SPRING 2014

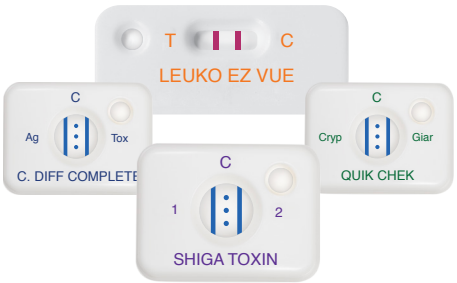
DIARRHEA DIGEST

SPECIAL 25TH ANNIVERSARY ISSUE

An irregular publication of TECHLAB,® Inc. dedicated to the etiology, diagnosis, and therapy of diarrheal diseases and related aspects of intestinal ecology

INSIDE

Brought to you by the makers of the enteric suite of rapid diagnostics



TECHLAB®

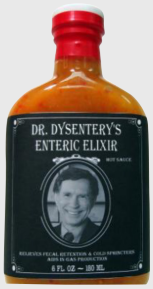
CELEBRATING 25 YEARS OF EXCELLENCE IN MEDICAL DIAGNOSTICS

diarrheadigest@techlab.com | www.techlab.com

Special 25th Anniversary Issue

Thanks for your support and specimens!

A brief history of 25 Years of TechLab (there are a lot of years missing --- we don't know what happened during those years)



Dr. Dysentery looks a lot like Dr. Tracy Wilkins (Cofounder, President until 2 years ago, and now CEO)

1989 – TechLab was incorporated by scientists from the Anaerobe Lab at Virginia Tech. Our work at the time focused on *C. difficile* disease (it still does) and microbiology of the gut. We brought two employees on board immediately --- they are still with us. If you've talked to TechLab over the years, you've probably talked to them.

1990 – Expanded to 2 labs and an office in the Virginia Tech Corporate Research Center and took on Contract Research while doing *C. difficile* research. We purchased much of our first equipment by one lump bid on items at a local scientific company going out of business --- we rented a U-Haul, went over and picked up the equipment. Autoclaves are very expensive but we got a good discount on our second one --- $300 for a stand-alone unit in great shape.

1991 – 1st issue of Diarrhea Digest; over the years, we routinely mailed each issue to about 2,000 clinical labs in the U.S. and about 300 labs overseas. We have now gone "green" and don't mail hard copies.

Our 1st FDA - cleared test - 1992

1992 – Started working with BioWhittaker Bioproducts, Inc. We had our first ELISA --- the *C. DIFFICILE TOX-A TEST* --- cleared for the market.

1995 – We began a long-term collaboration with Dr. William Petri at the University of Virginia because of our interest in intestinal parasites. That collaboration still continues (when we say long-term commitment, we mean it)

1997 – Started working with Wampole Laboratories because they bought our product line from BioWhittaker

2000 – TechLab celebrates a new millennium (apparently everyone else did too)

2002 – Started working with Inverness Medical Products because they bought Wampole

2003 – Made it to #2 on the list of "The Worst Jobs in Science" in the magazine based on the fact that we worked with feces. You should have seen the other "winners" on the list. Some of them we don't want to repeat; other jobs were not quite as harsh --- Brazil mosquito researcher, carcass cleaner for museums, hot zone superintendents for BL4 work, and interestingly, postdocs.

2007 – Inverness became Alere; our name has stayed the same all 25 years. You will see our brand name on the kits we produce.

2007-2008 - Started our Summer Internship Program to convince students that the intestine is exciting. Almost all of them have stayed in science --- bench microbiologists, professional schools in healthcare, clinical work, etc. --- we like to think we have stimulated their interest in science.

2013 – Received worldwide coverage on our *QUIK CHEK* format, a platform that was developed specifically for fecal testing. And we opened our new manufacturing facility in Radford, VA.

