1. INTENDED USE

The ProSpecT Giardia EZ Microplate Assay is a monoclonal antibody based diagnostic test for the qualitative detection of Giardia Specific Antigen (GSA) 65 in aqueous faecal samples.

2. SUMMARY

Giardia is now recognized as an important human intestinal disease in most parts of the world. Giardia lamblia is the most frequently identified protozoan in stools of human beings in all parts of the world, and is the most abundant of the public health laboratory parasites. This parasite has been implicated in a number of diarrhoeal disease in most areas of the world. The causative organism, Giardia, is the most frequently identified protozoan.

3. PRINCIPLE OF THE TEST

The ProSpecT Giardia EZ Microplate Assay is a solid phase enzyme immunoassay (EIA) using a monoclonal antibody. Specific Antigen (GSA 65) is a macromolecule that has been extracted from Giardia lamblia and is produced in abundant quantities by the molecular weight glycoprotein that is produced in abundant quantities by the organism. The ProSpecT product range: Wash Buffer, Colour Substrate and Anti-GSA with antimicrobial agents.

4. PRECAUTIONS

- Use reagents in the expiration date range as indicated on the package label.
- Dilute (x10) Wash Buffer concentrate to (x1) by adding 1 part to 9 parts distilled water. Colour Substrate is stable for 1 month when stored at 2°C to 8°C.
- Colour Substrate must 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 the unused Colour Substrate to the original bottle.
- Stop Solution: Do not mix different reagents with kits between different lot numbers.

5. KIT CONTENTS, PREPARATION FOR USE AND SHIPMENT

- One dropper bottle containing 25 ml of Wash Buffer.
- One dropper bottle containing 12 ml of Colour Substrate solution.
- One bottle containing 120 ml of a buffered wash solution.
- One bottle containing 4 ml of a buffered wash solution.
- Two positive controls.
- Two negative controls.
- Control (s)
- One dropper bottle containing 20 ml of a concentrated buffer solution with antimicrobial agents.
- One dropper bottle containing 120 ml of a (x10) concentrated buffer solution with antimicrobial agents.
- Wash Buffer: Use alone to stop the reaction.
- Colour Substrate: Dilute to (x1) before use.

6. MATERIALS REQUIRED BUT NOT PROVIDED

- PIPETTE
- Timer that measures minutes
- Microplate reader capable of reading 450 nm or 450/620 nm wavelength.
- Analysers.
- Controls.
- Computer software.
- Background absorbance.

7. COLLECTION OF Fecal SAMPLES

Samples, collected in the contamination free containers, can be used for the ProSpecT Giardia EZ Microplate Assay. Stock specimens should be collected in leak-proof, plastic containers.

8. PROCEDURE

a. Prepare the test by reading the test instructions and familiarizing yourself with the test components.

b. Dilute (x10) Wash Buffer concentrate to (x1) by adding 1 part to 9 parts distilled water. Colour Substrate is stable for 1 month when stored at 2°C to 8°C.

9. ANALYTICAL PRECAUTIONS

- Do not use reagents in the expiration date range as indicated on the package label.
- Do not use reagents beyond the expiration date.
- Do not use reagents that have been frozen or thawed.
- Do not mix different reagents with kits between different lot numbers.
- Dilute (x10) Wash Buffer concentrate to (x1) by adding 1 part to 9 parts distilled water. Colour Substrate is stable for 1 month when stored at 2°C to 8°C.
- Colour Substrate must 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 the unused Colour Substrate to the original bottle.
- Stop Solution
- Stop Solution: Do not mix different reagents with kits between different lot numbers.

10. PERFORMANCE LIMITATIONS

- The validity of results with the ProSpecT Giardia EZ Microplate Assay can be assessed using the ProSpecT Quality Control, section 9.

11. SENSITIVITY AND SPECIFICITY

Clinical studies were conducted to evaluate the performance of the ProSpecT Giardia EZ Microplate Assay using samples obtained from a large reference laboratory which performed O&P examinations. A total of 254 unpaired specimens were tested. 100% sensitivity and 100% specificity were observed. Forty-four of the Giardia negative control specimens contained parasites other than Giardia lamblia. There were seven specimens with GI infection (2.1%) which were O&P negative. Twenty-two of these were reproducibly positive in this assay and 4 of these were reproducibly negative in the O&P examination. The ProSpecT EZ Microplate Assay was shown to be less sensitive than O&P examination.

12. SAFETY

No specific safety precautions are required. Employees should wash their hands with soap and water after handling the specimen and reagent materials.

13. STABILITY

The ProSpecT EZ Microplate Assay is stable for 6 months when stored at 4°C to 8°C.
The intra-assay or within-run CV was evaluated by testing 24 wells with each of 4 positive specimens. The mean intra-assay CV was 4.23%.

### CROSS-REACTIVITY

The ProSpecT® Giardia EZ Microplate Assay has been tested with stool specimens found to be O&P positive for a number of faecal parasites. No cross reactivity was observed with any of the infectious agents listed below:

- Ascaris lumbricoides
- Entamoeba histolytica
- Blastoctysis hominis
- Enteroxus vermivorus
- Cryptosporidium parvum
- Roseobacter
- Cryptosporidium parvum
- Hymanospilinae inarens
- Dimetraea fragilis
- Isodimaebus butchelli
- Endolaxus name
- Strongyloides stercoralis
- Enteroxus coli
- Trichnutria ehrlichii
- Enteroxus hartmanni

### BIBLIOGRAPHY


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