Key Code TSMX7589B

www.oxoid.com/ifu

Europe +800 135 79 135 US 1 855 2360 190

CA 1 855 805 8539 ROW +31 20 794 7071

ProSpecT Giardia/ Cryptosporidium Microplate Assay

REF R2458496 .....96 Tests **EN**

1. INTENDED USE

ProSpecT™ Giardia/Cryptosporidium Microplate Assay is a qualitative enzyme immunoassay (EIA) used to screen for the presence of *Giardia* and *Cryptosporidium* Specific Antigens (GSA 65 and CSA) in aqueous extracts of faecal specimens.

2. SUMMARY

Giardia lamblia is the most frequently identified protozoan parasite in stool specimens submitted to U.S. public health laboratories[6]. The parasite has been implicated in a number of epidemics[8,9] and endemicity in the U.S. is well-recognized. Prevalence in adults is estimated at 4-7%[18]. Higher prevalence rates have been reported in children[1,26] and in homosexual males[14,16]. Acute symptoms of giardiasis may include diarrhoea, malabsorption, abdominal cramps, anorexia, nausea, weight loss, flatulence, anaemia, and general weakness lasting from several weeks to several months[28]. Chronic infections can also occur with or without an acute phase, are often associated with treatment failure, and may result in recurrent symptoms. Infection with *Giardia* may also be asymptomatic[5].

Cryptosporidiosis has recently been recognized as an important human disease in most areas of the world[11,15]. The causative agent, *Cryptosporidium* spp., has been identified in stool specimens of children and adults in many countries and most states in the United States[11]. The parasite has been implicated in severe disease in HIV-infected persons[17], day-care centres[2,3,24,25] and water-borne outbreaks[10,12,13] in the U.S. Groups at particular risk include immuno-compromised persons, especially those with HIV infection, family members and sexual partners of infected patients, children and caretakers in child day care centres, animal handlers and travellers[11]. Acute symptoms of cryptosporidiosis may include diarrhoea, abdominal pain, nausea and vomiting, fever, malaise, and respiratory problems lasting from several days to more than a month and often leading to persistent infection or death in immunologically deficient patients[11]. Infection with *Cryptosporidium* may also be asymptomatic.

Giardia (GSA 65) and *Cryptosporidium* (CSA) Specific Antigens are produced by the organisms as they multiply within the host intestinal tract. GSA 65 is a 65,000 molecular weight glycoprotein. GSA 65 and CSA are present only when infection is present and it is possible to find GSA 65 in stool specimens without visible signs of cysts or trophozoites[19,20,21] or CSA without the visible presence of oocysts[4,7,27]. The antigens are stable to transport through the host intestinal tract as well as to most routine procedures used to collect and transport stool specimens for microscopic examination[1,21,22,23]. Anti-GSA 65[1,20] and anti-CSA antibodies have not been found to cross react with other enteric parasites.

3. PRINCIPLE OF THE TEST

ProSpecT Giardia/Cryptosporidium Microplate assay is a solid phase immunoassay for the simultaneous detection of GSA 65 and CSA. Diluted stool specimens are added to break-away microplate wells on which anti-GSA 65 and anti-CSA antibody is bound. If either GSA 65 or CSA, or both, is present the antigens are 'captured' by the bound antibodies. The wells are incubated and then washed to remove unbound material. The enzyme conjugate (monoclonal anti-GSA 65 and polyclonal anti-CSA antibody labelled with horseradish peroxidase enzyme) is added. The wells are incubated and then washed to remove unbound enzyme conjugate. In a positive reaction, the GSA 65, CSA or both binds the enzyme conjugate to the well. The substrate for the enzyme, 3,3',5,5'-tetramethylbenzidine (TMB), is added. In a positive reaction, the enzyme bound to the well by GSA 65, CSA or both converts the substrate to a coloured reaction product. Colour development can be detected visually or spectrophotometrically. In a negative reaction, there is either no GSA 65 or CSA or an insufficient level of antigen present to bind the enzyme conjugate and no coloured reaction product develops.

4. SYMBOL DEFINITIONS

REF	Catalogue Number
IVD	In Vitro Diagnostic Medical Device
Σ	Contains sufficient for <n> tests
	Consult Instructions for Use (IFU)
8°C 2°C	Temperature Limitation (Storage Temp.)
LOT	Batch Code (Lot Number)
	Use By (Expiration Date)
	Manufacturer
DILUTED SAMPLE	Diluted Sample

5. KIT CONTENTS, PREPARATION FOR USE AND STORAGE

The ProSpecT Giardia/Cryptosporidium Microplate Assay includes sufficient reagents to perform Σ 96 tests.

