

dedicio®

Cryptosporidium Test (test cassette)

#511006D-10



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1. Intended Use

The dedicio® Cryptosporidium Test is a rapid chromatographic immunoassay for the qualitative detection of *Cryptosporidium parvum* antigens in human faecal specimens. The test is intended for use as an aid in the diagnosis of cryptosporidiosis and is designed for professional use only.

2. Introduction and Clinical Significance

Cryptosporidiosis is a diarrhoeal disease caused by microscopic parasites of the genus *Cryptosporidium*. Once an animal or a person is infected, the parasite lives in the intestine and passes into the stool. The parasite is protected by an outer shell that allows it to survive outside the human body for long periods of time and makes it very resistant to chlorine-based disinfectants. Both the disease and the parasite are commonly known as "Crypto."

3. Test Principle

The dedicio® Cryptosporidium Test is a qualitative lateral flow immunoassay for the detection of *Cryptosporidium parvum* antigens in human faecal samples. Monoclonal antibodies against *Cryptosporidium parvum* antigens are pre-coated in the test line region of the membrane. During testing, the sample reacts with other anti-*Cryptosporidium* antibodies coated onto coloured particles which were pre-dried on the internal test strip. The mixture migrates along the membrane by capillary action. In the case of a positive result, specific antibodies present on the membrane react with the mixture conjugate and generate a coloured line.

A green line should always appear in the control line region (C) and serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

4. Reagents and Materials Supplied

- 10 dedicio® Cryptosporidium test cassettes
- 10 specimen collection tubes with buffer
- 1 package insert

5. Additional Materials Required

- Specimen collection container
- Pipette (for liquid stool samples)
- Disposable gloves
- Timer

6. Storage & Stability

Store the test as packaged in the sealed foil pouch at 2-30°C. The test is stable until the expiration date printed on the foil pouch. The test cassette should remain in the sealed foil pouch until use.

Do not freeze tests.

7. Warnings and Precautions

- For professional *in-vitro* diagnostic use only.
- Carefully read through the test procedure prior to testing.
- Do not use the test beyond the expiration date indicated on the package.
- Do not use the test if the foil pouch is damaged.
- Do not reuse tests.
- Do not add samples to the reaction area (result area).

- In order to avoid contamination, do not touch the reaction area (result area).
- Avoid cross-contamination of specimens by using a new specimen collection tube for each specimen obtained.
- Do not substitute or mix components from different test kits.
- Do not eat, drink or smoke in the area where specimens and test kits are handled.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being assayed.
- Handle all specimens as if they contain infectious agents. Observe established precautions for microbiological risks throughout all procedures and standard guidelines for the appropriate disposal of specimens.
- The test kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled in accordance with usual safety precautions (e.g., do not ingest or inhale).
- Humidity and temperature can adversely affect test results.
- Used testing materials should be discarded according to local regulations.

8. Specimen Collection and Preparation

Specimen Collection and Storage:

A sufficient quantity of feces should be collected (1-2 g or 1-2 mL for liquid sample). Stool samples should be collected without preservatives or transport media in clean and dry containers. Samples can be stored in the refrigerator (2-8°C) for up to 1-2 days prior to testing. For longer storage (maximum 1 year) 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. Repeated freezing and thawing cycles are not recommended.

Specimen preparation:

Use a separate specimen collection tube with buffer for each sample. Unscrew the cap of the tube and insert the applicator stick into the faecal specimen four times to collect approx. 125 mg of the sample.

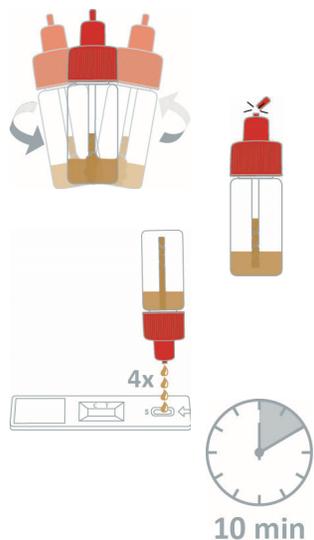
Close the tube with the buffer and stool sample. Shake the tube to ensure good sample dispersion. For liquid stool samples, collect the faecal specimen with a pipette and add 125 µL to the specimen collection tube with buffer.



9. Test Procedure

Bring the tests and samples with buffer to room temperature (15-30°C) prior to testing. Do not open foil pouches until you are ready to perform the assay. Use a separate test cassette for each sample.

