

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 testing⁷

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

Performance of Toxin A/B vs cytotoxicity testing⁷

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

Ordering Information for TECHLAB[®] *C. difficile* tests

<i>C. DIFF QUIK CHEK COMPLETE</i>[®] Detects <i>C. difficile</i> GDH and Toxins A & B in fecal samples	T30525C / 30525C / T5038 T30550C / 30550C	25 tests 50 tests
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<i>TOX A/B QUIK CHEK</i>[®] Detects <i>C. difficile</i> Toxins A & B in fecal samples	T5033 / 30394	25 tests
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<i>C. DIFF CHEK</i>^{™-60} Detects <i>C. difficile</i> GDH in fecal samples	TL5025 / 30392	96 wells
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<i>C. DIFFICILE TOX A/B II</i>[™] Detects <i>C. difficile</i> Toxins A & B in fecal samples	T5015 / 30397	96 wells
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<i>C. DIFFICILE TOX B TEST</i> Detects Toxin B in fecal samples	T5003	96 wells (48 tests)
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- Polage, C. et al. Overdiagnosis of *Clostridium difficile* Infection in the Molecular Test Era. *JAMA Intern Med.* 2015; 175(11):1792-1801.
- Dubberke, E.R. et al. Strategies to prevent *Clostridium difficile* infections in acute care hospitals. *Infect. Control Hosp. Epidemiol.* 2008;29(S1): S81-S92.
- 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).
- Magill, S. et al. Multistate Point-Prevalence Survey of Health Care-Associated Infections. *N Engl J Med.* 2014; 370(13):1198-1208.
- ESCMID (2016), Update of the diagnostic guidance document for *Clostridium difficile* infection.
- 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.
- C. DIFF QUIK CHEK COMPLETE* Package Insert (US) vH Issued 04/2015.

For more information, contact your **TECHLAB[®]** Representative

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

Developed and manufactured by



PROVEN DIAGNOSTIC PERFORMANCE

TECHLAB[®]

C. DIFF QUIK CHEK COMPLETE[®]

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

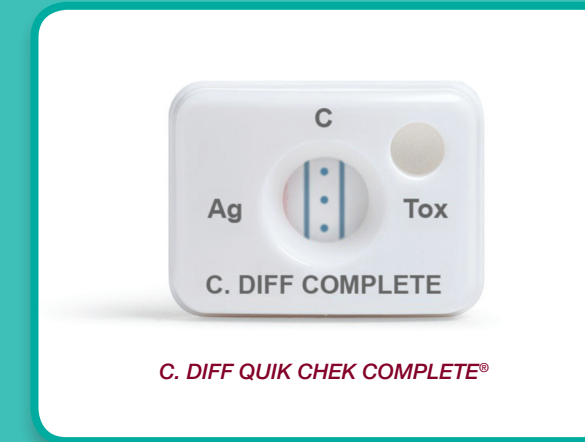


C. DIFF QUIK CHEK COMPLETE[®]

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.



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

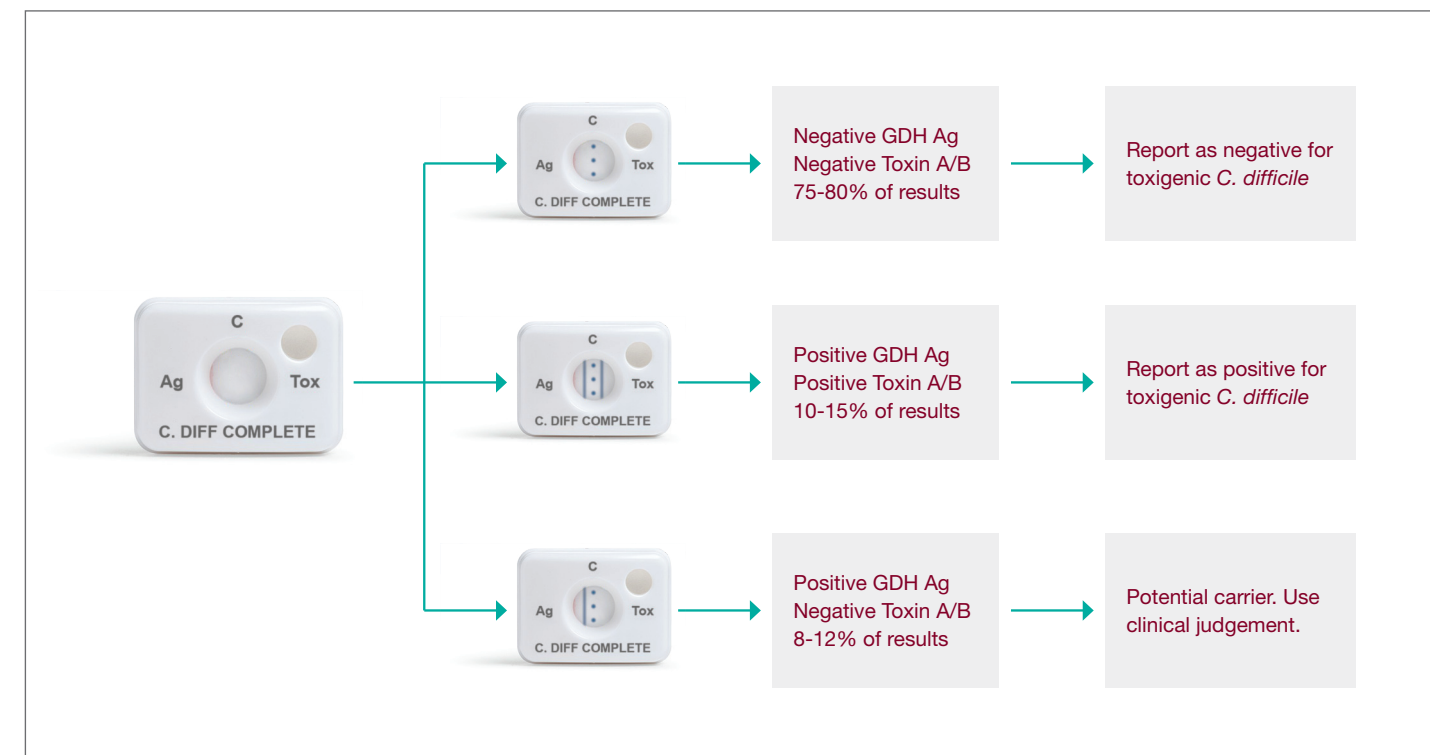
QUIK CHEK[™] technology is more sensitive and reliable than lateral flow assays as it combines the advantages of a classic ELISA test with the rapid cassette format.

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.



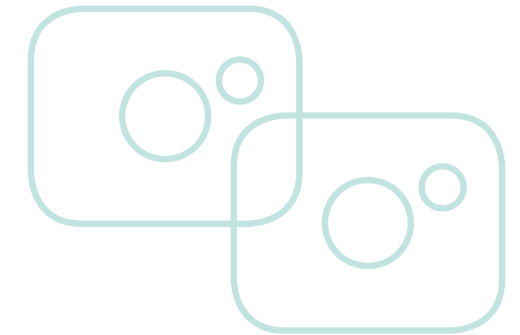
Updated ESCMID guidelines⁵ published in 2016 recommend:

- ▶ 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 μ L Diluent
 - 1 drop Conjugate
 - 25 μ L (1st graduation) of specimen
 - Mix thoroughly
- 2** Transfer 500 μ L (highest graduation) from tube to small Sample Well. Keep the cassette at room temperature and wait 15 minutes.
- 3** Add 300 μ L 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.