

A simple stool sample
can **speak volumes** on
intestinal inflammation



Get a reliable first read on intestinal inflammation with
LACTOFERRIN TESTING

NON-INVASIVE • SENSITIVE • SPECIFIC • COST-EFFECTIVE



Brought to you by the developers of the trusted
C. DIFF QUIK CHEK COMPLETE® test



PROVEN PERFORMANCE IN
GI DISEASE DIAGNOSTICS

Lactoferrin: a highly reliable marker of intestinal inflammation

What is lactoferrin?

Lactoferrin is a protein found in fecal leukocytes, also known as white blood cells. When there is inflammation in the intestines, leukocytes are shed into the stool. Numerous clinical studies over the last decade have established that fecal lactoferrin levels closely correlate with levels of intestinal inflammation. Elevated lactoferrin, therefore, is a biomarker for fecal leukocytes and a highly reliable indicator of intestinal inflammation.

What conditions can lactoferrin help to identify?

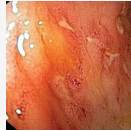
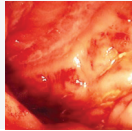
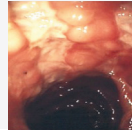
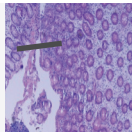
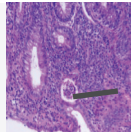
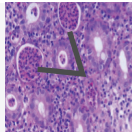
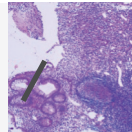
Many different conditions cause inflammation, but two diseases, in particular, are often associated with intestinal inflammation: **Inflammatory Bowel Disease (IBD)** and **Clostridium difficile disease/infection (CDI)**. IBD is the primary cause of noninfectious intestinal inflammation and can be difficult to distinguish from other intestinal disorders, especially **Irritable Bowel Syndrome (IBS)**. CDI is the primary cause of infectious intestinal inflammation. IBD and CDI are often found together in a single patient. Assessing fecal lactoferrin by means of a simple stool sample provides clinicians with a non-invasive yet reliable way to initially assess the inflammation status of their patients, and to determine if further testing is needed.

For disorders involving intestinal inflammation, the **treat to target** objective is mucosal healing.

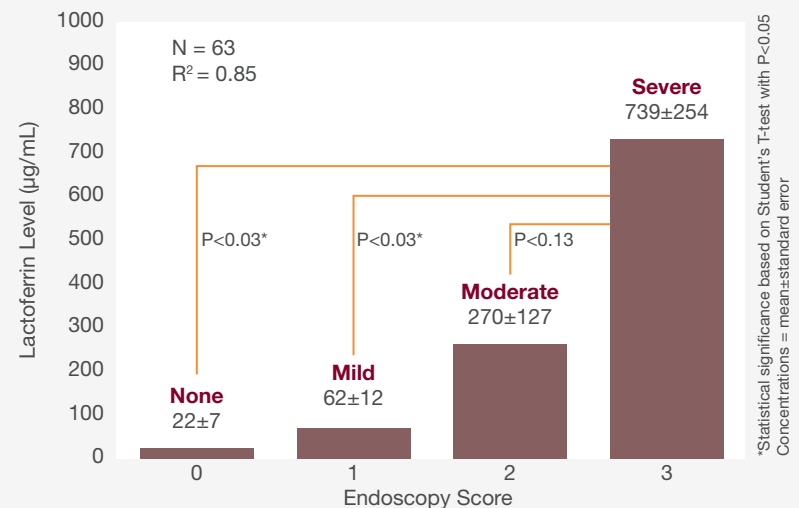


The science behind the biomarker: Lactoferrin levels parallel inflammation

Endoscopic Pictures (top) & Histologic Slides (bottom) of Intestines

No acute inflammation Score = 0	Mild inflammation Score = 1	Moderate inflammation Score = 2	Severe inflammation Score = 3
			
Mean lactoferrin = 22 ± 7 $\mu\text{g/mL}$	Mean lactoferrin = 62 ± 12 $\mu\text{g/mL}$	Mean lactoferrin = 270 ± 127 $\mu\text{g/mL}$	Mean lactoferrin = 739 ± 254 $\mu\text{g/mL}$
			
