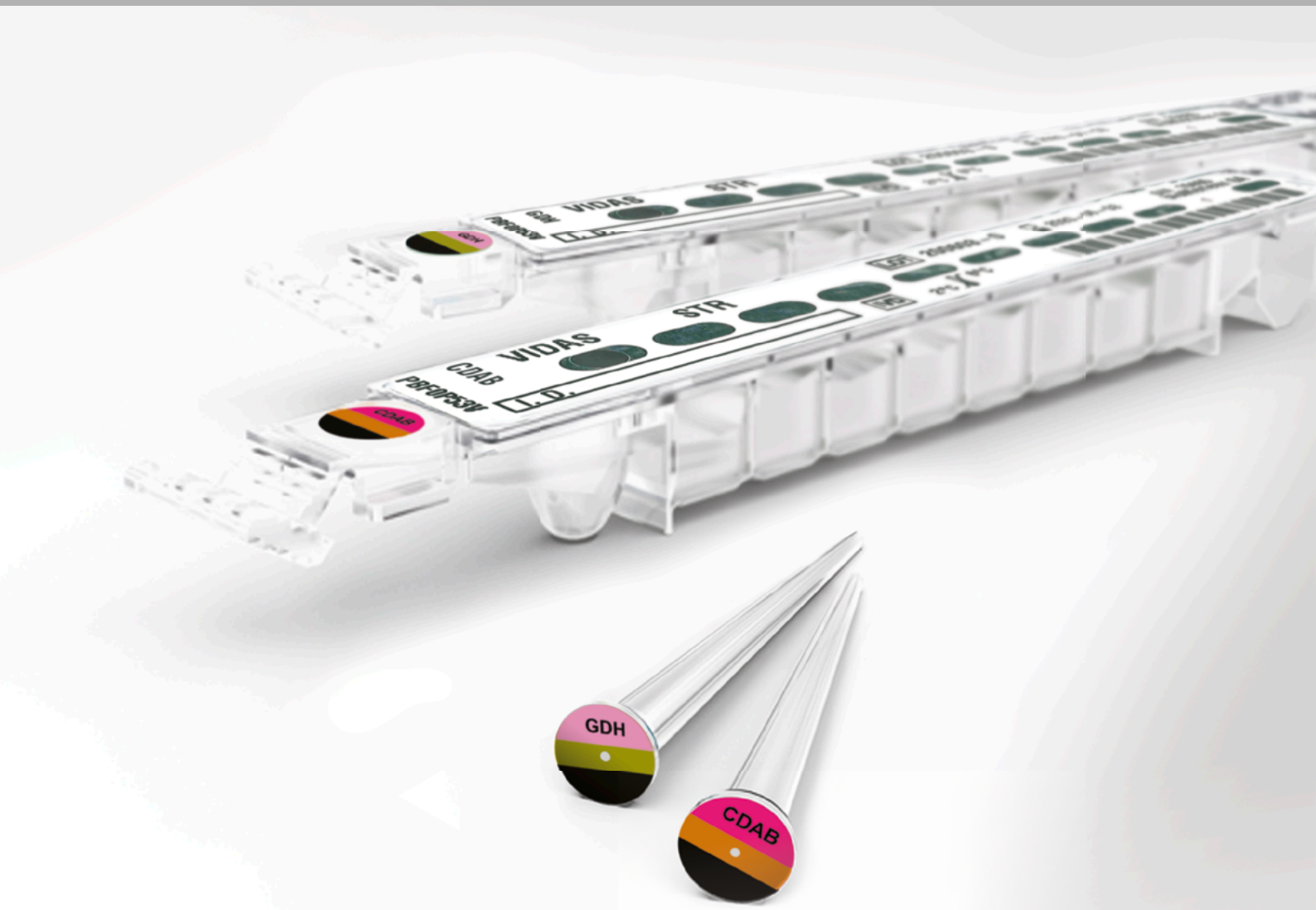
BIOMÉRIEUX

VIDAS® *C. difficile* GDH
VIDAS® *C. difficile* TOXIN A & B

Optimize your antibiotic stewardship approach to *Clostridioides difficile* infection testing



PIONEERING DIAGNOSTICS

Did you know ?

Classed as worldwide threat – between **1/6** and **1/16** patients die by Day 30 after diagnosis of *Clostridioides difficile* infection (CDI)[1,2]

Typical cost per primary CDI episode - **$10,000**/case[3]

46% reduction in CDI cases through an Antimicrobial Stewardship Program[4]

Fighting Antibiotic Resistance: CDI Diagnosis is Key

***C. difficile* causes diarrheal infections and is highly transmissible.**
Preventing transmission and controlling outbreaks as well as giving the appropriate antimicrobial treatment to the patient requires.
Relying on clinical diagnosis alone to make a diagnosis of CDI is not sufficient[5].

