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NADAL® C. difficile Toxin A/B Test (test cassette)

REF 582008

IVD CE

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NADAL® C. difficile Toxin A/B Test (Ref. 582008)

1. Intended Use

The NADAL® C. difficile Toxin A/B Test is a rapid chromatographic immunoassay for the qualitative detection of *C. difficile* Toxin A&B antigens in human stool specimens to aid in the diagnosis of *C. difficile* infection.

2. Introduction and Clinical Significance

Clostridium difficile is an anaerobic, gram-positive, spore-forming bacterium. The key feature that enables it to persist in patients and physical environments for long periods of time and facilitates its transmission is the ability of *C. difficile* to form spores. *C. difficile* is transmitted through the fecal-oral route.

Clostridium difficile is the principal pathogen related to antibiotic associated diarrhea and/or pseudomembranous colitis in hospitalized patients.

Mature colonic bacterial flora in a healthy adult is generally resistant to *C. difficile* colonization. However, if the normal colonic flora is altered, resistance to colonization is lost. Thus, any factor associated with alteration of the normal enteric flora increases the risk of *C. difficile* colonization after exposure to antibiotics, especially those with broad-spectrum activity such as penicillins, cephalosporins and clindamycin.

C. difficile can release two high-molecular-weight toxins, toxin A and toxin B. These are responsible for the clinical manifestations, which range from mild, self-limited watery diarrhea to fulminant pseudomembranous colitis, toxic megacolon, and death.

3. Test Principle

The NADAL® C. difficile Toxin A/B Test is a qualitative immunoassay for the detection of *C. difficile* Toxin A and Toxin B antigens in human stool samples. The membrane is pre-coated with antibodies against Toxin A and antibodies against Toxin B antigens on the corresponding test line regions. During testing, the sample binds to the anti-Toxin A and anti-Toxin B antibodies on the conjugate pad. The mixture moves upward on the membrane by capillary action. In the case of a positive result the specific antibodies present in the test line regions will react with the mixture conjugates and generate one or two coloured test lines. A green coloured line (third line) should always develop in the control line region. It serves as an internal test control and as verification that sufficient volume of specimen has been added and proper membrane wicking has occurred.

4. Reagents and Materials Supplied

- 10 NADAL® C. difficile Toxin A/B test cassettes
- 10 specimen collection vials with buffer
- Package insert

5. Additional Materials Required

- Specimen collection container
- Disposable gloves
- Timer

6. Storage & Stability

Store as packaged in the sealed pouch either refrigerated or at room temperature (2-30°C). The test is stable through to the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze.

7. Warnings and Precautions

- For professional *in-vitro* diagnostic use only.
- Do not use the test beyond the expiration date.
- The test should remain in the sealed pouch until use.
- Do not use the test if the pouch is damaged.
- All operations linked to the use of the test must be performed in accordance with *Good Laboratory Practices* (*GLP*).
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not eat, drink or smoke in the area where the specimens and kit reagents are handled.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test should be discarded in a proper biohazard container after testing.
- The test must be carried out within 2 hours after opening the sealed pouch.

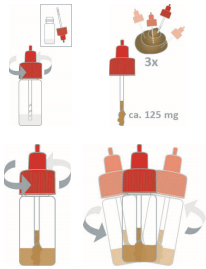
8. Specimen Collection and Preparation

Collect sufficient quantity of feces (1-2 g or 1-2 mL for liquid sample). Stool samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-8°C) for 24-48 hours prior to testing. For longer storage the specimen must be kept frozen at –20°C. In this case, the sample should be completely thawed, and brought to room temperature before testing.

9. Test Procedure

Specimen preparation:

Use a separate specimen collection vial for each sample. Unscrew the cap of the vial and introduce the stick into three different spots of the fecal specimen to collect 125 mg of sample.



Close the vial containing the buffer and stool sample.

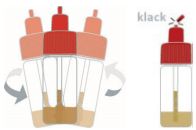
Shake the vial in order to ensure good sample dispersion.

