



Abstract: P995

Evaluation of the Giardia-strip: an *in vitro* immunochromatographic test for the detection of *Giardia lamblia* cysts in faecal specimens

D. Van Kerkhoven, M. Lontie, J. Verhaegen, K. Lagrou

(Leuven, BE)

Objectives: Giardiasis is a diarrhoeal illness caused by *Giardia lamblia*, a one-celled parasite that lives in the intestine of humans and animals. The disease is diagnosed by microscopical identification of cysts or trophozoites in faeces, using direct mounts as well as concentration procedures. Since these analyses are labour-intensive and require a skilled microscopist, antigen detection tests (direct fluorescent antibody (DFA), enzyme immunoassay (EIA) and rapid, dipstick-like tests) have been developed as alternatives. We have evaluated the performance of a commercially available one-step immunochromatographic membrane test using specific monoclonal antibodies against the cyst membrane antigens of *G. lamblia*, the Giardia-strip (CorisBioconcept).

Methods: The test performance was evaluated with known positive ($n = 18$) and negative ($n = 55$) stool specimens for *G. lamblia*, tested by the standard ova and parasite (O&P) examination as the golden standard. Faeces with other parasites (8 *Endolimax nana*, 8 *Entamoeba coli*, 4 *Entamoeba histolytica* and 1 *Ancylostoma*) and *Staphylococcus aureus* (3) were included to evaluate the specificity of the test. These fresh and unpreserved samples, obtained from the laboratory of UZ Gasthuisberg and Medisch Centrum voor Huisartsen Leuven, were frozen and maintained at -20°C prior to testing. The Giardia-strip was used according to the manufacturer's instructions.

Results: By the Giardia-strip, 17 of the 18 known positive specimens were positive and 54 of the 55 Giardia-negative samples were negative (94.4% sensitivity, 98.2% specificity, 94.4% positive predictive value and 98.2% negative predictive value), compared to (O&P) which is considered as the reference method. The Giardia false-positive discrepant sample came from a patient who was on holiday in Tunisia. Microscopy on a control sample of the same patient remained negative. The missed positive specimen by the Giardia-strip contained many cysts. No cross-reactions with other parasites or *S. aureus* were observed in this study.

Conclusion: The Giardia-strip has an excellent sensitivity and specificity for the detection of *G. lamblia* in stool. The test is easy to perform (no concentration prior to testing), suitable for single sample analysis and has a short turn-around-time (15 minutes). This diagnostic kit may be very beneficial in the absence of trained microscopists. However, it cannot substitute the routine O&Ps as only *G. lamblia* is detected.

Evaluation of the *Giardia*-strip: an in vitro immunochromatographic test for the detection of *Giardia lamblia* cysts in faecal specimens

D. Van Kerkhoven^{1*},
M. Lontie², J. Verhaegen¹ and K. Lagrou¹

Department of Microbiology, University Hospital Leuven¹ and Medisch Centrum Huisartsen, Leuven²

* phone: +32-16-34 70 40 fax: +32-16-34 79 31

e-mail: Dana.VanKerkhoven@uz.kuleuven.ac.be

1. Abstract

The *Giardia*-strip (CorisBioconcept) is a immunochromatographic membrane test that detects *Giardia lamblia* in fresh or frozen, unfixed human faecal specimens. By using specific antibodies, antigens specific for this organism are captured and immobilized on a membrane. Test performance was evaluated with known positive and negative stool specimens (a total of 73 specimens). On the basis of the results of the reference method (O&P), the sensitivity, the specificity and the positive and negative predictive value were as follows: 94.4, 98.2, 94.4 and 98.2% respectively. This rapid diagnostic test does not take the place of routine O&P examinations, but is very useful when trying to diagnose *Giardia* infections, especially in the absence of trained microscopists.