"Absence of clinical suspicion and use of sub-optimal laboratory diagnostic methods mean that an estimated 40 000 inpatients with CDI are potentially undiagnosed each year in 482 European hospitals."
Davies *et al,* 2014

Antimicrobial Stewardship Programs can reduce the risk of CDI[6] by implementing:

- **Early, cost-efficient testing that helps avoid over-diagnosis:** 2- or 3-step diagnostic algorithm that includes a fecal toxin text method[7]
- **Optimized antibiotic use:** reduce frequency & duration of infection, limit use of treatments with higher CDI risk, treat according to local epidemiology & strain types[8]
- **Prompt patient isolation & infection control measures**

"Less than 50% of 500 European hospitals were using optimum testing methods for CDI as defined by European guidelines."
Crobach *et al*, 2016

VIDAS® *C. difficile* GDH and VIDAS® *C. difficile* TOXIN A & B

Optimize your Antibiotic Stewardship approach to *Clostridioides difficile* infection testing

VIDAS® *C. difficile* GDH assay:
a qualitative test for the detection of *C. difficile* antigen in stool specimens from patients suspected of having CDI.

VIDAS® *C. difficile* TOXIN A & B assay:
a qualitative test for the detection of *C. difficile* toxin A and toxin B in stool specimens from patients suspected of having CDI.

Both tests can be used on-demand on the VIDAS® family of instruments.

Cost-efficient[10,11]

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

VIDAS® *C. difficile* GDH and VIDAS® *C. difficile* TOXIN A & B

➔ **Greater clinical value for clinicians:** actionable results due to excellent clinical performance

VIDAS *C. difficile* GDH [a] Rapid, accurate screening of *Clostridioides*	VIDAS *C. difficile* TOXIN A & B [b] Provides high PPV of toxin presence for definitive CDI diagnosis
95.8% Sensitivity	**88.3%** Sensitivity
90.0% Specificity	**99.8%** Specificity

[a] Compared to Bacterial Culture CCFA. [b] Compared to Cellular Cytotoxicity Assay.
Source: VIDAS® *C. difficile* GDH and VIDAS® *C. difficile* TOXIN A & B package inserts.

IDSA/SHEA Update for Clinical Practice Guidelines for CDI

Adapted from McDonald et al, *Clin Infect Dis.* 2018;66:987-994

Laboratory testing algorithm chosen based on agreement between the clinician and laboratory to:

1. Not send stool samples on patients receiving laxatives &
2. Only send stool samples of patients with unexplained and new onset diarrhea (≥ 3 unformed stools in 24 hrs)

If YES there is agreement

NAAT alone OR

Stool toxin test* as part of multistep algorithm rather than toxin test alone

	TEST 1	TEST 2	TEST 3
OR	GDH EIA	+ Toxin EIA	
OR	GDH EIA	+ Toxin EIA	+ Arbitrated by NAAT
	NAAT	+ Toxin EIA	

If there is NO agreement

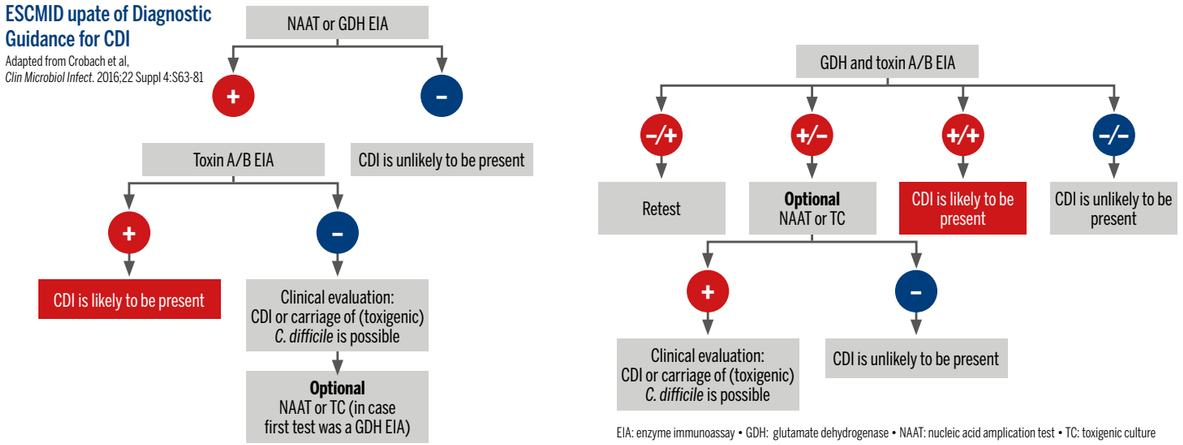
Stool toxin test* as part of multistep algorithm rather than NAAT alone

	TEST 1	TEST 2	TEST 3
OR	GDH EIA	+ Toxin EIA	
OR	GDH EIA	+ Toxin EIA	+ Arbitrated by NAAT
	NAAT	+ Toxin EIA	

* Approved stool EIA toxin tests vary widely in sensitivity. Laboratories should choose a toxin test with sensitivity in the upper range of sensitivity as reported in the literature [146-149, 156].