See also **Precautions,** section **6**.

The expiration date of each kit is stated on the package label.

Store all components at 2 to 8°C.

Before use, bring all reagents to room temperature (20 - 25°C) and mix gently. Return the unused reagents to the refrigerator after use.

All reagents, except the Wash Buffer, are supplied at working strength. Reagents can be dispensed directly from the dropper bottles or poured out for use with multichannel pipettes. If excess reagent has been poured, the excess should be discarded. Do not pour excess reagent back into the bottle.

Instructions for Use
Transfer pipettes
Microplate Strip Holder and Cover
Procedure Card

MICROTITRATION PLATE

Microplate* (8 wells / strip)

12 strips coated with rabbit anti-GSA 65 and anti-CSA antibody. Unused microplate strips should be stored in the foil pouch containing desiccant to exclude moisture.

CONJUGATE

Enzyme Conjugate*

One dropper bottle containing 25 ml of horse-radish peroxidase labelled mouse monoclonal anti-GSA 65 and rabbit anti-CSA with antimicrobial agents.

CONTROL +

***Giardia* Positive Control**

One dropper bottle containing 4 ml of a buffered solution with inactivated Giardia antigen, and antimicrobial agents.

CONTROL +

***Cryptosporidium* Positive Control**

One dropper bottle containing 4 ml of *Cryptosporidium* Oocyst extract in a buffered solution with antimicrobial agents.

CONTROL −

Negative Control

One dropper bottle containing 4 ml of a buffered solution with a red dye, and antimicrobial agents

SAMPLE DILUENT

Specimen Dilution Buffer

One bottle 120 ml of a buffered solution with rabbit serum, a red dye and antimicrobial agents. Also available seperately as code R247061.

WASH BUFFER (x10)

Wash Buffer

One bottle 120 ml of a (x10) concentrated buffered solution with antimicrobial agents. Dilute (x10) Wash Buffer concentrate to (x1) by adding 1 part concentrate to 9 parts distilled or deionised water. Diluted Wash Buffer is stable for 1 month when stored at 2 - 8°C.

SUBSTRATE TMB

Colour Substrate

One dropper bottle containing 25 ml of 3,3',5,5'-tetramethylbenzidine (TMB) in buffer.
The Colour Substrate should be stored in and used from the light protected bottle in which it is provided. If an aliquot is removed from the original bottle for any reason, do not return unused Colour Substrate to the original bottle.

STOP SOLUTION

Stop Solution

One dropper bottle containing 12 ml of 0.46 mol/l Sulphuric acid.

***Note:** Do not interchange reagents between kits with different lot numbers.

6. PRECAUTIONS

IVD

The reagents are for *in vitro* diagnostic use only.

For professional use only.
Please refer to the Safety Data Sheet (SDS) and product labelling for information on potentially hazardous components.

HEALTH AND SAFETY INFORMATION

6.1. Reagents are prepared from biological materials and should be handled as potentially infectious material. Discard using appropriate biohazard procedures.

6.2. Do not pipette by mouth. Wear disposable gloves and eye protection while handling specimens and performing the assay. Wash hands thoroughly when finished.

6.3. Specimens may contain potentially infectious agents and should be handled at Biosafety Level 2 as recommended in the CDC/NIH manual, "Biosafety in Microbiological and Biomedical Laboratories", 5th Edition.

6.4. Wash Buffer contains potential skin sensitiser (< 1% v/v). Avoid skin contact. Wear disposable Vinyl or Nitrile gloves.

6.5. Discard used Wash Buffer in appropriate biohazard containers.

ANALYTICAL PRECAUTIONS

6.6. Carefully read and follow all instructions in this Instruction for Use.

6.7. Reagents are provided at the necessary working strength, with the exception of the Wash Buffer concentrate. Do not dilute reagents, except where instructed.

6.8. Do not use reagents beyond the expiration dates. Expiration dates are printed on each reagent label. Use of reagents beyond the expiration date may affect the accuracy of results.

6.9. The following common reagents may be used across the ProSpecT product range: Wash Buffer, Colour Substrate and Stop Solution.