For liquid stool samples, aspirate the fecal specimen with a dropper and add 125 µL into the specimen collection vial with buffer.

Test Procedure

Bring the test cassettes, stool samples and buffer to room temperature (15-30°C) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the NADAL® C. difficile Toxin A/B test cassette from its sealed pouch and use it as soon as possible.
2. Shake the specimen collection vial to ensure good sample dispersion. Break off the tip of the vial.



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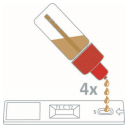
3. Use a separate test cassette for each sample. Dispense 4 drops of the sample into the specimen well (S). Start the timer.
4. Read the result at 10 minutes after dispensing the sample.



10. Result Interpretation

Positive:

Toxin A positive:

In addition to the green line in the control region (C), a red-coloured line will develop in the test region (T1).

Toxin B positive:

In addition to the green line in the control region (C), a red-coloured line will develop in the test region (T2).

Toxin A/B positive:

In addition to the green line in the control region (C), two red-coloured lines develop in the test region (T1) and in test region (T2).

The intensity of the red coloured test lines (T1 and T2) will vary depending on the concentration of antigens in the specimen. However, neither the quantitative value, nor the rate of increase of antigens can be determined by this qualitative test.

Negative:

Only one green line develops in the control region C. No test lines develop.

Invalid:

No line develops in the control region (C). This indicates a possible error in the performance of the test. A new test should be performed.

Note: Insufficient specimen volume, incorrect procedural techniques or reagent deterioration are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit and contact your distributor.

11. Quality Control

An internal procedural control is included in the test:

A green line developing in the control line region (C) confirms sufficient specimen volume and correct procedural technique.

12. Limitations

- The NADAL® C. difficile Toxin A/B Test will only detect the presence of parasites in the stool specimen (qualitative detection) and should be used for the detection of Toxins A and/or B antigens in feces specimens only. Neither the quantity nor the rate of increase in antigen concentration can be determined by this test.
- An excess of sample may cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
- Some stool samples can decrease the intensity of the control bands.
- The test must be carried out within 2 hours after opening the sealed pouch.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of *Clostridium difficile* infection.
- The NADAL® C. difficile Toxin A/B Test provides a presumptive diagnosis of infection caused by *Clostridium difficile*. All results must be interpreted together with other clinical information and laboratory findings available to the physician.

13. Expected values

Clostridium difficile is associated with 95-100% of the cases of pseudomembranous colitis, 60-75% of the cases of antibiotic-associated colitis and 35% of the cases of antibiotic-associated diarrhea.

14. Performance Characteristics

Sensitivity and specificity

Stool samples from patients with diarrhea were studied. The NADAL® C. difficile Toxin A/B Test in comparison with other commercial immunoassay tests showed:

Sensitivity >99%

Specificity >99%

Cross reactivity:

An evaluation was performed to determine the cross reactivity of the NADAL® C. difficile Toxin A/B Test. There is no cross-reactivity with common gastrointestinal microorganisms occasionally present in feces.

Campylobacter spp.	***Helicobacter pylori***	***Salmonella spp.***
***E. coli* O157:H7**	***Shigella spp.***	***Yersinia spp.***
Listeria monocytogenes	***Staphilococcus aureus***	***Yersinia enterolitica***

15. References

1. Wren, M.W.D, et al. "Laboratory diagnosis of *Clostridium difficile* infection. An evaluation of tests for faecal toxin, glutamate dehydrogenase, lactoferrin and toxigenic culture in the diagnostic laboratory". British Journal of Biomedical Science, 66 (1), 2009.
2. Vaishnavi, Ch., "Clinical spectrum & pathogenesis of *Clostridium difficile* associated diseases". Indican J. Med. Res. 131, April 2010, pp 487-499.
3. Poutanen, S. M. et al."*Clostridium difficile*-associated diarrhoea in adults", CMAJ, 171(1) July 2004, pp. 51-58.

