

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

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## 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 *ImmunoCard 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**

Parameter	<i>QUIK CHEK</i> ® <i>Giardia</i>	<i>QUIK CHEK</i> ® <i>Crypto</i>	<i>ImmunoCard STAT!</i> ® <i>Giardia</i>	<i>ImmunoCard STAT!</i> ® <i>Crypto</i>	<i>Xpect</i> ® <i>Giardia</i>	<i>Xpect</i> ® <i>Crypto</i>
Sensitivity (%)	78	100	78	100	56	58
Specificity (%)	100	100	44	50	78	100
Positive Predictive Value (%)	100	100	58	80	71	100
Negative Predictive Value (%)	82	100	67	100	64	55
TN/TP	9/7	6/12	4/7	3/12	7/5	6/7
FN/FP	2/0	0/0	2/5	0/3	4/2	5/0

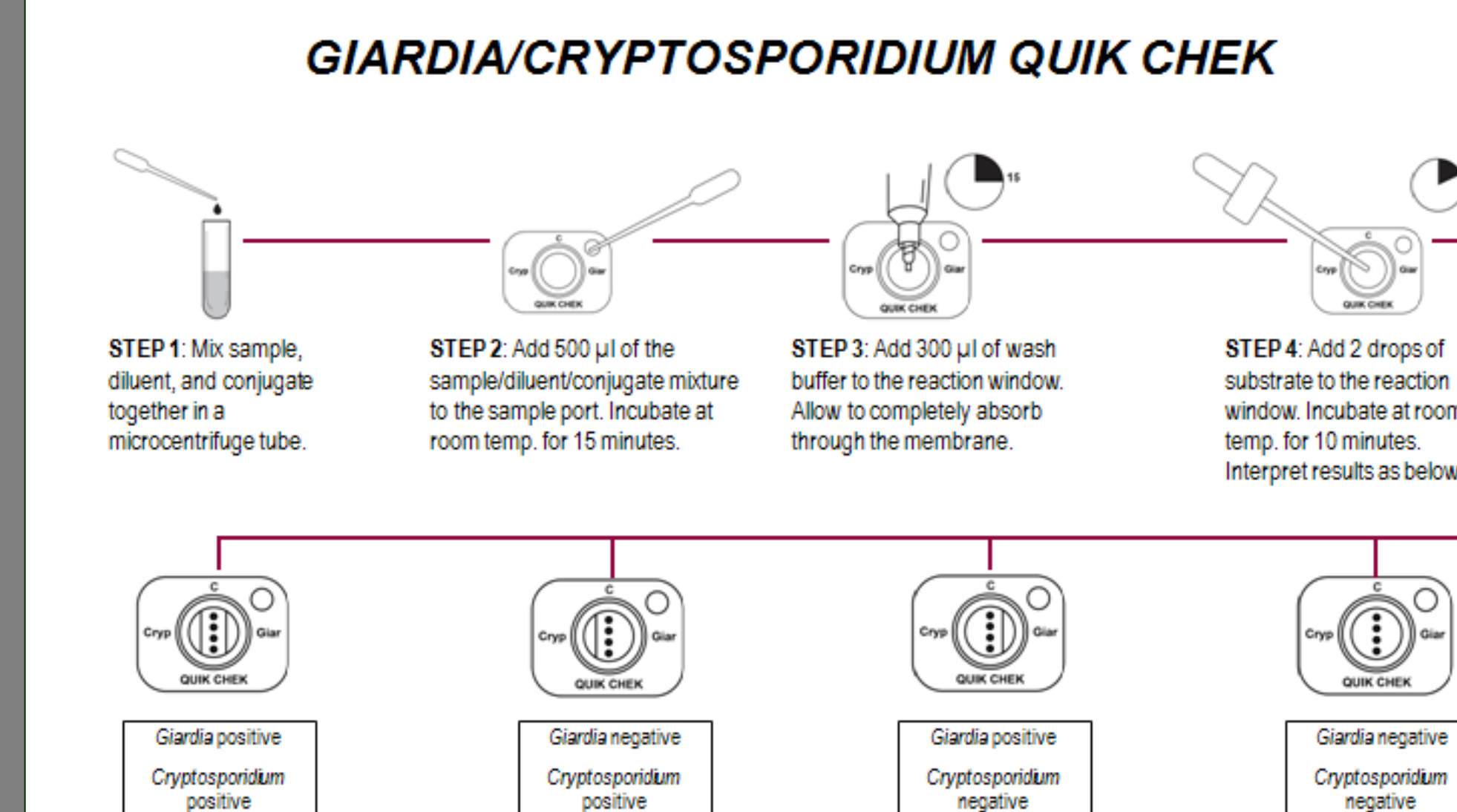
**Table 2. Results of the three rapid antigen tests for *Giardia* and *Cryptosporidium* using both ELISA as the reference standard, and for ELISA discrepant results real time PCR. TP/TN=True Positive/True negative. FN/FP=False Negative/False Positive.**

Parameter	<i>QUIK CHEK</i> ® <i>Giardia</i>	<i>QUIK CHEK</i> ® <i>Crypto</i>	<i>ImmunoCard STAT!</i> ® <i>Giardia</i>	<i>ImmunoCard STAT!</i> ® <i>Crypto</i>	<i>Xpect</i> ® <i>Giardia</i>	<i>Xpect</i> ® <i>Crypto</i>
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 CHEK*® and other rapid antigen tests are reliable for routine diagnosis of *Giardia* and *Cryptosporidium* in stool samples.



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