6.10. Microbial contamination of reagents may decrease the accuracy of the assay. Avoid microbial contamination of reagents by using sterile disposable pipettes when removing aliquots from reagent bottles.

6.11. Allow all reagents and specimens to reach room temperature (20 - 25°C) before use.

6.12. Microplate strips must be stored in the resealable foil pouch, with desiccant, to protect microplate wells from moisture.

6.13. Stool samples must be thoroughly mixed prior to specimen processing to ensure accurate representation of the specimen. DO NOT CONCENTRATE SPECIMENS BEFORE TESTING.

6.14. Colour Substrate is sensitive to light exposure. If the reagent is exposed to light and develops colour, the reagent must be discarded.

6.15. Persons who are colour blind or visually impaired may not be able to read the test visually and should use spectrophotometric readings to interpret results.

6.16. Add reagents to the test wells in the same order throughout the procedure. To avoid contamination do not touch the fluid in the wells with the bottle tips.

6.17. Time each incubation accurately. Start timing after adding reagent to the last well on each microplate being tested. To ensure accurate timing, process no more than three 96 well plates at one time. Deviation from the established procedure may alter the performance of the assay.

6.18. It is important to hold the dropper bottles vertically and that the drop forms at the tip of the nozzle. If the nozzle becomes wet, a drop of incorrect volume will form around the end and not at the tip; if this occurs dry the nozzle before progressing.

7. COLLECTION OF FAECAL SPECIMENS

Specimens collected for routine microscopic examination can be used for the ProSpecT Giardia/Cryptosporidium Microplate Assay.

FRESH Unpreserved stool specimens should be collected in clean, leak-proof plastic containers, stored at 2 - 8°C and tested within 48 hours.

FROZEN If unpreserved specimens cannot be tested within 48 hours, they should be frozen at -20 to -70°C.

PRESERVED Stool specimens collected in 10% formalin, MF or SAF fixatives may be refrigerated (2 - 8°C) or stored at room temperature (20 - 25°C) and should be tested within 2 months after collection.

CARY BLAIR Stool specimens collected in Cary Blair Transport Medium (or equivalent) should be refrigerated or frozen and tested within 1 week. Stool specimens that have been concentrated or treated with PVA fixatives are not suitable for use.

SWAB/DIAPER Stool specimens obtained from rectal swabs and diapers are acceptable. Please note the use of super absorbent diapers is not acceptable.

8. TEST PROCEDURE

REQUIRED MATERIALS PROVIDED

See **Kit Contents**, section **5**

MATERIALS REQUIRED BUT NOT PROVIDED

Stool specimen collection containers
Timer that measures minutes
Wash bottle for Wash Buffer
Distilled or deionised water

OPTIONAL MATERIALS NOT PROVIDED

Microplate reader capable of reading 450 nm or 450/620 to 650 nm
Cotton or rayon tipped applicator sticks
Micropipette to deliver volumes to 200 µl
Plastic or glass disposable test tubes
Vortex mixer with plate adapter or shaker

PROCEDURE

8.1. **Specimen Preparation for Assay**
Unpreserved specimens Prepare dilutions in tubes using 0.4 ml Specimen Dilution Buffer and one swab of specimen. Thoroughly coat the swab and rotate in the Specimen Dilution Buffer, express as much fluid as possible and discard the swab. Place a transfer pipette in each tube.

Preserved Specimens/Specimens in Transport Media Mix contents thoroughly by shaking the containers. No other preparation is necessary.

8.2. Open the foil pouch, remove the required number of microplate strips and place into a microplate strip holder. Use one well for the Negative Control and one well for each of the two Positive Controls. If using less than 8 wells, break off the required number of wells from a strip and return the unused wells to the foil pouch with desiccant. RESEAL POUCH TIGHTLY TO EXCLUDE MOISTURE AND RETURN TO THE REFRIGERATOR.

8.3. Add **4 drops** (200 µl) Negative Control to well A1. Add **4 drops** (200 µl) *Giardia* Positive Control to well B1 and **4 drops** (200 µl) *Cryptosporidium* Positive Control to well C1 taking care not to contaminate surrounding wells.

8.4. Using a transfer pipette add **2 drops** (100 µl) of Specimen Dilution Buffer (SDB) into each of the patient test wells. Do not add SDB to the control wells.

