

Performance evaluation of point-of-care test for detection of *Cryptosporidium* stool antigen in children and HIV infected adults

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Background

Gastro-enteritis is associated with significant morbidity and mortality in patients with HIV/AIDS and children, and *Cryptosporidium* is the most important parasite implicated. Detection of *Cryptosporidium* using microscopy is time consuming, labor-intensive and often unsuitable. To date, simple and rapid point-of-care tests have been developed by several commercial companies; however, there is dearth of information regarding their diagnostic significance in Ethiopia where *Cryptosporidium* and other parasites are prevalent. This study aimed at evaluating the performance of a rapid diagnostic test (RDT) for detection of *Cryptosporidium* stool antigen.

Methods

A cross-sectional study was conducted in Hawassa University Hospital, southern Ethiopia from May to November 2013. Faecal samples were collected from a total of 100 children and 250 HIV infected individuals with diarrhea or CD4 T-cell count lower than 200 cells/ μ l. Specimens were processed using direct, formol-ether concentration and modified Ziehl-Neelsen techniques for diagnosis of *Cryptosporidium* and other parasites. One hundred faecal samples (50 *Cryptosporidium* positives and 50 *Cryptosporidium* negatives but positive for other intestinal parasites) were tested using CoproStripTM*Cryptosporidium* kit (Savyon Diagnostics Ltd, Israel). Test parameters were calculated using microscopy of the modified Ziehl-Neelsen stained stool smear as reference method.

Results

The performance of the RDT was first compared to routine microscopic analysis (examination ≤ 10 min). The CoproStripTM*Cryptosporidium* RDT correctly detected 31 of 42 positive samples and 49 of 50 negative samples (i.e., 11 false negatives and 1 false positive). Sensitivity, specificity, PPV, NPV and accuracy were calculated to be 74, 98, 97, 84 and 88%, respectively. Upon thorough microscopic analysis (examination > 10 min), 8 more samples with very low oocyst density were found. However, these were missed by the kit and lower the sensitivity and NPV to 62 and 72%, respectively. No cross-reactivity was observed with any of helminthic or other protozoan parasites including *Isospora* and *Cyclospora* species.

Conclusion

Based on the results described herein, the CoproStripTM*Cryptosporidium* test could be used as an alternative to conventional microscopy especially where diagnosis of *Cryptosporidium* is limited due to time constraints, lack of experienced microscopists or unavailability of appropriate equipment/electricity.