1. Remove the dedicio® Cryptosporidium test cassette from the sealed foil pouch and use it as soon as possible.
2. Shake the specimen collection tube to ensure good sample dispersion. Break off the tip of the tube.
3. Dispense exactly 4 drops into the specimen well (S) of the test cassette. Start the timer.
4. Read the result at exactly 10 minutes after dispensing the sample.



10. Result Interpretation

Positive:

Two lines appear in the result window. A green line appears in the control line region (C) and a red line appears in the test line region (T).



Negative:

Only one green line appears in the control line region (C).



Invalid:

If no green control line (C) develops, the assay is invalid, regardless of the presence or absence of the red test line.



Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for the control line failure. In this case, review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit and contact your distributor.

Note:

The colour intensity of the red line in the test line region (T) may vary depending on the concentration of antigens in the specimen. However, neither the quantitative value nor the rate of increase in antigens can be determined with this qualitative test.

11. Quality Control

An internal procedural control is included in the test cassette: A green line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Good laboratory practice (GLP) recommends the use of control materials to ensure proper test kit performance.

12. Limitations

- The dedicio® Cryptosporidium Test only indicates the presence of *Cryptosporidium parvum* antigens in the

specimen (qualitative detection) and should be used for the detection of *Cryptosporidium parvum* antigens in faecal specimens only. Neither the quantitative value nor the rate of increase in antigen concentration can be determined with this test.

- An excess of sample may cause an inaccurate result (brown lines appear). Dilute the sample with buffer and repeat the test.
- Do not use specimens treated with solutions containing formaldehyde or its derivatives.
- If the test result is negative but clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of cryptosporidiosis.
- After one week of infection, the number of parasites in faeces decreases, making the sample less reactive. Stool samples should be collected within one week of the onset of symptoms.
- The test provides a presumptive diagnosis of cryptosporidiosis. All results should be interpreted together with other clinical information and laboratory findings available to the physician.

13. Expected Values

Cryptosporidium has caused several large waterborne disease outbreaks of gastrointestinal illness with symptoms that include diarrhea, nausea and/or stomach cramps. Those with severely weakened immune systems (that is, severely immunocompromised) are likely to have more severe and more persistent symptoms than healthy individuals.

14. Performance Characteristics

Sensitivity and specificity

Stool samples from patients in a local hospital in Spain were tested using the dedicio® Cryptosporidium Test and determined by microscopy techniques.

The following results were obtained using the dedicio® Cryptosporidium Test:

Sensitivity >99% and specificity >99%

Cross-reactivity

An evaluation was performed to determine the cross-reactivity of the dedicio® Cryptosporidium Test. There was no cross-reactivity found with common gastrointestinal microorganisms occasionally present in faeces:

<i>Campylobacter</i>	<i>Giardia lamblia</i>	<i>Shigella</i>
<i>Clostridium difficile</i>	<i>H. pylori</i>	<i>Staphylococcus aureus</i>
<i>E. coli O157:H7</i>	<i>Listeria</i>	
<i>Entamoeba histolytica</i>	<i>Salmonella</i>	

15. References

1. Hill DR, Nash TE. Intestinal Flagellate and Ciliate Infections. In: Guerrant RL, Walker DH, Weller PF, eds. Tropical Infectious Diseases. Principles, Pathogens & Practice. 2nd ed. Elsevier, Philadelphia. 2006:984-8.
2. Copue S, Delabre K, Pouillot R et al. Detection of *Cryptosporidium*, *Giardia* and *Enterocytozoon bienersi* in surface water, including recreational areas: a one year prospective study. FEMS Immunol Med Microbiol. 2006; 47:351-9.

Symbol	Deutsch	English	Français	Español	Italiano	Polski
	CE Konformitätszeichen	CE marking of conformity	Conformité 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
	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
	Chargenbezeichnung	Batch code	Code du 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
	Bestellnummer	Catalogue Number	Référence du catalogue	Número de catálogo	Riferimento di Catalogo	Numer katalogowy
	Hersteller	Manufacturer	Fabricant	Fabricante	Fabbricante	Producent
	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
	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
	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 begrænsning
	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	Spotřebujete do	Käytettävä viimeistään	Används före	Houdbaar tot	Udløbsdato	Tidtaking
	Número de catálogo	Katalogov číslo	Luettelonumero	Listnummer	Catalogus nummer	Bestilingsnummer	Katalog nummer
	Fabricante	Výrobce	Valmistaja	Tillverkare	Fabrikant	Fabrikant	Produsent
	Suficiente para <n> test	Dostačuje pro <n> testů	Lukumäärä <n> test	Räcker till <n> test	Voldoende voor <n> test	Tilstrækkeligt til <n> test	Tilstrækkelig for<n> tester



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