Our QUIK CHEK format

2014 – Two facilities in operation; R&D in Blacksburg, VA and Manufacturing in Radford, VA --- 125 employees

TECHLAB Research & Development 2014

TECHLAB Manufacturing 2014

Our 1st day working with fecal specimens

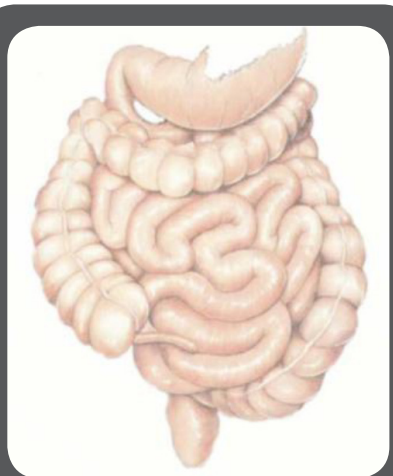
TECHLAB 1996 (the entire company)

TECHLAB®

#1 In The #2 Business

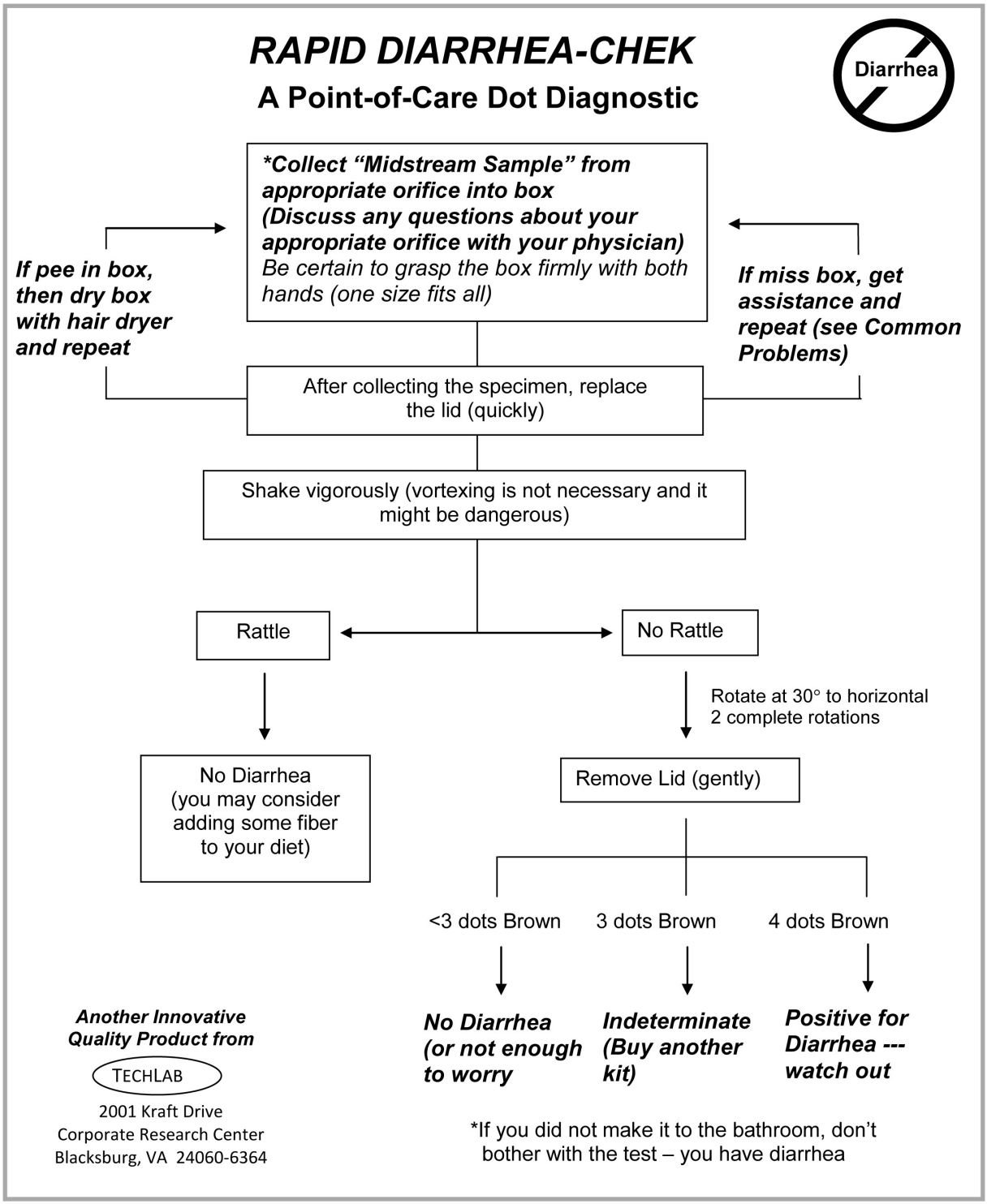
www.techlab.com

Our Workplace



Our TECHLAB Team 2014

Innovative Diarrhea Testing---
Why worry? Be sure with the new *DIARRHEA-CHEK! 100% accurate or you get a free kit!*



TECHLAB --- #1 in the #2 business!

