



Evaluation of a Novel Broad-Based Enteric Parasite Panel in a Low Prevalence Setting

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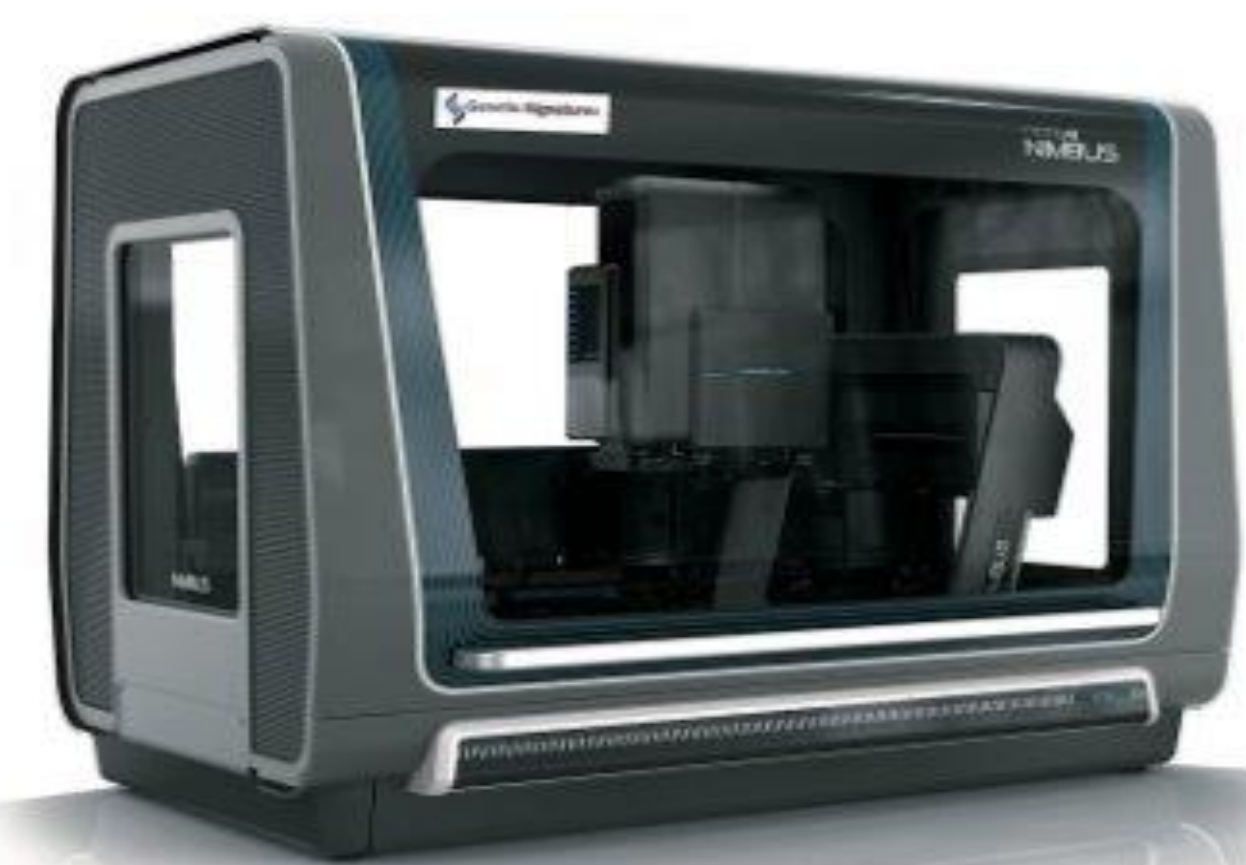
Background

Gastrointestinal enteric parasitic infections are common in the USA and numerous outbreaks are reported annually by the CDC. Molecular syndromic panel tests are superior to traditional O&P examinations for detection of these pathogens. The Investigational Use Only Genetic Signatures *EasyScreen*[™] Enteric Parasite Detection Kit uses proprietary 3base[™] technology to detect the following 8 organisms: *Cryptosporidium* spp., *Giardia intestinalis*, *Dientamoeba fragilis*, *Entamoeba histolytica*, *Blastocystis hominis*, *Enterocytozoon bieneusi*, *Encephalitozoon intestinalis*, and *Cyclospora cayetanensis*⁺. The goal of this study was to compare the *EasyScreen*[™] assay to the BD MAX Enteric Protozoan panel (standard of care platform at John Hopkins Hospital (JHH) in a low prevalence environment. The BD MAX assay only detects 3 of the 8 targets detected in the *EasyScreen*[™] assay.

