



VIDAS[®] *C. difficile* GDH
VIDAS[®] *C. difficile* TOXIN A & B
Automated and cost-efficient testing in one platform



PIONEERING DIAGNOSTICS

VIDAS® *C. difficile* GDH

VIDAS® *C. difficile* TOXIN A & B

HIGH SPECIFICITY AND SENSITIVITY

The VIDAS *C. difficile* GDH and TOXIN A & B (CDAB) are automated tests based on the enzyme-linked fluorescent assay technique (ELFA), for use on the VIDAS family of instruments.

- The VIDAS *C. difficile* GDH (glutamate dehydrogenase) assay is a qualitative test that detects the *C. difficile* antigen, glutamate dehydrogenase, as a screen for the presence of *C. difficile* in stool specimens from persons suspected of having *C. difficile* infection (CDI).
- The VIDAS *C. difficile* TOXIN A & B (CDAB) assay is a qualitative test that detects the *C. difficile* toxin A and toxin B in stool specimens from persons suspected of having *C. difficile* infection (CDI).

VIDAS <i>C. difficile</i> Clinical Performance				
	Sensitivity	Specificity	Negative Predictive Value (NPV)	Positive Predictive Value (PPV)
VIDAS <i>C. difficile</i> GDH ^a	95.6%	90.1%	99.1%	—
VIDAS <i>C. difficile</i> TOXIN A & B ^b	88.3%	99.8%	98.4%	98.1%

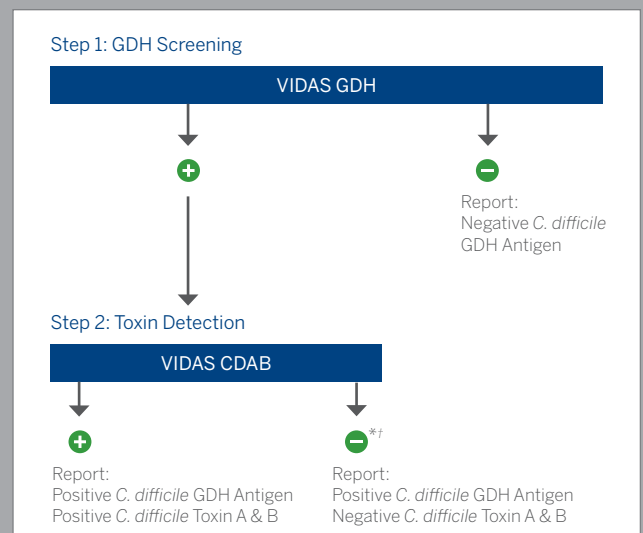
^aCompared to Culture

^bCompared to Cellular Cytotoxicity

Improve *C. difficile* diagnosis with an IDSA & SHEA guidelines recommended process.¹

“GDH testing is the initial screening step in 2- and 3-step algorithms that combine it with a toxin test and/or a molecular test for toxin gene detection. The combination has allowed for rapid results and improved sensitivity compared with toxin EIA testing alone, and can be economical.”

—IDSA & SHEA Clinical Practice Guidelines for *C. difficile* Infection¹



*Positive GDH or molecular results, combined with negative toxin (CDAB) result may indicate possible colonization. Clinical interpretation of test results should be made taking into consideration the patient history and the results of any other tests performed.^{1,3}

† Positive GDH result, combined with negative toxin (CDAB) result may be arbitrated by molecular testing (NAAT).¹



ADVANTAGES

The **ONLY** FDA cleared automated *C. difficile* GDH and TOXIN A & B assays

- Eliminate subjective test result interpretation
- Easy workflow for either individual or batch testing
- Load and go testing with minimal hands-on time
- Automatically store and send results to LIS