SHIGA TOXIN QUIK CHEK - Development of a versatile rapid immunoassay for the detection of Shiga toxin producing *Escherichia coli* in fecal samples

"Prompt, accurate diagnosis of STEC infection is important because appropriate treatment early in the course of infection might decrease the risk for serious complications such as renal damage and improve overall patient outcome."

Mild. Moderate. Severe. From mild stomach cramps to bloody stools and life-threatening hemolytic uremic syndrome (HUS), the severity of Shiga toxin producing *Escherichia coli* (STEC) infections varies depending upon the STEC strain and the susceptibility of the patient. STEC produce either one or both Shiga toxins (Stx1 and/or Stx2), both potent cytotoxins, with strains producing only Stx2 (*e.g.* O157:H7) associated with higher risk of HUS. Historically, STEC infections and outbreaks were attributable to undercooked beef products, such as hamburger. However, as evidenced by the 1996 and 2011 outbreaks in Japan and Germany, respectively, raw produce can also serve as a vector for STEC. Cattle are reservoirs for STEC and shed the bacteria in their manure. As cow manure frequently comes into contact with produce both intentionally (organic fertilizer) and unintentionally (pasture runoff), outbreaks linked to produce will most likely continue. The Japanese outbreak was linked to a classic O157:H7 strain in contaminated radish sprouts, but the culprit in the German sprout outbreak was an atypical O104:H4 strain that lacked many of the virulence factors usually associated with highly virulent STEC. The one trait associated with all STEC strains is the production of at least one Shiga toxin. By detecting the toxins, STEC positive samples can be identified regardless of the serotype or phenotype.

Fast. Accurate. Flexible. Three characteristics desired in any diagnostic assay, including those for STEC. The CDC *Recommendations for Diagnosis of Shiga Toxin--Producing Escherichia coli Infections by Clinical Laboratories states* that:

When developing the *SHIGA TOXIN QUIK CHEK*, the goal was to design a test that provided physicians with accurate information as soon as possible so that an appropriate treatment plan could be implemented. Historically, when a clinical laboratory receives a stool specimen for STEC testing, an overnight enrichment broth culture is first performed, and the following day the culture is tested for the presence of Shiga toxin. Rapid diagnosis of STEC infections is crucial, as inappropriate use of antibiotics and anti-motility agents increases the risk of the disease progressing to HUS as much as six-fold. Direct fecal testing provides the physician with vital information (presence or absence of Shiga toxin) a day sooner than methods requiring overnight culture. Furthermore, since not all samples grow when cultured, direct fecal testing avoids reporting of ambiguous results of "no growth" which may be falsely interpreted as negative. Should traditional culture testing be desired though, the flexibility of the *SHIGA TOXIN QUIK CHEK* allows for broth and plate culture samples as well.

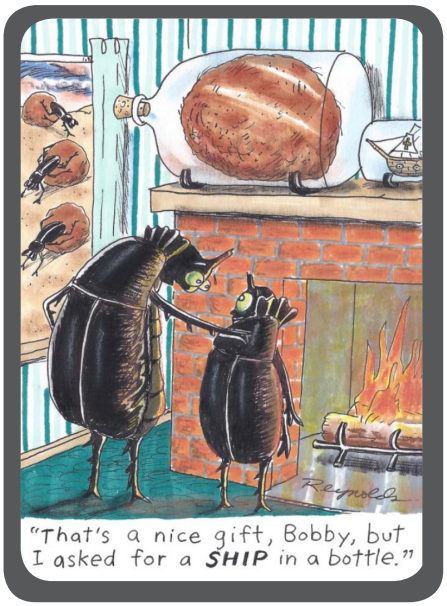
The Vero cell cytotoxicity neutralization assay is considered the reference standard for detection of Shiga toxin in fecal samples because of its ability to detect picogram amounts of toxin. While extremely sensitive, it is laborious and results are not available for 48-72 hours.