Mag = 50x Asymmetric crypt architecture	Mag = 400x A single crypt abscess	Mag = 250x Frequent crypt abscesses	Mag = 50x Greater neutrophil infiltration into the lamina propria

Correlation of Lactoferrin Levels to Endoscopy Score for Intestinal Inflammation



Lactoferrin testing provides a first read on IBS/IBD

Suspected IBS/IBD patient

Detecting elevated lactoferrin levels can help to differentiate active IBD from IBS.

Intestinal inflammation distinguishes active Inflammatory Bowel Disease (IBD) from Irritable Bowel Syndrome (IBS). A positive test result for elevated fecal lactoferrin in persons who have tested negative for infectious etiologies should alert the physician to possible IBD, which warrants further testing. A negative result may signal a functional disorder like IBS, which is non-inflammatory.



Diagnosed IBD patient

Measuring lactoferrin levels can help to indicate the degree of IBD severity.

Levels of fecal lactoferrin correlate with levels of IBD activity and may be used as an indicator of mucosal healing. Lactoferrin levels can also help to predict IBD relapse and help to guide IBD treatment decisions.



Lactoferrin was the first United States FDA-cleared non-invasive biomarker to aid in the **differentiation of active IBD from IBS.**



Lactoferrin testing also gives insight into *C. difficile*

Suspected *C. difficile* patient

Detecting elevated lactoferrin levels can help to confirm the diagnosis of true CDI.

Toxins A and B are the primary diagnostic targets for *C. difficile* infection (CDI) and both toxins elicit a strong leukocyte response during infection. Elevated lactoferrin is a biomarker for fecal leukocytes and an indicator of intestinal inflammation. Knowing whether a patient has intestinal inflammation, therefore, can be useful when assessing for true *C. difficile* infection.



Diagnosed *C. difficile* patient

Measuring lactoferrin levels can help to indicate the degree of CDI severity.

C. difficile disease presents with a range of severity levels, ranging from mild to severe. Treatment usually includes metronidazole, for mild cases, and vancomycin, fidaxomicin and fecal microbiome transplant (FMT) for more severe cases. Stratifying patients for disease severity can be difficult in elderly patients who have comorbid disease. Studies have shown that more severe disease includes higher WBC counts, low serum albumin, and higher lactoferrin levels. Lactoferrin levels can help determine severity of disease for targeting and optimizing treatment.



OF PARTICULAR BENEFIT

Lactoferrin in pediatric IBD care

Approximately 20% of IBD patients are diagnosed in childhood, yet many methods of monitoring IBD activity are difficult for both the parents and the child. Parents may be reluctant for their child to undergo repeated colonoscopy given the perceived risk of the procedure. Routine laboratory measurement of serum biomarkers requires phlebotomy which is invasive and often provokes severe anxiety. Several clinical indices are dependent on the patient being able to describe their symptoms. Patients less than five years of age may not be able to communicate symptoms such as abdominal discomfort.

Lactoferrin testing is a non-invasive approach that causes less stress for parents and children and offers a sensitive and specific indicator of active disease.



Lactoferrin in obstetric IBD care

IBD is most often diagnosed in the second through fourth decades of life—a period that coincides with likely childbearing years for female patients. Twenty-five percent of patients conceive for the first time after their diagnosis. Pregnancy with IBD, however, can be challenging. Research indicates that women with IBD are at higher risk for developing gestational diabetes, delivering preterm, and requiring cesarean section. The majority of patients with active disease will continue to have it throughout pregnancy, yet some IBD medications are contraindicated during gestation, making treatment more difficult. To ensure a successful pregnancy, close monitoring and management of IBD during the conception period and pregnancy is therefore essential. **Lactoferrin testing can help to non-invasively monitor disease activity and guide treatment decisions for women during this time.**

