CLINICIAN

Would actionable *C. difficile* test results in less than 30 minutes improve patient care?

C. difficile infections pose a serious threat and require rapid clinical decisions. The *C. DIFF QUIK CHEK COMPLETE*® test differentiates patients with active infections from colonized carriers by detecting the disease-causing toxins A & B and Glutamate Dehydrogenase (GDH) antigen as a marker of bacteria presence.

Provide therapy and implement infection control measures for those who really need it.

LABORATORY

Would actionable *C. difficile* results in less than 30 minutes improve your operational and cost efficiencies?

Laboratory diagnostics for *C. difficile* are the key for patient care. The *C. DIFF QUIK CHEK COMPLETE*® test combines fast, accurate and actionable results with ease of use.

Report results fast and with confidence. Repeat testing is not necessary.

INFECTION CONTROL

Would actionable *C. difficile* test results in less than 30 minutes help prevent onward transmission and lower infection control costs?

Rapid reaction times to contagious gastrointestinal infections like *C. difficile* heavily rely on rapid and accurate diagnosis. The *C. DIFF QUIK CHEK COMPLETE*® GDH antigen sensitivity and Negative Predictive Value (NPV) are equal to molecular test as shown in numerous studies,[6] and are more cost effective than any other method.[4]

Act faster and prevent onward transmission in a more cost efficient way compared to other methods.

Clinical Performance Summary

Performance of GDH antigen testing vs cytotoxicity testing[7]	
n=	1126
Sensitivity	98.7%
Negative Predictive Value (NPV)	99.8%

Performance of Toxin A/B vs cytotoxicity testing[7]	
n=	1126
Sensitivity	87.8%
Specificity	99.4%
Positive Predictive Value (PPV)	95.8%
Negative Predictive Value (NPV)	98.1%
Correlation	97.8%

1. Polage, C. et al. Overdiagnosis of *Clostridium difficile* Infection in the Molecular Test Era. *JAMA Intern Med.* 2015; 175(11):1792-1801.
2. Dubberke, E.R. et al. Strategies to prevent *Clostridium difficile* infections in acute care hospitals. *Infect. Control Hosp. Epidemiol.* 2008;29(S1): S81-S92.
3. Cohen, S.H et al. Clinical Practice Guidelines for *Clostridium difficile* Infection in Adults: 2010 Update by the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA). *Infect. Control Hosp. Epidemiol.* 2010;31(5).
4. Magill, S. et al. Multistate Point-Prevalence Survey of Health Care-Associated Infections. *N Engl J Med.* 2014; 370(13):1198-1208.
5. ESCMID (2016), Update of the diagnostic guidance document for *Clostridium difficile* infection.
6. Swindells, J., Brenwald, N., Reading, N. and Oppenheim, B. Evaluation of Diagnostic Tests for *Clostridium difficile* Infection. *J Clin Microbiol.* 2010; 48(2):606-608.
7. *C. DIFF QUIK CHEK COMPLETE* Package Insert (US) vH Issued 04/2015.

Ordering Information for TECHLAB® *C. difficile* tests

C. DIFF QUIK CHEK COMPLETE® Detects *C. difficile* GDH and Toxins A & B in fecal samples	T30525C / 30525C / T5038 T30550C / 30550C	25 tests 50 tests
TOX A/B QUIK CHEK® Detects *C. difficile* Toxins A & B in fecal samples	T5033 / 30394	25 tests
C. DIFF CHEK™-60 Detects *C. difficile* GDH in fecal samples	TL5025 / 30392	96 wells
C. DIFFICILE TOX A/B II™ Detects *C. difficile* Toxins A & B in fecal samples	T5015 / 30397	96 wells
C. DIFFICILE TOX B TEST Detects Toxin B in fecal samples	T5003	96 wells (48 tests)

For more information, contact your TECHLAB® Representative

Call +1-540-953-1664 or visit www.techlab.com

Developed and manufactured by

TECHLAB®

PROVEN DIAGNOSTIC PERFORMANCE

TECHLAB®

C. DIFF QUIK CHEK COMPLETE®

Get the complete diagnostic picture with just one test using EIA technology

C. DIFF QUIK CHEK COMPLETE®

Does your current diagnostic method allow you to treat the right patients?

