

Customer Case Study: University of Kentucky

Reviving In-House Testing: Genetic Signatures' FDA-cleared solution restores comprehensive parasite detection to the lab

– Julie Ribes, MD, PhD, Director – Microbiology

The FDA clearance of the Genetic Signatures multiplex PCR parasite panel for the detection of diarrheal disease is a real bonus for labs wanting a comprehensive approach to detecting the clinically significant protozoal parasites causing diarrhea. In comparison to other assays that detect only a few of the significant pathogens, the Genetic Signatures panel provides that one stop shopping for parasite detection.

During COVID times, our lab needed to make the dreadful decision to outsource our microscopic ova and parasite (O&P) examinations to make room for a huge piece of instrumentation to perform COVID PCRs 24/7. We redeployed our O&P staff to perform plate reading activities as they were already multi-tasking, and then hired new staff to learn PCR techniques. The O&P followed in the footsteps of the Microsporidia examination that had been outsourced to a reference lab years earlier. Although it made sense to make these changes, our lab recognized that we could never reengage with the traditional O&P testing methods.

The plan was to await FDA approval of a comprehensive diarrheal PCR panel to address this service gap. The Genetic Signatures diagnostic solution replaces a time-consuming manual microscopic assay with a standardized batch PCR assay that is much faster to complete. With the microscopic aspects removed, it is now easier to maintain competence in this testing. Once fully implemented, we expect the current turn-around time from sample receipt to decrease from 5-10 days down to 1-2 days.

Genetic Signatures' assay has worked well with raw stool, stool in Cary Blair and stool in Total Fix in our validation experience. Due to the comprehensive coverage of this panel, we can abandon traditional O&P for the detection of the 8 key parasite targets and reserve the O&P wet mount microscopic examination

for the detection of helminth eggs and larvae. Genetic Signatures' solution is a much more sensitive and rapid approach to the detection of these significant pathogens.

In addition to the big players (*Giardia*, *Cryptosporidium*, *Entamoeba histolytica*, and *Cyclospora*) the Genetic Signatures multiplex assay also detects the two most common Microsporidia causing diarrhea, *Enterocytozoon bieneusi* and *Encephalitozoon intestinalis*. Additionally, it also detects *Dientamoeba fragilis* and *Blastocystis hominis*.

This is a game changer for the diagnosis of diarrhea, especially in immunocompromised patient populations such as those patients living with HIV/AIDS. Including Microsporidia, *Dientamoeba fragilis*, and *Blastocystis hominis* will make diagnosing these causes of diarrhea much easier for practitioners. These organisms are often overlooked because the testing is not readily accessible.

We see Genetic Signatures' diagnostic solution for gastrointestinal parasites as the way forward to provide rapid and reliable results to better serve our diverse patient populations in the paediatrics, the international adoption, international travel, Ryan White, GI and oncology clinic settings who may have parasitic causes for their diarrhea.

We're excited to finally see this FDA 510(k) clearance being announced.



Left: **Jeff Roberts**
Supervisor for Clinical Microbiology

Right: **Ben Cobb**
Lead Technician
Molecular Microbiology

References:

1. Hajjari ST, Gobena RK, Chauhan NM, Enriso F. Prevalence of Intestinal Parasite Infections and Their Associated Factors among Food Handlers Working in Selected Catering Establishments from Bule Hora, Ethiopia. *Biomed Res Int*. 2021 Aug 19;2021:6669742. doi: 10.1155/2021/6669742. PMID: 34458370; PMCID: PMC8397551.
2. United States Census Bureau. (2024) *State and World Population Clock*. <https://www.census.gov/popclock/>
3. Sandler RS, Everhart JE, Donowitz M, et al. The burden of selected digestive diseases in the United States. *Gastroenterology*. 2002;122:1500–
4. Amin DM. Seasonal prevalence of intestinal parasites in the United States during 2000. *Am J Trop Med Hyg*. 2002 Jun;66(6):799–803. doi: 10.4269/ajtmh.2002.66.799. PMID: 12224595.
5. Karpovs, Karl K., et al. "Results of Testing for Intestinal Parasites by State Diagnostic Laboratories, United States, 1987: Morbidity and Mortality Weekly Report: Surveillance Summaries, vol. 40, no. SS-4, 1991, pp. 25–JSTOR, <http://www.jstor.org/stable/24675438>. Accessed 28 May 2024.
6. Stark, D. (2023). *Genetic Signatures Webinar Series: Syndromic PCR testing for GI parasites including Dientamoeba fragilis and microsporidia, and their role in gastrointestinal disease*. <https://geneticsignatures.com/us/resource/advances-in-gastrointestinal-parasite-testing-molecular-detection-of-gi-parasites/>
7. Schmidt MA, Groom HC, Rawlings AM, Mattison CP, Salas SB, Burke RM, et al. Incidence, Etiology, and Healthcare Utilization for Acute Gastroenteritis in the Community, United States. *Emerg Infect Dis*. 2022;28(11):2234–2242. <https://doi.org/10.3201/eid2811.220247>
8. Sandler RS, Stewart WF, Liberman JN, Ricci JA, Zorich NL. Abdominal pain, bloating, and diarrhea in the United States: prevalence and impact. *Dig Dis Sci*. 2000 Jun;45(6):1166–71. doi: 10.1023/a:1005554103531. PMID: 10877233.
9. Centers for Disease Control and Prevention. (2024) *Traveler's Health*. <https://www.cdc.gov/travel/yellowbook/2024/posttravel-evaluation/persistent-diarrhea-in-returned-travelers>
10. Stark, D.; Barratt, J.; Ellis, J.; Harkness, J.; Marriott, D. Repeated Dientamoeba fragilis Infections: A Case Report of Two Families from Sydney, Australia. *Infect. Dis. Rep.* 2009, 1, e4. <https://doi.org/10.4081/idr.2009.1280>
11. Couturier, M. (2023). *Genetic Signatures Webinar Series: The Burden of Gastrointestinal Parasites and Advances in Ova and Parasite Diagnostic Screening*. <https://geneticsignatures.com/us/resource/molecular-op-webinar-1/>