

Evaluation of Rapid Antigen Point-of-Care Tests for the Detection of *Giardia* and *Cryptosporidium* in Human Fecal Specimens



¹Juliana Minak, MD, ²Mamun Kabir, MS, ²Iqbal Mahmud, ¹Yue Liu, BS, ¹Lei Liu, PhD, ²Rashidul Haque, MD, ¹William A. Petri, Jr.* ¹Division of Infectious Diseases and International Health, University of Virginia School of Medicine, Charlottesville VA USA, and the ²International Centre for Diarrhoeal Disease Research, Bangladesh, Dhaka, Bangladesh

Abstract

Context: In Bangladesh, a new parasite rapid antigen test was investigated demonstrating accuracy and feasibility. For *Giardia,* it had a sensitivity and specificity of 94% and 100%. For *Cryptosporidium,* it had a sensitivity and specificity of 100% and 100%. These are higher or equal compared to other tests on the market.

Objective: To compare the performance of three rapid antigen tests for stool samples with results of ELISA and PCR testing to detect *Giardia* and *Cryptosporidium* in a cohort of children from Dhaka, Bangladesh where *Giardia* and *Cryptosporidium* infections are common.

Design: Stool specimens were obtained from a cohort of children in an area of Dhaka, Bangladesh where *Giardia* and *Cryptosporidium* infections are prevalent.

Results: One hundred and seventeen of both diarrheal and non-diarrheal specimens were tested at the International Centre for Diarrheal Disease Research, Bangladesh. All samples were fresh fecal specimens stored at -20°C and defrosted for use. As a qualitative standard of measurement of the presence/absence of either or both of the antigens, individual ELISAs for *Giardia* and *Cryptosporidium* were performed using the *GIARDIA II* and *CRYPTOSPORIDIUM II* (TECHLAB®, Inc.). The 117 stool samples were tested by all three rapid antigen tests according to each manufacturer's directions. PCR tests were performed on all specimens with discrepant results, in addition to 10% of the other samples.

Using both ELISA, and for the 18 discrepant samples PCR, as reference standards for *Giardia*, *QUIK CHEK®* had a sensitivity, specificity, positive predictive value and negative predictive value of 94%, 100%, 100% and 98% respectively. For *Cryptosporidium*, *QUIK CHEK®* had a sensitivity, specificity, positive predictive value and negative predictive value of 100%, 100%, 100% and 100% respectively (Table 2). This compared favorably to **Immuno** *Card* **STAT!**® and Xpect® tests.

Conclusions: The GIARDIA/CRYPTOSPORIDIUM QUIK CHEK® can be used reliably for routine diagnosis of Giardia and Cryptosporidium in stool samples. For the detection of Giardia and Cryptosporidium, the QUIK CHEK® has higher or equal sensitivity and specificity compared to the other two products, ImmunoCard STAT!® and Xpect®. The QUIK CHEK® is a rapid test which can be run at the bedside of the patient and requires minimal equipment and training making it a valuable tool in patient care.

Results

Table 1. Results of the three rapid antigen tests for Giardia and Cryptosporidium compared to real time PCR as the reference standard. 18 samples with discrepant results between the rapid antigen tests and ELISA were tested by real time PCR QUIK CHEK® QUIK CHECK® Immuno Card Immuno Card Xpect® Parameter **Xpect®** Giardia STAT!® STAT!® Giardia Crypto Crypto Crypto Giardia Sensitivity (%) 58 78 100 Specificity (%) 100 100 100 44 Positive Predictive 100 58 100 71 100 Value (%) 67 55 Negative Predictive 64 Value (%) TN/TP 6/12 3/12 7/5 9/7 4/7 6/7 FN/FP 2/5 2/0 0/0 0/3 4/2 5/0

Table 2. Results of the three rapid antigen tests for Giardia and Cryptosporidium using both ELISA as the reference standard, and for ELISA discrepant results real time PCR. TP/TN=True Positive/True negative. FN/FP=False Negative/False Positive.

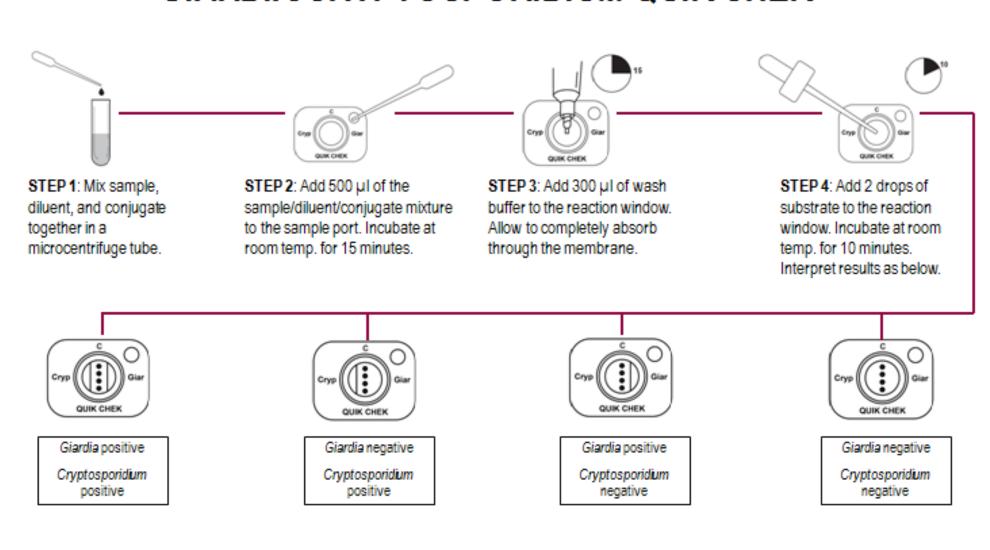
and for Elion discrepant results real time i oit. If fine inde i ositive, frae negative, i with a last negative, i also i ositive.						
Parameter	QUIK CHEK® Giardia	QUIK CHECK® Crypto	Immuno <i>Card</i> STAT!® <i>Giardia</i>	Immuno <i>Card</i> STAT!® <i>Crypto</i>	Xpect® <i>Giardia</i>	Xpect® Crypto
Sensitivity (%)	94	100	94	100	88	82
Specificity (%)	100	100	94	97	98	100
Positive Predictive Value (%)	100	100	86	90	94	100
Negative Predictive Value (%)	98	100	98	100	95	95
TN/TP	83/32	89/28	78/32	86/28	81/30	89/23
FN/FP	2/0	0/0	2/5	0/3	4/2	5/0



Conclusions

The Giardia/Cryptosporidium QUIK CHECK® and other rapid antigen tests are reliable for routine diagnosis of Giardia and Cryptosporidium in stool samples.

GIARDIA/CRYPTOSPORIDIUM QUIK CHEK





Acknowledgements

We are indebted to the patients and their families for making this study possible. The pediatric cohort was supported by NIH grant AI043596.

Contact information

Bill Petri
Infectious Diseases and International Health
University of Virginia
wap3g@virginia.edu