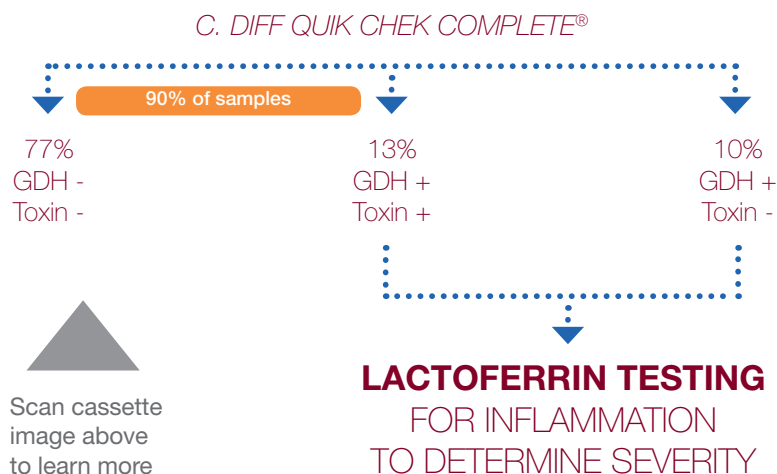
Introducing a **comprehensive algorithm** for *C. difficile* testing



**LACTOFERRIN
TESTING**
for Inflammation



Testing Algorithm



Scan cassette
image above
to learn more
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QUIK CHEK
COMPLETE*[®]

***C. DIFF QUIK CHEK COMPLETE*[®] plus lactoferrin testing
is a winning combination for more effective CDI treatment.**

Clostridium difficile infection involves a range of clinical presentations—from mild, self-limiting diarrhea to life-threatening pseudomembranous colitis and megacolon. Moderate to severe CDI cases require early identification for better outcomes and decreased mortality, especially among the elderly.

To achieve this, studies support the routine determination of both the presence of stool toxin and the degree of intestinal inflammation as an indicator of disease severity in CDI patients. Adding lactoferrin testing for intestinal inflammation to *C. DIFF QUIK CHEK COMPLETE*[®] testing for stool toxin provides a comprehensive algorithm for assessing CDI. Together, these tests quickly, easily, and non-invasively confirm true CDI and reveal the severity of infection, enabling clinicians to better manage their most vulnerable CDI patients.

Lactoferrin testing provides a number of clinical benefits

Lactoferrin testing is reliable.

Elevated levels of lactoferrin have been proven to correlate with endoscopic and histologic patterns of intestinal inflammation. Lactoferrin is stable in feces for up to 2 weeks at room temperature and for much longer periods at $\leq -20^{\circ}\text{C}$. It is the most stable fecal biomarker available for intestinal inflammation, and is more reliable than microscopy for detecting fecal leukocytes since it does not rely on intact leukocytes (which degrade in stool within hours).

Lactoferrin testing is non-invasive.

Lactoferrin testing relies only on a fecal sample and thus reduces patient anxiety about having to submit to more invasive procedures. It provides a patient-friendly first read on inflammation and helps to rapidly identify those relatively few patients who will warrant further investigation. Avoiding unnecessary endoscopy in pediatric patients, who usually require deep sedation or anesthesia for the procedure, is particularly beneficial. Lactoferrin testing is also very well-suited to pregnant women seeking non-invasive methods.

Lactoferrin testing is sensitive and specific.

Lactoferrin testing has a sensitivity of 81.5 and a specificity of 96.5. Unlike, white blood cell count, it is specific to intestinal inflammation.

Lactoferrin testing is cost-effective.

By ruling out active IBD, lactoferrin testing helps to prevent unnecessary endoscopy, resulting in significant cost savings for both the patient and the health system. It also prevents unnecessary or mistargeted antibiotic use for suspected *C. difficile* patients.



Lactoferrin testing can make the diagnosis and treatment of IBS, IBD, and CDI much **quicker and easier for you and your patient.**

Lactoferrin testing is available in two formats to fit your needs

1 QUALITATIVE TESTING

Qualitative lactoferrin testing provides a **positive or negative** result for elevated levels of fecal lactoferrin. It can rapidly and non-invasively:

- Distinguish between patients with IBS and active IBD.
- Identify IBD patients with active inflammation.
- Provide convenient results for smaller clinics with appropriately-licensed in-house labs.