Methods

This project was conducted using prospectively collected de-identified remnant stool samples in Total-Fix transport media from symptomatic patients suspected of a parasite infection. Samples tested were a mix of fresh and frozen samples. All samples tested were in Total-Fix. According to the BD MAX assay's package insert the approved sample types are unpreserved or 10% formalin-fixed stool specimens. Johns Hopkins performed an in house validation for the use of Total-Fix samples on this BD MAX assay. For samples that exhibited inhibition on the initial Genetic Signatures run with 25 µL of sample, a repeat with a smaller volume of 10 µL was performed in accordance with the *EasyScreen*[™] instructions for use.

Genetic Signatures GS-1 System workflow



Samples received and lysed

Sample processing & PCR setup

PCR amplifications & results

Results

[Table 1](#)

Overall Results Genetic Signatures result

	Positive	Negative	Total
BD max results			
Positive	7	3	10
Negative	*22	268	290
Total	29	271	300

*17 were positive on *EasyScreen*[™] with BD MAX off panel targets

[Table 3](#)

Invalid and repeat testing

Samples failed on initial run	Samples that resolved on repeat with 10uL
55	26

There are 4 samples on which repeat testing was not performed.

[Table 4](#)

Discrepant Analysis

Breakdown of the additional 17 *Easy Screen* positive, BD MAX off panel targets.

- *Blastocystis hominis* -13 (one with *E. bieneusi*)
- *Cyclospora cayetanensis* - 2
- *Encephalitozoon intestinalis* – 2

Breakdown of *Easy Screen* Negative, BD MAX positive samples.

- *Giardia intestinalis* - 1
- *Cryptosporidium* spp. - 2

Breakdown of *Easy Screen* Positive, BD MAX negative samples.

- *Giardia intestinalis* - 1
- *Entamoeba histolytica* -3
- *Cryptosporidium* - 2

[Table 2](#)

Comparison of BD Max on panel target positive samples

A. *Giardia intestinalis*

Genetic Signatures result

	Positive	Negative
BD max results		
Positive	4	1
Negative	1	294

B. *Entamoeba histolytica*

Genetic Signatures result

	Positive	Negative
BD max results		
Positive	0	0
Negative	3	297

C. *Cryptosporidium* spp.

Genetic Signatures result

	Positive	Negative
BD max results		
Positive	0	2
Negative	2	296

Results

A total of 300 samples were tested on both platforms. The overall positivity rate for all valid samples was 9.67%. 243 samples were negative on initial testing by both the BD MAX and *EasyScreen*[™] assays. An additional 26 samples that failed on the initial run were repeated, and were also negative. Another 25 samples tested by the *EasyScreen*[™] assay failed twice.

The BD MAX assay detected 7 positive samples—5 *G. intestinalis* and 2 *Cryptosporidium* spp. Of these positives, the *EasyScreen*[™] assay missed one of the *Cryptosporidium* spp. positive samples and in the second sample detected *C. cayetanensis*, but did not detect the *Cryptosporidium* spp. Both *EasyScreen*[™] and the BD MAX missed one *G. intestinalis* that was detected on the other assay.

The BD MAX missed 3 *E. histolytica* detected by *EasyScreen*[™]. The Limit of Detection is not defined in the BD MAX assay's package insert for Total-Fix media. The *EasyScreen*[™] Cycle threshold values for these 3 were 44.98, 39.6 and 35.83, respectively.

There were 4 coinfections with *B. hominis*, one with *C. cayetanensis*, one with *Cryptosporidium* spp, one with *G. intestinalis* and one with *E. bieneusi*. The *EasyScreen*[™] assay detected an additional 17 positive samples for targets not included on the BD MAX panel, 13 of which contained *B. hominis*, 2 samples positive for *E. intestinalis* and 2 samples positive for *C. cayetanensis*.

Overall concordance between the *EasyScreen*[™] and BD MAX assays was 91.7% and the negative percent agreement was 92.4%. When considering only the BD MAX targets, the revised overall agreement was 97.3%.

Conclusions

The Genetic Signatures *EasyScreen*[™] Enteric Parasite Detection Kit has the potential to detect a broader range of parasite pathogens than existing syndromic panels. Some of the additional targets, such as the *Microsporidium* species, are of particular importance in immunocompromised patients.

Acknowledgements

Genetic Signatures provided the instruments and kits for this project.

⁺ On May 29, 2024 the *EasyScreen* assay received FDA 510K clearance.