

**DIAMONDIAL
GDH RAPID TEST**



DIAMONDIAL
Diagnostic Mondial Laboratories

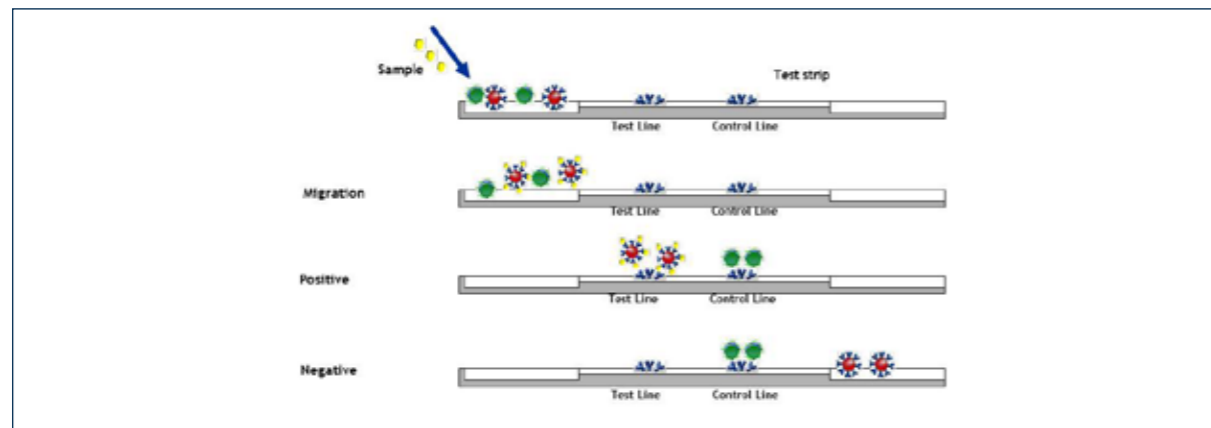


C. DIFFICILE GDH TEST DM-DML6600 C. DIFFICILE AG (GDH) DEVICE

A rapid one step test for the qualitative detection of Clostridium difficile glutamate dehydrogenase antigen in human feces.

- identify GDH in one step
- different colour lines for easy identification results in 10 minutes
- easy to use – no specific equipment required
- rule out false negatives analytic sensitivity GDH 0,8 ng/ml

PRINCIPLE OF THE TEST



TEST PROCEDURE

Step 1
Unseal the cap and use the stick to pick up the sample.

Step 2
Close the tube with the blunt end and shake the tube in order to assure good sample dispersion.

Step 3
Cut the end of the cap and dispense 4 drops or 100µl into the specimen well (S) marked with an arrow.

Step 4
Wait for colored bands to appear. Read the result at 10 minutes.

1. Remove the C. difficile Ag (GDH) Device from its pouch and use it as soon as possible.
2. Shake the specimen collection vial to assure good sample dispersion. Break off the cap of the vial.
3. Use a separate device for each sample. Dispense exactly 4 drops into the specimen well (S). Start the timer.
4. Read the result at 10 minutes after dispensing the sample.

SUMMARY AND EXPLANATION

The C. difficile Ag (GDH) Device test is a rapid chromatographic immunoassay for the qualitative detection of Clostridium difficile glutamate dehydrogenase antigen in human feces specimens to aid in the diagnosis of Clostridium difficile.

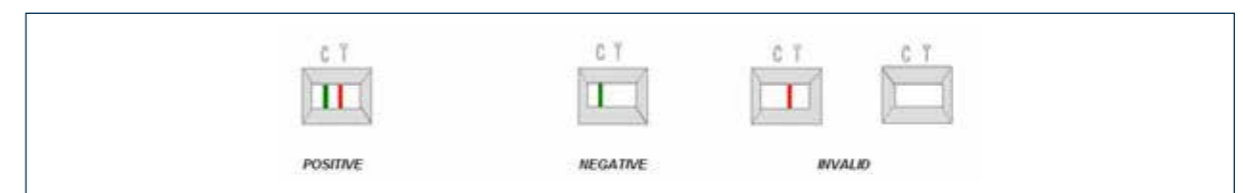
Clostridium difficile Glutamate Dehydrogenase (GDH) is an enzyme produced in large quantities by all toxigenic and non-toxigenic strains of Clostridium difficile, making it an excellent marker for the organism.

The sample reacts with the colored particles coated with anti-GDH antibodies on the test strip. The mixture moves upward on the membrane. The colored particles conjugate migrates.

Positive result:

Red colored line: indicates GDH antigen
Green colored line: control band region

READING RESULTS



(GDH)	INTERPRETATION OF THE RESULTS
+	Two lines appears across the central window in the result line region, a red test line marked with the letter T and in the control line region, a green control line marked with the letter C.
-	Only one green band appears across the central line region marked with the letter C (control line).
Any other result	A total absence of the green control coloured band regardless the appearance or not of the red test line. Note: Insufficient specimen volume, incorrect procedural techniques or procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit and contact your local distributor.
RED/No lines	

CONFIRMATION

The DiaMondial C. difficile Antigen Test device is a screening test with excellent NPV. It is strongly recommended to confirm all positive results, preferably by a NAAT method (PCR).

K. Culbreath et al. J. Clin. Microbiol., September 2012



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