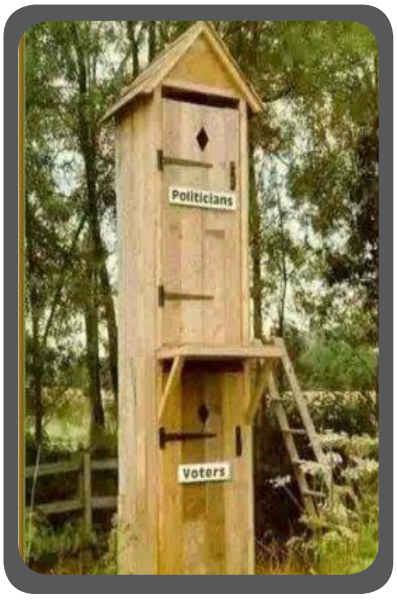
To obtain the same level of sensitivity as the Vero cell assay, the proven *QUIK CHEK* format was chosen. Highly specific antibodies combined with the signal amplification of horseradish peroxidase and an ultra-sensitive TMB substrate provides a level of sensitivity not obtainable with traditional lateral flow methods.

In a recent clinical study, 531 patient samples were tested directly (without culture) for the presence of Shiga toxin with both the *SHIGA TOXIN QUIK CHEK* and a Vero cell cytotoxicity neutralization assay. The *SHIGA TOXIN QUIK CHEK* correlated 100% with the Vero cell assay, detecting all 9 positive samples identified by the Vero cell assay. When broth cultures of the same 9 positive samples were tested, however, only 7 were detected by the Vero cell assay and the *QUIK CHEK*. Direct fecal testing detected 2 samples that would have been missed if only fecal broth culture testing had been performed, suggesting fecal broth cultures may not always accurately reflect in vivo Shiga toxin production in patients infected with STEC.

A variety of factors beyond the scope of this article could explain differences between *in vivo* and *in vitro* Shiga toxin production by STEC. Depending upon the scenario (patient symptoms, severity, history, etc.) there are valid roles for both direct fecal and broth culture testing for Shiga toxin.

In summary, the *SHIGA TOXIN QUIK CHEK* is fast, accurate, and flexible. It combines the speed and simplicity of a rapid test with the sensitivity and specificity of a Vero cell assay. Combined with the option of testing fecal samples directly as well as cultures, the *SHIGA TOXIN QUIK CHEK* provides the flexibility to meet the needs of any laboratory, physician, or clinical scenario.





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Lytle, MB. How does a False Negative EHEC test result put your hospital and your patients at RISK? Webinar March 27 2014.

Distinguishing inflammatory bowel disease (IBD) from irritable bowel syndrome (IBS) --- more reliable than ever with fecal lactoferrin for gut inflammation

Two formats help distinguish IBD from IBS. The *IBD-SCAN*® is a quantitative ELISA for measuring concentrations of fecal lactoferrin. The *IBD EZ VUE*® test is a simple-to-use immunochromatographic test for qualitative detection of elevated fecal lactoferrin.

See what the experts are saying ...

"Fecal lactoferrin is sensitive and specific for detecting inflammation in chronic IBD."
Fecal lactoferrin is a sensitive and specific marker in identifying intestinal inflammation. S Kane, W Sandborn, P Rufo, A Zholudev, J Boone, D Lyerly, M Camilleri, and S Hanauer. 2003. Am J Gastro 98:6. 1309-1314.

"Lactoferrin can be detected using simple and cheap techniques and it has excellent stability in feces over a long period of time."
Questions and Answers on the role of fecal lactoferrin as a biological marker in inflammatory bowel disease. J Gisbert, A McNicholl, and F Gomollon. 2009. Inflamm Bowel Dis 1-9.

"Fecal calprotectin and fecal lactoferrin correlate closely with disease activity in UC and CD, and are useful objective biomarkers of mucosal healing and monitoring of the treatment response."
Diagnostic and prognostics of inflammatory bowel disease with fecal neutrophil-derivied biomarkers calprotectin and lactoferrin. T Sipponen. 2013. Dis Di 31. 336-344.