8.5. Mix preserved specimens or specimens in transport media by vigorously shaking the containers. Using a transfer pipette add **2 drops** of specimen to the 100 µl SDB in the wells. For unpreserved specimens add **2 drops** pre-diluted specimen (see **Specimen Preparation** 8.1 above) to 100 µl SDB in the well.

8.6. **Cover** microplate and incubate at room temperature (20 - 25°C) for **60 minute**s. Begin timing after the addition of the last specimen.

8.7. Shake out or aspirate the contents of the wells. Wash by completely filling each well with **diluted** Wash Buffer (~350-400 µl/well). Shake out or aspirate all fluid from the wells after each wash. Wash a total of **3 times**. After the last wash remove contents and strike plate on clean paper towels or aspirate. Remove as much Wash Buffer as possible but do not allow the wells to dry out at any time.

8.8. Add **4 drops** (200 µl) of Enzyme Conjugate to each well.

8.9. **Cover** microplate and incubate at room temperature (20 - 25°C) for **30 minutes**.

8.10. Shake out or aspirate and wash each well **5 times** as in step 8.7

8.11. Add **4 drops** (200 µl) of Colour Substrate to each well.

8.12. **Cover** microplate and incubate at room temperature (20 - 25°C) for **10 minutes**.

8.13. Add **1 drop** (50 µl) Stop Solution to each well. Gently tap or vortex the wells until the yellow colour is uniform. Read reactions within **10 minutes** after adding the Stop Solution.

8.14. Read visually or spectrophotometrically at 450 nm (single wavelength) or 450/620 to 650 nm (dual wavelength).

9. QUALITY CONTROL

Positive and Negative Controls must be included each time the test is performed. The Positive and Negative Controls serve as both reagent and procedural controls. The controls are intended to monitor for substantial reagent failure. The Positive Control will not ensure precision at the assay cut-off.

The optical density (O.D.) of the Negative Control should be ≤ 0.100 at 450 nm or < 0.070 at 450/620 to 650 nm. The Negative Control should be colourless when read visually. If yellow colour equal to 1+ or greater on the Procedure Card is present in the Negative Control, the test should be repeated with careful attention to the wash procedure.

The O.D. of both Positive Controls should be ≥ 0.300 at 450 nm or 450/620 to 650 nm, after the O.D. of the Negative Control is subtracted and should be equal to or greater than the 2+ reaction when read visually. If yellow colour less than 2+ on the Procedure Card is present in either of the Positive Controls, call for technical assistance.

10. RESULTS

Refer to the enclosed Procedure Card for colour interpretations.

VISUAL

10.1. Read the test results by comparing with the reaction colours on the Procedure Card.
Positive: yellow colour of at least 1+ intensity
Negative: colourless
Note: Tests with faint yellow colour (less than 1+) should be repeated.
Negative: A colourless reaction is a negative result and indicates that no GSA 65 or CSA or an undetectable level of antigen is present in the sample tested.

SPECTROPHOTOMETRIC

10.3. Read results at either single (450 nm) or dual (450/620 to 650 nm) wavelength.

10.4. Read the optical density (O.D.) for the Negative Control.

10.5. Subtract the O.D. of the Negative Control well from the O.D. readings of the Positive Control wells and the test wells before interpreting results.
Note: Readers may be set to blank on the Negative Control well so that the Negative Control well O.D. is automatically subtracted from all of the other readings. If the reader does not have this capability, blank on air and subtract the O.D. of the Negative Control well from the O.D. readings of the Positive Control wells and test wells before interpreting results.

10.6. Read the test results:
Positive: O.D. of ≥ 0.050 blanked value
(i.e. after the O.D. of the Negative Control is subtracted)
Negative: O.D. of < 0.050 blanked value
(i.e. after the O.D. of the Negative Control is subtracted)

10.7. Interpretation of spectrophotometric results:

Positive: If the blanked O.D. reading is equal to or greater than 0.050 in the test well, the sample contains GSA 65 or CSA or both and the test is positive.
Negative: A blanked O.D. reading less than 0.050 is a negative result and indicates that no GSA 65 or CSA or an undetectable level of antigen is present in the sample tested.
***Note:** Any wells that are visually clear but give an O.D. reading that is inconsistent with the visual interpretation should be considered a discrepant reading and examined for the presence of bubbles, small particles in the wells, or an opaque film on the bottom of the well. To remove the film, wipe the underside of the wells and read the O.D. again. If the discrepancy between visual and O.D. readings persists, repeat the test.