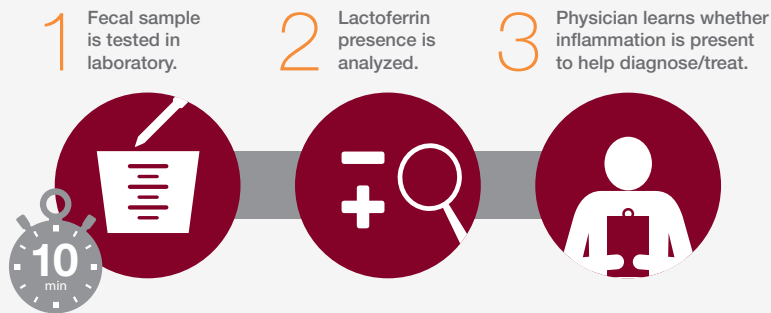


2 QUANTITATIVE TESTING

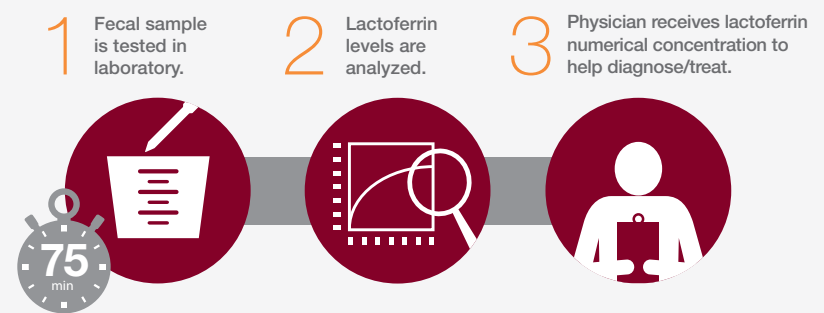
Quantitative lactoferrin testing provides a **quantitative measurement** of fecal lactoferrin. It helps to quickly and non-invasively:

- Distinguish between patients with IBS and active IBD.
- Assess inflammation levels during IBD treatment to help direct treatment and to aid in predicting relapse.
- Assess *C. difficile* disease severity and guide treatment.

HOW QUALITATIVE TESTING WORKS



HOW QUANTITATIVE TESTING WORKS



Qualitative and quantitative lactoferrin testing is **covered by most insurance plans.**



HOW TO ORDER LACTOFERRIN TESTING

Both qualitative and quantitative lactoferrin testing can be easily ordered through most laboratories.

QUALITATIVE TESTING
CPT CODE **83630**

QUANTITATIVE TESTING
CPT CODE **83631**

Suggested reading on lactoferrin

Lactoferrin and CDI

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Lactoferrin and IBS/IBD

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Fecal lactoferrin for diagnosis of symptomatic patients with ileal pouch-anal anastomosis.

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See more evidence-based literature at lactoferrintesting.com

Care to know more? It's easy to learn about lactoferrin testing online or by phone.

- Visit us online at **lactoferrintesting.com**.
- See current research and clinical data on lactoferrin testing at **techlab.com/poster-gallery**.
- Visit the **TECHLAB Inc YouTube channel** for product demonstration videos.
- Call our tech support team at **1-800-TECHLAB** (in US) or **+1-540-953-1664** (outside US) Monday-Friday from 8:30am-5:00pm ET.
- Or e-mail us at **lactoferrin@techlab.com**.

ABOUT TECHLAB®

For over 25 years, physicians have trusted TECHLAB, Inc. to provide high quality, non-invasive, *in vitro* diagnostics for gastrointestinal disorders. TECHLAB is the manufacturer of the FDA-cleared qualitative and quantitative fecal lactoferrin diagnostics for intestinal inflammation. Lactoferrin is a stable and reliable biomarker that can aid in the differentiation of active IBD from IBS, as well as an indicator of severity of other infectious disease states.



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