"Lactoferrin is useful to differentiate between IBD and IBS, and can be used as an adjunct to blood parameters to determine IBD patients who have ongoing inflammation."
Faecal lactoferrin – a novel test to differentiate between the irritable and inflamed bowel? R Sidhu, P Wilson, A Wright, C Yau, F D'Cruz, L Foye, S Morley, A Lobo, M Mcalindon and D Sanders. 2010. Aliment Pharmacol Ther 37. 1365-1370.

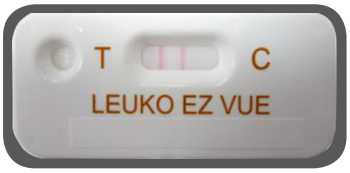
"The tests are inexpensive, reliable and are more accurate at predicting clinical disease activity than serum markers of inflammation or endoscopic appearance."
Faecal calprotectin or lactoferrin can identify postoperative recurrence in Crohn's disease. C Lamb, M Mohiuddin, J Gicquel, D Neely, F Bergin, J Hanson, and J Mansfield. 2009. British Journal of Surgery 96:663-674.

"These tests are safe, simple, and noninvasive markers of intestinal inflammation in children with active IBD."
Fecal calprotectin and lactoferrin as noninvasive markers of pediatric inflammatory bowel disease. M Joishy, I Davies, M Ahmed, J Wassel, K Davies, A Sayers, and H Jenkins. 2008. J Pediatr gastroenterol Nutr. 48:1. 48-54.

"Firstly, fecal lactoferrin and calprotectin are sensitive and specific markers for the detection of intestinal inflammation in IBD patients."
Inflammatory bowel disease activity assessed by fecal calprotectin and lactoferrin: correlation with laboratory parameters, clinical, endoscopic and histological indexes. A Viera, C Fang, E G Rolim, W Klug, F Steinwurz, L Rossini, and P Candelaria. 2009. BMC 2:221. 1-7.

"The PhiCal Test and IBD-SCAN are highly accurate for discrimination IBD from IBS."
Discriminating IBD from IBS: Comparison of test performance of fecal markers, blood leukocytes, CRP, and IBD antibodies. M Schoepfer, P Trummler, B Seeholzer, B Seibold-Schmid, and F Seibold. 2007. Inflamm Bowel Dis. 14:1. 32-39.

LEUKO EZ VUE™ --- easier and more sensitive than microscopy for fecal leukocytes



Diarrheal diseases represent one of the primary causes of morbidity throughout the world. They are caused by many different pathogens --- viruses (rotavirus, norovirus, enteric adenoviruses), bacteria (enterotoxigenic *E. coli, Shigella, Salmonella, Campylobacter,* and toxigenic *Clostridium difficile*), and parasites (*Giardia, Cryptosporidium*, and *Entamoeba histolytica*).

Diarrheal diseases can be classified into inflammatory and non-inflammatory diarrhea. Non-inflammatory diarrheas typically include those caused by viruses and parasites (although dysentery caused by *E. histolytica* is inflammatory). These often can be treated with simple oral rehydration therapy. Inflammatory diarrheas, on the other hand, tend to be more serious and need to be followed up by more extensive testing. This type of diarrhea is caused by pathogens such as *Shigella, Salmonella, Campylobacter jejuni*, and *C. difficile*, and leukocytes are found in feces in large numbers. Many clinical labs determine the presence of fecal leukocytes by microscopy, thus confirming inflammatory diarrhea and the need for additional testing. However, microscopy has several major disadvantages. These are overcome by fecal lactoferrin testing.

With microscopy, a primary concern is the stability of leukocytes. In a study by May et al., the authors concluded that a significant number of specimens were false negative due to possible degeneration of cells. In another study by Granville et al. involving patients with inflammatory gastrointestinal (GI) diseases (breached mucosa with enteric infections, intestinal inflammation, bloody stool and acute vascular insufficiency etc.) versus those with noninflammatory causes (no lower GI disease, impaction, IBS, constipation etc.), only 32% of patients with infectious gastroenteritis were positive. In addition, there were patients with endoscopy-confirmed intestinal inflammation who were negative for leukocytes by microscopy. The fecal lactoferrin assay avoids false negative results because lactoferrin is not degraded during transit time in the bowel or during infection by toxins of pathogens such as *C. difficile*.