ESCMID upate of Diagnostic Guidance for CDI

Adapted from Crobach et al, *Clin Microbiol Infect.* 2016;22 Suppl 4:S63-81



EIA: enzyme immunoassay • GDH: glutamate dehydrogenase • NAAT: nucleic acid amplication test • TC: toxigenic culture

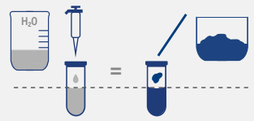
Sample Preparation Quick Guide

Refer to the appropriate VIDAS package insert for the full sample preparation instructions

SEMI-SOLID STOOLS

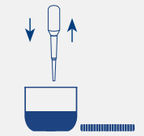
1. Homogenize stool

2. Using a gauge tube with **200µL** of water as a volume reference, transfer **200mg** of stool to a centrifuge tube

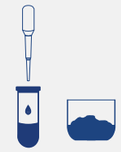


LIQUID STOOLS

1. Homogenize stool



2. Dispense **200µL** of stool to a centrifuge tube



3. Add **1000µL** of **R1** and homogenize

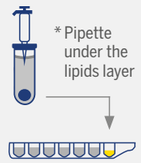
4. Vortex

5. Centrifuge (2-25°C) **10 min** — 3,000g

GDH OR **CDAB**

5. Centrifuge (2-25°C) **5 min** — 12,000g

6. Transfer **300µL of supernatant** to strip

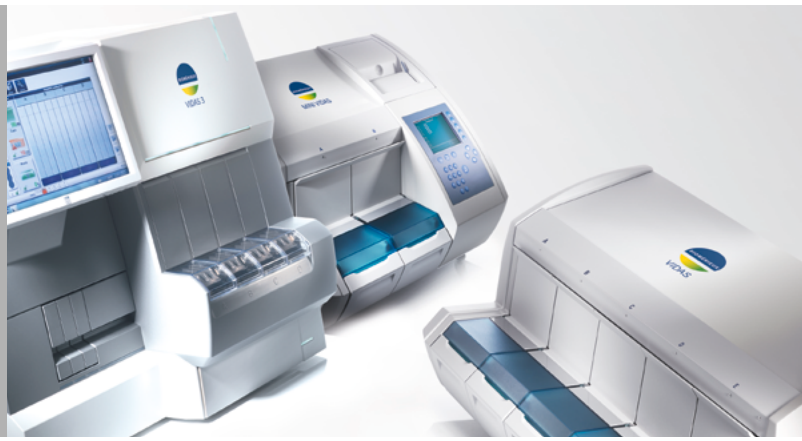


* Pipette under the lipids layer

bioMérieux's complete *C. difficile* solution:

VIDAS® 3 · CHROMID® · VITEK® MS · VITEK® 2 · API® · ETEST® · FILMARRAY®

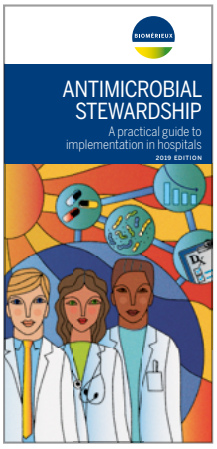
AVAILABLE ON INSTRUMENTS OF THE VIDAS® FAMILY: VIDAS®, MINI VIDAS® AND VIDAS® 3

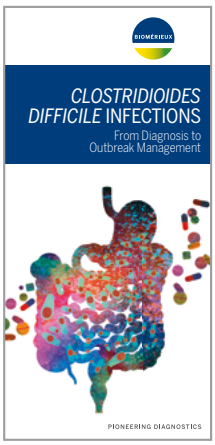


TECHNICAL SPECIFICATIONS

	VIDAS® *C. difficile* GDH	VIDAS® *C. difficile* TOXIN A & B
Reference	30125	30118
Tests/kit	60	60
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

TWO EDUCATIONAL BOOKLETS are available for more information on *Clostridioides difficile* infection and Antimicrobial Stewardship





See package insert for more details

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