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Symbol	Deutsch	English	Français	Español	Italiano	Polski
CE	CE Konformitätszeichen	CE marking of conformity	Conforme aux normes européennes	Conformidad europea	Conformità europea	Znak zgodności CE
	Gebrauchsanweisung beachten	Consult instructions for use	Consulter la notice d'utilisation	Consúltense las instrucciones de uso	Consultare le istruzioni per l'uso	Przestrzegać instrukcji obsługi
IVD	*in-vitro*-Diagnostika	*in-vitro* diagnostic medical device	Dispositif médical de diagnostic *in-vitro*	Producto sanitario para diagnóstico *in-vitro*	Dispositivo medico-diagnostico *in-vitro*	Tylko do diagnostyki *in-vitro*
	Temperaturbegrenzung	Temperature limitation	Limites de température	Límite de temperatura	Limiti di temperatura	Temperatura przechowywania
LOT	Chargenbezeichnung	Batch code	Numéro de lot	Código de lote	Codice lotto	Numer serii
	Nicht zur Wiederverwendung	Do not reuse	Ne pas réutiliser	No reutilizar	Non riutilizzare	Tylko do jednorazowego użytku
	Verwendbar bis	Use by	Utiliser jusqu'au	Fecha de caducidad	Utilizzare entro	Data ważności
REF	Bestellnummer	Catalogue Number	Référence du catalogue	Número de catálogo	Riferimento di Catalogo	Numer katalogowy
	Hersteller	Manufacturer	Fabricant	Fabricante	Fabbricante	Producent
Σ	Ausreichend für <n> Ansätze	Sufficient for <n> tests	Suffisant pour "n" tests	Suficiente para <n> utilizaciones	Sufficiente per "n" saggi	Wystarczający na <n> Powtórzeń

Symbol	Português	Český	Suomi	Svenskt	Nederlands	Dansk	Norsk
CE	Conformidade com as normas europeias	CE certifikát	CE-merkitty	CE-märkning	CE-markering	CE-mærkning	CE standardisert
	Consultar as instruções de utilização	Viz návod k použití	Katso käyttöohjetta	Läs bruksanvisningen	Raadpleeg de gebruiksaanwijzing	Se brugsanvisningen	Les bruksanvisning nøye
IVD	Dispositivo médico para diagnóstico *in-vitro*	Diagnostický zdravotnický prostředek *in-vitro*	*in-vitro* - diagnostiikkaan tarkoitettu lääkinnällinen laite	Medicinteknisk produkt avsedd för *in-vitro*-diagnostik	Medisch hulpmiddel voor in-vitrodiagnostiek	Medicinsk udstyr til *in-vitro*-diagnostik	*in-vitro* diagnostic medisinsk enhet
	Limites de temperatura	Teplotní omezení	Lämpötilarajat	Temperatur-begränsning	Temperatuurlimiet	Temperatur-begrænsning	Temperatur begrensning
LOT	Código do lote	Kód šarže	Eräkoodi	Satsnummer	Code van de partij	Batchkode	Merking
	Não reutilizar	Pro jednorázové použití	Kertakäyttöinen	Får inte återanvändas	Niet opnieuw gebruiken	Må ikke genbruges	Må ikke brukes om igjen
	Prazo de validade	Spotřebujte do	Käytettävä viimeistään	Används före	Houdbaar tot	Udløbsdato	Tidtaking
REF	Número de catálogo	Katalogov éčíslo	Luettelonumero	Listnummer	Catalogus nummer	Best il l ingsnummer	Katalog nummer
	Fabricante	Výrobce	Valmistaja	Tillverkare	Fabrikant	Fabrikant	Produsent
Σ	Suficiente para <n> test	Dostačuje pro <n> testů	Lukumäärä <n> test	Räcker till <n> test	Voldoende voor <n> test	Tilstrækkeligt til <n> test	Tilstrekkelig for<n> tester

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