Microscopy	Fecal Lactoferrin
Not standardized	Highly standardized with FDA-cleared test
Specimens must be examined within minutes of collection due to instability of leukocytes	Fecal lactoferrin is very stable in feces and specimens can be tested days after collection
Difficult to interpret; requires expertise in microscopy	Easy to read results --- the presence of a visible line indicates inflammation

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Granville, L A, Cernoch, P, Land, GA and JR Davis. 2004. Performance Assessment of the Fecal Leukocyte test for Inpatients. J. Clin. Microbiol. 42:1254-1256.

NEW ARTICLES: *Recent results show that C. difficile 027 causes severe infections*

Boone, J et al. 2013. Elevated lactoferrin is associated with moderate to severe *Clostridium difficile* disease, stool toxin, and 027 infection. Eur. J. Clin. Microbiol. Infect. Dise 32:1517-1523.

See, I et al. 2014. NAP1 strain type predicts outcomes from *Clostridium difficile* infection. Clin. Infect. Dis. Advance Access published March 5, 2014.

STOOL NOTES

Headline News

Australian company sells $1.3M 22-karat gold toilet paper *BY LEE MORAN*

Baby-poop bacteria help make healthy sausages *By Charles Q Choi*

AirPnP rent-out-your-toilet app launched for Mardi Gras *BBC News*

Thank Your Gut Bacteria For Making Chocolate Healthful *by MICHAELEEN DOUCLEFF*

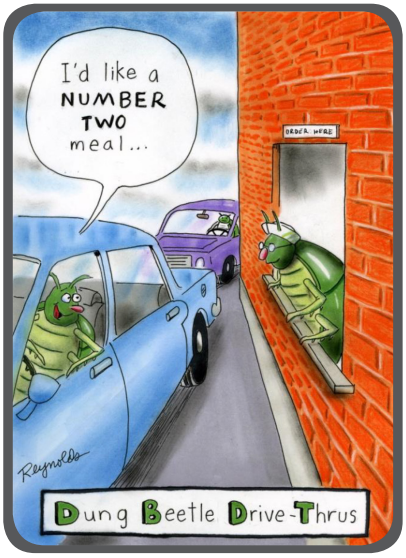
Beer brewed from coffee beans pooped by elephants sells out in 1 day
Stories *on Dashboard*

Norwegian hunter misses moose, shoots man on toilet (P.S., the man on the toilet is probably ticked off but he's ok) *by Reuters*

North-east woman decorates dog poo with strawberries and cream *Evening Express*

Inca success in Peruvian Andes "thanks to llama dung" *by Caroline Anning BBC News*

New world record for world's fastest toilet on wheels *BBC News*



I take Aspirin for the headache caused by the Zyrtec I take for the hayfever I got from Relenza for the uneasy stomach from the Ritalin I take for the short attention span caused by the Scopoderm TSS I take for the motion sickness I got from the Lomotil I take for the diarrhea caused by the Xenical for the uncontrolled weight gain from the Paxil I take for the anxiety from Zocor I take for my high cholesterol because exercise and a good diet are just too much trouble.

Randy Chestnut, *stand-up comedian, writer, and actor*

Jerry Seinfeld made it clear: "Dogs are the leaders of the planet. If you see two life forms, one of them's making a poop, the other one's carrying it for him, who would you assume is in charge?"

ENTERIC PARASITE QUIK CHEKs --- developing rapid immunoassays specific for the three most prevalent enteric protozoan parasites – Giardia, Cryptosporidium and Entamoeba histolytica

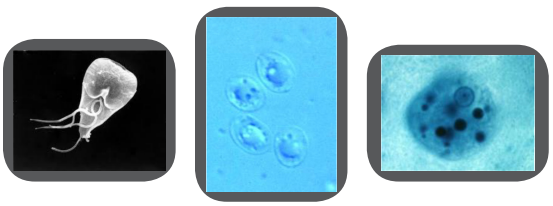
THE BIG THREE PARASITES. The enteric protozoa *Giardia* spp., *Cryptosporidium* spp., and *Entamoeba histolytica* share the characteristics of food and water-borne transmission, a low infectious dose, and environmental stability. *Giardia* is most common, *Cryptosporidium* stands out as an important cause of chronic diarrhea without effective treatment in AIDS patients, and *E. histolytica* infections can be lethal. The oocyst of *Cryptosporidium* is resistant to the levels of chlorine used in drinking and recreational water; *E. histolytica* and *Giardia* are less resistant, but also cause drinking water epidemics[1,2]. The National Institute of Allergy and Infectious Disease Blue Ribbon Panel on Biodefense Agents B&C considered these three organisms the highest priority biodefense parasites[3].