11. PERFORMANCE LIMITATIONS

The validity of results with the ProSpecT Giardia/Cryptosporidium Microplate Assay depends on the control reaction performing as expected. See **Quality Control**, section **9**.

A negative test result does not exclude the possibility of the presence of *Giardia / Cryptosporidium*, and may occur when the antigen level in the sample is below the detection level of the test. Correlation between the amount of antigen in a sample and clinical presentation has not been established.

As with all IN VITRO diagnostic tests, results should be interpreted by the clinician in conjunction with clinical findings and/or other laboratory results.

Proper specimen collection and processing are essential to achieve optimal performance of the assay. Optimal test results are obtained from specimens tested as soon after collection as possible. See **Collection of Faecal Specimens**, section **7**.

ProSpecT Giardia/Cryptosporidium Microplate Assay has been classified as high complexity.

12. EXPECTED VALUES

The prevalence of *Giardia* and *Cryptosporidium* infection varies in different populations and geographic areas. In the U.S., the incidence of *Giardia* is approximately 4-7% with higher prevalence rates in children[22] and in homosexual males[9,14]. The incidence of *Cryptosporidium* is approximately 0.5-3.0% with higher prevalence rates in children[25] and in homosexual males[10,11].

13. PERFORMANCE CHARACTERISTICS

SENSITIVITY AND SPECIFICITY

Clinical studies were conducted to evaluate the performance of the ProSpecT Giardia/Cryptosporidium Microplate assay. Specimens were obtained from a large clinical reference laboratory in the U.S. and one in Canada, several hospital laboratories in various parts of the U.S., an outbreak of Giardiasis investigated by a public health department laboratory, clinical trials with AIDS patients and a clinical investigation of cryptosporidiosis conducted with normal volunteers. Specimens were unpreserved or in Cary Blair bacterial transport medium or preserved in 10% formalin, SAF, or MF (MIF).

A total of 495 specimens were tested; 131 positive for *Giardia* by ova and parasite (O&P) or fluorescent antibody (DFA) microscopic examination, 89 positive for *Cryptosporidium* by acid fast (AF) or DFA microscopic examination, 180 negative for both *Giardia* and *Cryptosporidium* by DFA and 95 positive by O&P for other parasites including 10 specimens positive for Rotavirus by electron microscopy. The performance of the ProSpecT Giardia/ Cryptosporidium Microplate Assay (EIA) with these specimens was:

A. Combined Data

		Microscopy +	Microscopy -	
EIA	+	218	1	
	-	2	274	
		220	275	495

Sensitivity 218/220 = 99.1% (96.8 - 99.9%)
Specificity 274/275 = 99.6% (98.0 - 100%)

B. *Giardia* + Specimens: Spectrophotometric Interpretation of Results

		Microscopy +	Microscopy -	
EIA	+	130	1	
	-	1	274	
		131	275	406

Sensitivity 130/131 = 99.2% (95.8 - 100%)
Specificity 274/275 = 99.6% (98.0 - 100%)

C. *Giardia* + Specimens: Visual Interpretation of Results

		Microscopy +	Microscopy -	
EIA	+	128	1	
	-	3	274	
		131	275	406

Sensitivity 128/131 = 97.7% (93.5 - 99.5%)
Specificity 274/275 = 99.6% (98.0 - 100%)

D. *Cryptosporidium* Positive Specimens: Spectrophotometric and Visual Interpretation of Results

		Microscopy +	Microscopy -	
EIA	+	88	1	
	-	1	274	
		89	275	364

Sensitivity 88/89 = 98.9% (93.9 - 100%)
Specificity 274/275 = 99.6% (98.0 - 100%)

Numbers in parentheses are 95% confidence intervals.

ANALYTICAL SENSITIVITY

The ProSpecT Giardia/Cryptosporidium Microplate Assay detects approximately 0.8 ng/ml GSA 65 and 20 ng/ml CSA.

REPRODUCIBILITY

The inter-assay or run-to-run coefficient of variation (C.V.) was evaluated by selecting 15 specimens (5 negatives, 5 *Giardia* positives and 5 *Cryptosporidium* positives) with varying optical density readings. Each specimen was tested in 10 wells per run for three consecutive runs. The mean inter-assay CV was 5.45%.

