

Easy to Use*

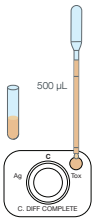
- Total assay time **< 30 min**
- Graduated pipet volumes for **accurate** sampling
- Built-in **quality controls** in every cassette

1 Add:
-750 µL diluent
-1 drop conjugate
-25 µL sample

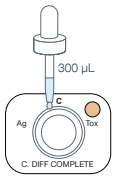


2 Mix & add 500 µL to cassette, incubate 15 minutes

15 min

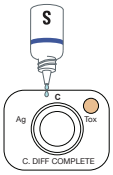


3 Add 300 µL wash buffer



4 Add 2 dropssubstrate, read at 10 minutes

10 min



*For complete instructions for use, see the package insert.

Testing Algorithm

C. difficile Testing Algorithm[2,7]

Both tests **positive** = Positive for toxigenic *C. difficile*

Positive antigen (GDH) and **Negative** toxin

Report as *C. difficile* present but toxin not detected. Testing for inflammation with *LEUKO EZ VUE*® can aid in treatment decisions, as recommended by the American College of Gastroenterology.

Both tests **negative** = Negative for toxigenic *C. difficile*

Clinical Performance Summary

Performance of GDH antigen portion vs. cytotoxicity testing[6]

n =	1126
Sensitivity	98.7%
Negative Predictive Value (NPV)	99.8%

Performance of toxins A & B portion vs. cytotoxicity testing[6]

n =	1126
Sensitivity	87.8%
Specificity	99.4%
Positive Predictive Value (PPV)	95.8%
Negative Predictive Value (NPV)	98.1%
Correlation	97.8%

All data calculated from package insert.

Order Information

C. DIFF QUIK CHEK COMPLETE®

Moderately Complex
25 Test Kit / 50 Test Kit
Catalog No. 23900552 (25 Tests)
Catalog No. 23900551 (50 Tests)
CPT® Codes: 87324 / 87449

Actual reimbursement may vary. Alere cannot guarantee or promise coverage or payment for any particular item or service from any payer or health benefit plan. It is the individual provider's responsibility to determine appropriate coding for a particular service.

1. Association for Professionals in Infection Control and Epidemiology (APIC). 2008. National Prevalence Study of *Clostridium difficile* in U.S. Healthcare Facilities.
2. American Society for Microbiology (ASM). 2010. *A Practical Guidance Document for the Laboratory Detection of Toxigenic Clostridium difficile* http://www.asm.org/images/pdf/Clinical/clostridiumdifficile9-21.pdf
3. Swindells et al. 2010. *J Clinical Microbiology.* 48(2): 606-608.
4. Quinn et al. 2010. *J Clinical Microbiology.* 48(2): 603-605.
5. Sharp et al. 2010. *J Clinical Microbiology.* 48(6): 2082-86.
6. *C. DIFF QUIK CHEK COMPLETE*® Package Insert, 11/2009.
7. Fekety, R. 1997. ACG Guidelines for the Diagnosis and Management of *Clostridium difficile*-Associated Diarrhea and Colitis. *Am J Gastroenterology.* 92(5): 739-750.

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