Giardia – 9.5 cases/100,000 USA population. *Giardia* is the most common parasite identified in stool samples of individuals in the US, present in about 4-7% of stool specimens submitted to clinical laboratories for parasite testing[4]. It is also the most common pathogenic cause of acute diarrhea in returning travelers worldwide[5], being implicated as the cause of 44% of waterborne outbreaks with a defined pathogenic origin[4].

Cryptosporidium – 1.4 cases/100,000 USA population. *Cryptosporidium* parvum and *C. hominis* are the predominant causes of *Cryptosporidiosis* in humans; both species are detected by TechLab's *Cryptosporidium* immunoassays[6]. A 2013 global multicenter study utilized the TechLab enteric parasite immunoassays to describe *Cryptosporidium* as a leading cause of moderate to severe diarrhea and death in children under five in low resource settings[7].

Entamoeba histolytica – 1.2 cases/100,000 USA population. *Entamoeba histolytica* causes 27% of acute diarrheal cases in returning travelers worldwide[5], and is seen in the U.S. among immigrants from developing countries[8]. Critical to *E. histolytica* diagnosis is differentiation from colonization by non-pathogenic *Entamoeba* spp. such as *E. dispar*, which is 3-fold to 10-fold more common than *E. histolytica* infection. TechLab is the only manufacturer to develop *Entamoeba* immunoassays specific for pathogenic *E. histolytica*[8,9].

DETECTING THE BIG THREE. The traditional screening test, light microscopic ova and parasite (O&P) exam of stool, is laborious, requires expertly trained personnel, and suffers from poor sensitivity and specificity. This is especially a concern because there is a worsening shortage of technical personnel trained to perform parasitologic diagnostic procedures in clinical laboratories[10]. Immunofluorescent microscopy has become a recognized gold standard due to its improved sensitivity and specificity. However, the technique is expensive, time consuming, and requires highly trained personnel.



Diagnosis of giardiasis by light microscopy is insensitive, requiring analysis of 3 consecutive specimens to approach 90% sensitivity[4]. Identification of cryptosporidiosis uses labor-intensive and insensitive acid-fast staining techniques shown to have a 2-fold to 80-fold higher limit-of-detection (oocysts/g stool) than immunoassays depending on fecal consistency[4]. The diagnosis of intestinal amebiasis by

microscopy in community hospital labs can approach 10% sensitivity, and false positive results occur due to misidentification of the morphologically-identical and non-pathogenic *E. dispar*[11]. One study demonstrated that microscopy for *Entamoeba histolytica* was only 9.5% specific due to the prevalence of non-pathogenic *Entamoeba* species[12]. Due to logistical and performance issues with traditional O&P microscopic examination of stool, detection of parasite antigen in stool by enzyme immunoassay is the current diagnostic method of choice[10,13].

Techlab's *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK* test is a rapid membrane enzyme immunoassay for the simultaneous qualitative detection and differentiation of *Giardia* cyst antigen and *Cryptosporidium* oocyst antigen in a single test device. It is intended for use with human fecal specimens from patients with gastrointestinal symptoms to aid in the diagnosis of *Giardia* and/or *Cryptosporidium* gastrointestinal infection. *The GIARDIA/CRYPTOSPORIDIUM QUIK CHEK* demonstrated >99% correlation to microwell ELISA and immunofluorescence microscopy with fresh, frozen and preserved specimens during clinical evaluations at 3 international testing sites. In an independent evaluation compared to ELISA and real time PCR, the *GIARDIA/CRYPTOSPORIDIUM QUIK CHEK* provided superior performance to other *Giardia/Cryptosporidium* rapid assays[14].