Quickly rule out negative patients

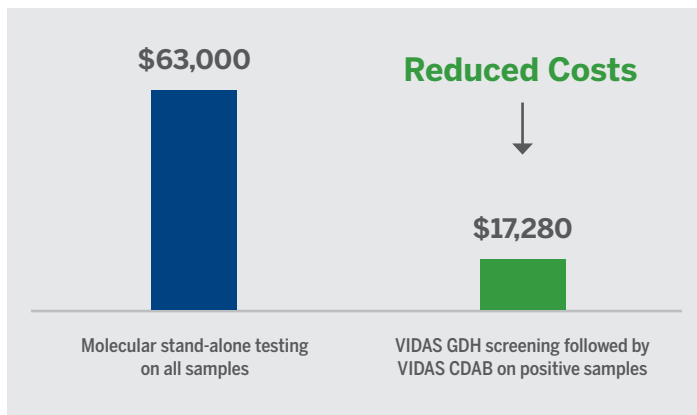
- Screen samples with a high sensitivity and high NPV GDH test¹
- Get GDH test results < 1hr

Avoid overdiagnosis of *C. difficile* infections³

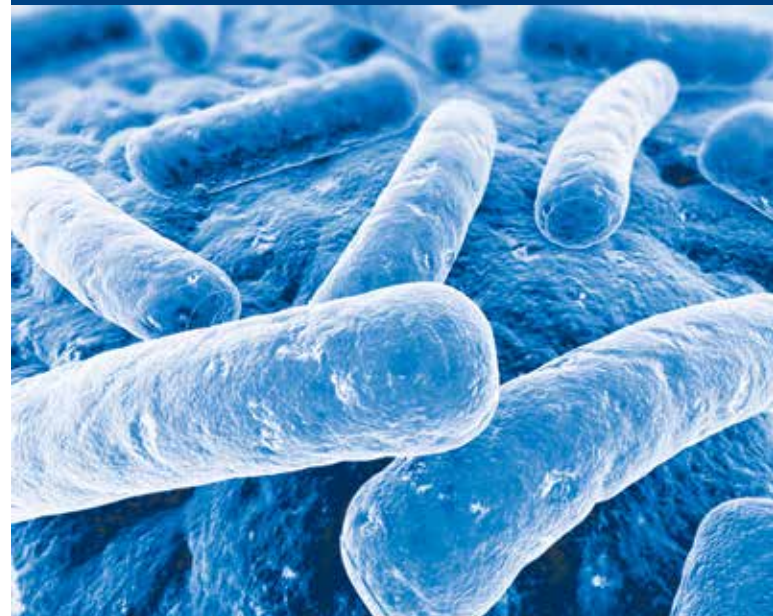
- Use a high PPV toxin test as an aid for diagnosing *C. difficile* associated disease^{2,3}
- Detect both toxigenic *C. difficile* producing toxin A and toxin B with a single toxin test

Cost effective^{1,4}

Potential annual test cost savings by using the two-step process with VIDAS *C. difficile*:



- Based on theoretical data/5 patients a day
- Assumes 80% rule-out with GDH
- Average price molecular assay \$35/test





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TECHNICAL SPECIFICATIONS

	VIDAS® <i>C. difficile</i> GDH	VIDAS® <i>C. difficile</i> TOXIN A & B
Reference	30125-01	30118-01
Tests/kit	60	60
Time to result	Within approximately 50 minutes	Within approximately 75 minutes
Sample type	Fecal specimen	Fecal specimen
Sample volume	200 µL	200 µL
Sample volume after pre-treatment	300 µL	300 µL
Calibration frequency	28 days	14 days
CPT code	87449	87324

See package insert for more details

bioMérieux Complete *C. difficile* Solution:



To place an order, visit

www.biomerieuxDIRECT.com

REFERENCES

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- Ticehurst JR, Aird DZ, Dam LM, Borek AP, Hargrove JT, Carroll KC. Effective detection of toxigenic *Clostridium difficile* by a two-step algorithm including tests for antigen and cytotoxin. *J Clin Microbiol*. 2006;44(3):1145-1149.