Sample #		Mean O.D.	Standard Deviation	%CV
1	Negative	0.061	0.003	4.43
2	Negative	0.065	0.005	7.23
3	Negative	0.057	0.002	4.04
4	Negative	0.060	0.005	7.83
5	Negative	0.060	0.002	3.83
6	*Giardia* +	0.774	0.038	4.91
7	*Giardia* +	1.992	0.107	5.37
8	*Giardia* +	2.530	0.097	3.83
9	*Giardia* +	2.715	0.039	1.44
10	*Giardia* +	2.859	0.060	2.10
11	*Cryptosporidium* +	0.183	0.013	7.27
12	*Cryptosporidium* +	0.754	0.026	3.41
13	*Cryptosporidium* +	0.820	0.069	8.38
14	*Cryptosporidium* +	1.219	0.153	12.55
15	*Cryptosporidium* +	1.858	0.096	5.18

The intra-assay or within-run CV was evaluated by selecting 15 specimens (5 negatives, 5 *Giardia* positives and 5 *Cryptosporidium* positives) with varying optical density readings. Each specimen was tested in 10 wells. The mean intra-assay CV was 5.41%.

Sample #		Mean O.D.	Standard Deviation	%CV
1	Negative	0.056	0.002	3.57
2	Negative	0.060	0.003	5.00
3	Negative	0.059	0.002	3.39
4	Negative	0.063	0.006	9.52
5	Negative	0.058	0.002	3.45
6	*Giardia* +	0.755	0.043	5.70
7	*Giardia* +	2.000	0.071	3.55
8	*Giardia* +	2.546	0.143	5.62
9	*Giardia* +	2.724	0.044	1.62
10	*Giardia* +	2.857	0.057	2.00
11	*Cryptosporidium* +	0.186	0.013	7.39
12	*Cryptosporidium* +	0.722	0.026	3.37
13	*Cryptosporidium* +	0.807	0.072	8.92
14	*Cryptosporidium* +	1.474	0.174	11.80
15	*Cryptosporidium* +	1.949	0.121	6.21

CROSS-REACTIVITY

The ProSpecT Giardia/Cryptosporidium Microplate Assay has been tested with stool specimens found to be positive for a number of faecal pathogens. No cross-reactivity was observed with any of the infectious agents listed below.

Ascaris lumbricoides	*Entamoeba histolytica*
Blastocystis hominis	*Hymenolepis nana*
Chilomastix mesnili	*Iodamoeba butschlii*
Dientamoeba fragilis	*Isospora spp.*
Diphyllobothrium latum	Rotavirus
Endolimax nana	*Strongyloides stercoralis*
Entamoeba coli	*Taenia spp.*
Entamoeba hartmanni	*Trichuris trichiura*