Techlab's *E. HISTOLYTICA QUIK CHEK* test is a rapid membrane enzyme immunoassay for the specific identification of *E. histolytica* antigen. It is intended for use with human fecal specimens from patients with gastrointestinal symptoms to aid in the specific diagnosis of *E. histolytica* gastrointestinal infection. Techlabs *E. histolytica* tests are the only immunoassays available worldwide for the specific detection of *E. histolytica*[8,9]. Other *Entamoeba* tests cross-react with non-pathogenic *Entamoeba* species. In clinical testing, the *E. HISTOLYTICA QUIK CHEK* demonstrated 100% correlation with microwell ELISA[15].

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Clostridium difficile Testing: Still Challenging

In 2003, we wrote a minireview for the Journal of *Clinical Microbiology* entitled "*Clostridium difficile* testing: after 20 years, still challenging". At the time of the article, disease-causing atypical strains that produced only toxin B had been characterized by us and by others. These atypical strains carried a nonexpressed truncated part of the toxin A gene and produced a toxin B molecule that was more toxic than toxin B that had been characterized. In the article, we stated the importance of using tests that detected both toxin A and toxin B instead of toxin A-only tests so that these strains would not be missed. Little did any of us realize at the time that a new ribotype --- 027 --- was in the process of creating havoc for healthcare. Ribotype 027 produced a typical toxin A and toxin B, so in this regard, it wasn't too different. But it also carried the genes for a third toxin designated binary toxin. Binary toxin had been described in the early

1990s but no one knew its clinical significance --- we still don't. In addition, this strain was resistant tofluoroquinolones, a trait very much responsible for its rapid spread in hospitals.

Now let's jump to 2014. Because of 027, *C.difficile* has leapfrogged over MRSA as the primary hospital-acquired infection. It now is associated with community-acquired disease. It can cause disease in children, something that was (and still is) questionable due to the fact that so many healthy infants carry toxigenic *C.difficile*. And in the U.S., there are more cases of *C. difficile* disease than ever. On the bright side, we have a greater variety of tests at our disposal, so the technology has advanced since 2003. But the basic challenge we brought forward in our 2003 minireview still remains --- how to tell if *C. difficile* is causing the diarrhea in a *C. difficile*-positive patient? "C. diff" has become a household name and an oversimplification is to conclude that if the organism is present, it is the cause of diarrhea.

This disease is far from a simple "presence of organism equals disease". *C. difficile* is the most commonly *recognized* cause of antibiotic associated diarrhea (AAD) --- but as a reality check, we don't know what causes the majority of AADs. What makes the diagnosis of this disease so challenging is this --- anytime the normal flora is disrupted, whether it's by antibiotics, laxatives, norovirus infections, or whatever, and the person is around *C. difficile* spores, there is the risk of becoming infected. This is the reason why the rates are so high in hospitals. It's also the reason why *C. difficile* is present in healthy infants (i.e., until their flora gets established), healthy patients in hospitals ("carriers" who pick up the spores), and is carried transiently in non-*C. difficile* diarrheas (disrupted flora). This is why lab tests need to be used as their "Intended Use" states --- in vitro diagnostic aids to be used in conjunction with patient history.

For these reasons, tests that detect glutamate dehydrogenase (GDH) and toxin produced by *C.difficile* actively growing in the intestine are very accurate. This algorithm approach has been supported by recent studies in the United Kingdom showing that lab tests for GDH and especially toxin provide an accurate assessment of *C. difficile*-caused diarrhea. In addition to lab tests for *C. difficile* analytes and as part of improving patient healthcare, there needs to be an emphasis on better ways to assess disease severity because not every *C. difficile* patient needs to be treated with more antibiotics. In this regard, we believe that tests for intestinal inflammation can help identify *C. difficile* patients who have moderate to severe disease and need prompt therapy.

Back in 2003, we felt that the title of our minireview was very appropriate due to "new" *C. difficile* challenges --- it still is.

C. DIFF QUIK CHEK COMPLETE®

- Guidelines now recommend GDH screening in combination with toxin testing to improve sensitivity.
- The *C. DIFF QUIK CHEK COMPLETE®* test is the only device that simultaneously detects both GDH antigen and Toxins A & B.
- Algorithm testing provides a more complete diagnostic picture than molecular testing alone because antigen and toxins are detected.
- Sensitivity and Negative Predictive Value (NPV) of GDH are equivalent to PCR when compared to cytotoxicity or toxigenic culture.
- **99.8%** NPV gives you confidence that negative results are accurate.
- Approximately **90%** of samples can be reported in < 30 min.


#1
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