2. Introduction and objectives

Giardiasis is a diarrhoeal illness caused by *Giardia lamblia*, a one-celled parasite that lives in the intestine of humans and animals. The disease is diagnosed by microscopical identification of trophozoites or cysts in faeces, using direct mounts as well as concentration procedures. As cyst excretion can be intermittent, at least three stool specimens should be examined before infection can be excluded. Since these analyses are labour-intensive and require a skilled microscopist, antigen detection tests (direct fluorescent antibody (DFA), enzyme immunoassay (EIA) and rapid, dipstick-like tests) have been developed as alternatives. We have evaluated the performance of a commercially available one-step immuno-chromatographic membrane test using specific monoclonal antibodies against the cyst membrane antigens of *G. lamblia*, the *Giardia*-strip (CorisBioconcept) (Fig. 1).

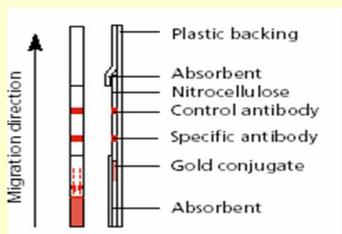


Figure 1: *Giardia*-strip (CorisBioconcept)

3. Methods

The test performance was evaluated with known positive (n = 18) and negative (n = 55) stool specimens for *G. lamblia*, tested by the standard ova and parasite (O&P) examination as the golden standard. Faeces with other parasites (8 *Endolimax nana*, 8 *Entamoeba coli*, 4 *Entamoeba histolytica* and 1 *Ancylostoma*) and *Staphylococcus aureus* (3) were included to evaluate the specificity of the test. These fresh and unpreserved samples, obtained from the laboratory of UZ Gasthuisberg and Medisch Centrum voor Huisartsen Leuven, were collected in clean, leak-proof containers and were frozen and maintained at -20 °C prior to testing. The *Giardia*-strip was used according to the manufacturer's instructions (Fig. 2).

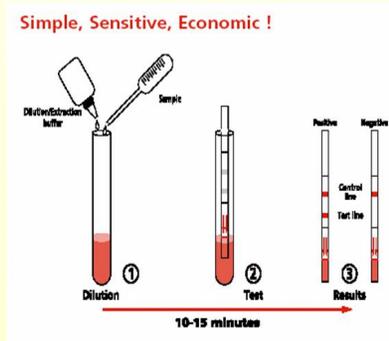


Figure 2: Procedure of the test

4. Results

By the *Giardia*-strip, 17 of the 18 known positive specimens were positive and 54 of the 55 *Giardia*-negative samples were negative, compared to O&P which is considered as the reference method (Table 1).

The *Giardia* false-positive discrepant sample came from a patient who had been on holiday in Tunisia. Microscopy on a control sample of the same patient remained negative. The missed positive specimen by the *Giardia*-strip contained many cysts.

Table 1: Results of comparing the *Giardia*-Strip results with the findings of optical microscopy.

	Micro pos	Micro neg	Total
Strip pos	17	1	18
Strip neg	1	54	55
Total	18	55	73

Strip: *Giardia*-strip (CorisBioconcept)

Micro: standard ova & parasite examination

Sensitivity = 94.4 % (17/18)

Specificity = 98.2 % (54/55)

Reliability = 97.3 % (71/73)

Positive Predictive Value = 94.4 % (17/18)

Negative Predictive Value = 98.2 % (54/55)

No cross-reactions with other parasites or *Staphylococcus aureus* were observed in this study.

5. Discussion and conclusions

- The *Giardia*-strip has an excellent sensitivity and specificity for the detection of *G. lamblia* in stool.
- The test is easy to perform (no concentration prior to testing), suitable for single sample analysis and has a short turn-around-time (15 minutes).
- Although the reagent costs for the *Giardia*-strip may be more than those for the routine O&P methods, the labour costs will be considerably less.

The *Giardia*-strip test may be very beneficial in the absence of trained microscopists and in possible day care and waterborne outbreak situations (as a screening tool). However, it cannot substitute the routine O&Ps as only *G. lamblia* is detected!