14. BIBLIOGRAPHY

1. **Addiss, D.G., 1991.**
   Evaluation of a commercially available Enzyme-Linked Immunoabsorbent Assay for *Giardia lamblia* antigen in stool.
   J. Clin. Microbiol. 29(6):1137-1142.
2. **Alpert, G, et. al., 1986.**
   Outbreak of Cryptosporidiosis in a day care centre.
   Pediatrics 77(2):152-157.
3. **Anon., 1984.**
   Cryptosporidiosis among children attending day-care centres - Georgia, Pennsylvania, Michigan, California, New Mexico.
   Morbid Mortal Weekly Rep. 33(42):599-601.
4. **Arrowood, M.J. och C.R. Sterling, 1989.**
   Comparison of conventional staining methods and monoclonal antibody-based methods for *Cryptosporidium* oocyst detection.
   J. Clin. Microbiol. 27(7):1490-1495.
5. **Black, R.E. et al., 1977.**
   Giardiasis in day care centres: evidence of person to person transmission.
   Pediatrics 60(4):486-491.
6. **Center for Disease Control, Atlanta, GA, 1978.**
   Intestinal parasite surveillance-United States 1976.
   Morbid. Mortal. Weekly Rep. 27(20):167-168.
7. **Chapman, P.A., B.A. Rush och J. McLauchlin, 1990.**
   An enzyme immunoassay for detecting *Cryptosporidium* in faecal and environmental samples.
   J. Med. Microbiol. 32:233-237.
8. **Craun, G.F., 1979.**
   Waterborne giardiasis in the United States: a review.
   Am. J. Publ. Health 69(8):817-819.
9. **Craun, G.F., 1986.**
   Waterborne giardiasis in the United States 1965-84.
   Lancet I:513-514.
10. **D'Antonio, R.G., et. al., 1985.**
    A waterborne outbreak of cryptosporidiosis in normal hosts.
    Ann. Intern. Med. 103:886.
11. **Dubey, J.P., C.A. Speer och R. Fayer, eds., 1990.**
    Cryptosporidiosis of Man and Animals.
    CRC Press.
12. **Gallaher, M.M., et. al., 1989.**
    Cryptosporidiosis and surface water.
    Am. J. Public Health 79(1):39-42.
13. **Hayes, E.B., et. al., 1989.**
    Large community outbreak of cryptosporidiosis due to contamination of a filtered public water supply.
    N. Eng. J. Med. 320(21):1372-1376.
14. **Kean, B.H. et al., 1979.**
    Epidemic of amoebiasis and giardiasis in a biased population.
    Brit. J. Ven. Dis. 55:375-378.
15. **Leech, J.H., M.A. Sande och R.K. Root, eds., 1988.**
    Parasitic Infections.
    Churchill Livingstone.
16. **Meyers, J.D. et al., 1977.**
    Giardia lamblia infection in homosexual men.
    Brit. J. Ven. Dis. 53:54-55.
17. **Navin, T.R. och A.M. Hardy, 1984.**
    Cryptosporidiosis in patients with AIDS.
    J. Infect. Dis. 155:150.
18. **Rendtorff, R.C., 1979.**
    The experimental transmission of *Giardia lamblia* among volunteer subjects in waterborne transmission of Giardiasis
    (Jakubowski, W., och Hoff, J.C., eds.), pp.64-81. EPA, U.S., Cincinnati, OH.
19. **Rosoff, J.D., och H.H. Stibbs, 1986.**
    Isolation and identification of a *Giardia lamblia*-Specific Stool Antigen (GSA 65) useful in coprodiagnosis of giardiasis.
    J. Clin. Microbiol. 23(5):905-910.
20. **Rosoff, J.D., och H.H. Stibbs, 1986.**
    Physical and chemical characterization of a *Giardia lamblia*-Specific Antigen useful in the coprodiagnosis of giardiasis.
    J. Clin. Microbiol. 24(6):1079-1083.
21. **Rosoff, J.D. et al., 1989.**
    Stool Diagnosis of giardiasis using a commercially available enzyme immunoassay to detect *Giardia*-specific antigen 65 (GSA 65).
    J. Clin. Microbiol. 27(9):1997-2002.
22. **Schieven, B.C. och Z. Hussain, 1990.**
    Evaluation of an enzyme immunoassay test kit for diagnosing infections with *Giardia lamblia*.
    Serodiag and Immunother 4:109-113.
23. **Sonnad, S., L. Bahrami, P. O'Hanley, 1991.**
    Compatibility Assessment of Three Common Transport Media Systems with the ProSpecT™ / *Giardia* Immunoassay.
    Presenterad vid årsmötet 1991 för American Society for Microbiology Meeting, Session 20.
24. **Stehr-Green, JK, et. al., 1987.**
    Shedding of oocysts in immunocompetent individuals infected with *Cryptosporidium*.
    Am. J. Dis. Child, 140:1213.
25. **Taylor, JP, et. al., 1985.**
    Cryptosporidiosis outbreak in a day-care centre.
    Am. J. Dis. Child. 139:1023-1025.
26. **Visvesvara, G.S., 1982.**
    Giardiasis in Children.
    J. Pediatr. Gastroentrol Nutr. 1(4):463-465.
27. **Ungar, B.L.P., 1990.**
    Enzyme-linked immunoassay for detection of *Cryptosporidium* antigens in faecal specimens.
    J. Clin. Microbiol. 28:2491.
28. **Wolfe, M.S., 1979.**
    Managing the patient with giardiasis: clinical, diagnostic and therapeutic aspects.
    In: Waterborne Transmission of Giardiasis (Jakubowski, W., and Hoff, J.C., eds.), pp.39-52. EPA, U.S., Cincinnati, OH.

15. PACKAGING

REF R2458496 .....96 Tests

CE

Oxoid Ltd Wade Road Basingstoke Hants, RG24 8PW UK

For technical assistance please contact your local distributor.

IFU X7589B, Revised September 2013 Printed in the UK