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NONINVASIVE TESTS FOR FECAL LACTOFERRIN DIFFERENTIATE IBD FROM IBS

Inflammatory bowel disease (IBD), which includes ulcerative colitis (UC) and Crohn's disease (CD), affects as many as 600,000 people in the U.S. each year. Irritable bowel syndrome (IBS) affects up to 20% of the population. In fact, IBS is second only to the common cold as the reason for most physician office visits in the U.S (*1*).

IBS is characterized by a cluster of symptoms, such as abdominal pain, bloating, cramping, and alternating bouts of diarrhea and constipation. Although symptoms of IBD and IBS are similar, IBS is a noninflammatory disorder. In the past, clinicians diagnosed IBS according to symptom-based criteria. Unfortunately, with that diagnostic method, patients awaiting a diagnosis often suffered for years. Now, with the **TechLab®**'s **IBD-CHEK®** test, IBS can be diagnosed qualitatively in a matter of days. The **IBD-SCAN®** test is a quantitative assay that can be used to determine the level of inflammation and, subsequently, the effectiveness of therapy.

Why Choose Lactoferrin as a Fecal Biomarker?

Fecal lactoferrin is a stable protein secreted by the mucosa and contained within the azurophilic granules of neutrophils. Lactoferrin is bactericidal because of its iron-binding properties, and thus, is one of the body's defense mechanisms and an excellent marker of inflammation. An infection or chronic condition such as CD and UC can cause intestinal inflammation, as can microbes such as *Clostridium difficile, Salmonella, Shigella, Giardia, Entamoeba histolytica.* If those bacteria have been ruled out, a positive *IBD-CHEK* test result (fecal lactoferrin is present) indicates that the patient has IBD, and not IBS. A negative test result indicates that the patient has IBS.

Currently, the *IBD-CHEK* and the *IBD-SCAN* are the only FDA-cleared laboratory tests available for determining active IBD versus active IBS. Other tests, such as erythrocyte sedimentation rate or C-reactive protein, are not specific or sensitive for determining intestinal inflammation. Serological tests, such as pANCA and ASCA can be useful in distinguishing CD from UC, but their low sensitivities (e.g., 23%–41%) prohibit their use as an initial screen for determining IBD versus IBS.

Studies Show the Effectiveness of *IBD-CHEK* and *IBD-SCAN*

A multicenter study conducted at the University of Chicago, the Mayo Clinic, and Children's Hospital in Boston evaluated

the sensitivity and specificity of the *IBD-CHEK* in detecting fecal lactoferrin levels in patients with UC (n = 80), CD (n = 104), or IBS (n = 31), and healthy controls (n = 56) (*2*). The researchers found that fecal lactoferrin was 90% specific for identifying inflammation in patients with active IBD and that elevated fecal lactoferrin without an infectious cause was 100% specific in ruling out IBS. They concluded that elevated levels of fecal lactoferrin are predictive of intestinal inflammation and can be used to select patients with chronic abdominal pain and diarrhea of unknown origin for further colonoscopy.

Lead researcher Mansour Parsi, MD, and his team within the Department of Gastroenterology at the Cleveland Clinic examined 60 consecutive adult IBD patients who had undergone ileal pouch-anal anastomosis. They reported increased frequency of bowel movements, urgency, and abdominal pain (*3*). Dr. Parsi and his colleagues reported that symptomatic patients with endoscopically proven pouch inflammation had significantly higher levels of fecal lactoferrin than those with irritable pouch syndrome (IPS). They concluded, "If fecal lactoferrin levels are low, IPS can be diagnosed; if fecal lactoferrin is high, pouch endoscopy with biopsy is warranted to distinguish among different causes of inflammation."

Stephan Buderus, MD, at the University Children's Medical Center (Bonn, Germany), quantitatively measured fecal lactoferrin levels as a marker of therapeutic response following infliximab therapy in pediatric patients with severe CD (*4*). The study

showed that fecal lactoferrin decreases quickly after clinically successful treatment with infliximab in children with severe CD. Dr. Buderus and his colleagues concluded that monitoring the fecal lactoferrin levels of patients with IBD will allow physicians to "optimize the choice of invasive diagnostic procedures and to adjust drug dosing with the aim to tailor effective anti-inflammatory therapy." Given that approximately 1 million people in the U.S. suffer from CD and that the available therapies are very expensive, the ability of the *IBD-CHEK* to assess the effectiveness of pharmacologic therapy should reduce patient suffering and healthcare costs dramatically.

TechLab®, Inc. develops, manufactures, and distributes intestinal diagnostics worldwide, while retaining an emphasis on science and collaborations with universities. Products are focused in the areas of intestinal inflammation, antibiotic-associated diarrhea, and parasitology.

For more information concerning *IBD-CHEK* and *IBD-SCAN*, and a list of reference labs that perform the tests please call at 1-800-TECHLAB, or visit the company's Web site at www.techlab.com.

References:

1. Coulie, B, Camilleri, M. Irritable Bowel Syndrome. *Clin. Perspectives in Gastroenterology.* November/December 1999; 329-338.
2. Kane SV, Sandborn WJ, Rufo PA, *et al*. *Am J Gastroenterol* 2003;98:1309-14.
3. Parsi MA, Shen B, Achkar JP *et al*. *Gastroenterol* 2004;126:1280-86.
4. Buderus S, Boone J, Lyerly D, *et al*. *Dig Dis Sci*, 2004;49:1036-39.