- *C. difficile* toxins cause the disease symptoms. Only a test detecting active toxin production can help determine the course of treatment.
- Colonized *C. difficile* carriers are 5-10 times more common than patients with active infections in hospitals.[1] Treating carriers is often ineffective and increases the risk to the patient of acquiring a pathogenic infection.[2,3]
- Diarrhea is common in hospitals and may lead to a false *C. difficile* diagnosis if a test without toxin confirmation is used.[1,4]
- Even highly sensitive molecular tests are unable to differentiate colonized carriers from patients with active infections.[5]

The *C. DIFF QUIK CHEK COMPLETE®* test provides the complete diagnostic picture unlike any other standalone test. Incoming samples are simultaneously tested for GDH and Toxins A & B as recommended by the updated ESCMID Guidelines,[5] providing actionable *C. difficile* results in less than 30 minutes.

C. DIFF QUIK CHEK COMPLETE®

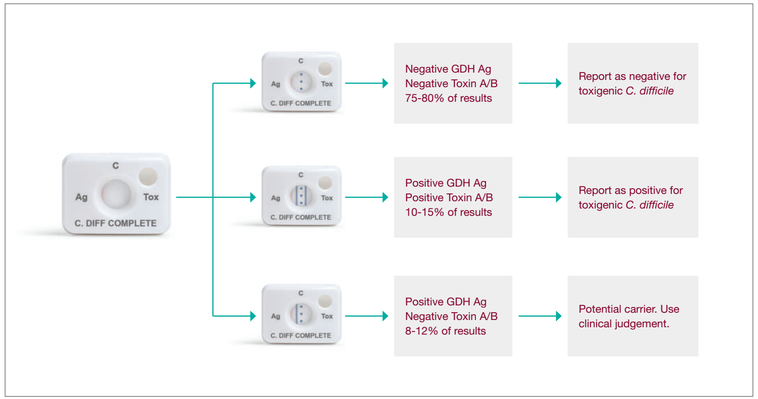
How does *C. DIFF QUIK CHEK COMPLETE®* rapid membrane ELISA technology compare to lateral flow?

QUIK CHEK™ technology is more sensitive and reliable than lateral flow assays as it combines the advantages of a classic ELISA test with the rapid cassette format.

The *C. DIFF QUIK CHEK COMPLETE®* test helps to avoid extensive healthcare costs due to misdiagnosis with a single test that indicates presence of the organism rather than disease.

Updated ESCMID guidelines[5] published in 2016 recommend:

- Against the use of a single rapid test as a standalone test, due to inadequate positive predictive value.
- The use of a 2-step algorithm starting with either GDH EIA or NAAT. Samples with a negative first test result can be reported as negative. Samples with a positive first test result should be tested further with a Toxin A & B EIA.
- Or screen samples simultaneously with both a GDH and toxin A/B EIA with an assay that includes both these targets in one system (*C. DIFF QUIK CHEK COMPLETE®*).

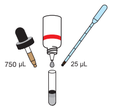


Easy to Use

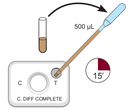
- Total assay time less than 30 minutes.
- Rapid membrane EIA technology including signal amplification and wash-step for enhanced clinical performance.
- Graduated pipet volumes for accurate sampling.
- Built-in quality controls in every cassette.

Assay Protocol

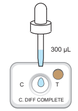
1 Add to a test tube:
- 750 µL *Diluent*
- 1 drop *Conjugate*
- 25 µL (1st graduation) of specimen
- Mix thoroughly



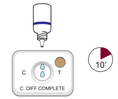
2 Transfer 500 µL (highest graduation) from tube to small *Sample Well*. Keep the cassette at room temperature and wait 15 minutes.



3 Add 300 µL *Wash Buffer* to large *Reaction Window*. Allow to completely absorb.



4 Add 2 drops *Substrate* to large *Reaction Window*. Keep the cassette at room temperature and wait 10 minutes. Read results.



For complete instructions for use,see the package insert.