# Does your patient suffer from **ABDOMINAL PAIN?**

Take the proactive approach to identify the condition.



Get a reliable indication of intestinal inflammation with lactoferrin testing.



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### How does lactoferrin correlate to intestinal inflammation?

# Elevated lactoferrin levels differentiate active IBD from IBS

Intestinal inflammation distinguishes active Inflammatory Bowel Disease (IBD) from Irritable Bowel Syndrome (IBS). When there is intestinal inflammation, as with IBD, activated neutrophils—a type of white blood cell—are released from the intestine into feces.

Lactoferrin, a glycoprotein found in activated neutrophils, is a highly sensitive marker of neutrophils and is found in high levels in fecal samples when intestinal inflammation is present. Lactoferrin, therefore, is a reliable biomarker of intestinal inflammation and effectively aids in the differentiation of active IBD from IBS.

Lactoferrin levels can also indicate the degree of disease severity in IBD patients, help to predict relapse, and guide treatment decisions.

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

#### Lactoferrin levels parallel IBD activity

#### Endoscopic Pictures (top) & Histologic Slides (bottom)

inflammation

Score = 1

Mild

No acute inflammation Score = 0



Mean lactoferrin = 22±7 ug/mL



Mag = 50x Asymmetric crypt architecture



Mean lactoferrin = 62±12 ug/mL



Mag = 400x A single crypt abscess



Moderate

inflammation

Mean lactoferrin = 270±127 µg/mL



Mag = 250x Frequent crypt abscesses



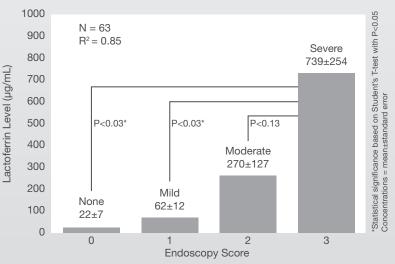


Mean lactoferrin = 739±254 µg/mL



Mag = 50x Greater neutrophil infiltration into the lamina propria

#### Correlation of Lactoferrin Levels to Endoscopy Score for Intestinal Inflammation



# Why should I choose lactoferrin testing?

# Lactoferrin testing offers a number of clinical benefits

Lactoferrin testing is reliable.

It has been proven that elevated levels of lactoferrin correlate with endoscopic and histologic patterns of intestinal inflammation. Lactoferrin is stable in fecal samples for up to 2 weeks at room temperature and for much longer periods at -20°C.

- Lactoferrin testing is quick.
  - The symptoms of intestinal disorders can be relatively unspecific, making the diagnosis of a functional disease such as IBS very difficult. These rapid tests aid in quickly differentiating IBS from active IBD.
- Lactoferrin testing is non-invasive.
  Lactoferrin testing relies only on a fecal sample and reduces patient anxiety about having to submit to more invasive procedures. Avoiding unnecessary endoscopy in pediatric patients, who usually require anesthesia for the procedure, is particularly beneficial.
- Lactoferrin testing can improve treatment.
  Results of repeat lactoferrin testing can aid in determining IBD therapy effectiveness, predicting relapse, and guiding treatment decisions.
- Lactoferrin testing is cost-effective.
  By helping to rule out IBD, lactoferrin testing helps to prevent unnecessary endoscopy, resulting in significant cost savings for both the patient and the health system.



Lactoferrin testing can make the diagnosis and treatment of IBD easier for you and your patient.

# What should I know about fecal lactoferrin testing?

diagnose/treat.

#### THE FECAL LACTOFERRIN SOLUTION:

Two different tests to meet your specific diagnostic needs

### IBD-SCAN®

The *IBD-SCAN*® test is an ELISA for the **quantitative** measurement of fecal lactoferrin. It helps you to quickly and non-invasively

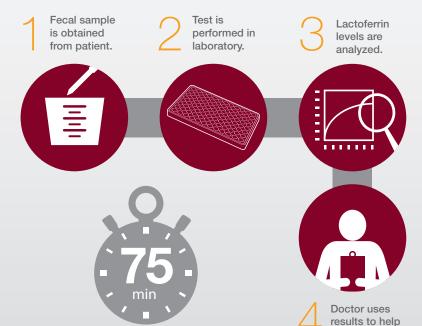
- distinguish between patients with IBS and active IBD;
- identify IBD patients with active inflammation;
- assess inflammation during IBD treatment & aid in predicting relapse.

### IBD EZ VUE®

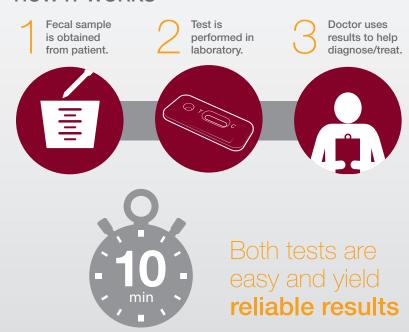
The *IBD EZ VUE*® test is an immunochromatographic lateral flow test for the **qualitative** detection of elevated fecal lactoferrin. It helps you to rapidly and non-invasively

- distinguish between patients with IBS and active IBD;
- identify IBD patients with active inflammation;
- obtain results with minimal sample preparation.

#### **HOW IT WORKS**



#### **HOW IT WORKS**



## What evidence-based literature exists on lactoferrin?



J. Däbritz, J. Musci, and D. Foell.

Diagnostic utility of faecal biomarkers in patients with irritable bowel syndrome.

2014. World Journal of Gastroenterol 20:2. 363-375.

R. Sidhu, P. Wilson, A. Wright, C. Yau, F. D'Cruz, L. Foye, S. Morley, A. Lobo, M. Mcalindon and D. Sanders.

Faecal lactoferrin—a novel test to differentiate between the irritable and inflamed bowel?

2010. Aliment Pharmacol Ther 31. 1365-1370.

T. Walker, M. Land, A. Kartashov, T. Saslowsky, D. Lyerly, J. Boone, and P. Rufo.

Fecal lactoferrin is a sensitive and specific marker of disease activity in children and young adults with inflammatory bowel disease.

2007. J Pediatr Gastroenterol Nutr 44:4. 414-422.

M. Parsi, B. Shen, J. Achkar, F. Remzi, J. Goldblum, J. Boone, D. Lin, J. Connor, V. Fazio, and B. Lashner. **Fecal lactoferrin for diagnosis of symptomatic patients with ileal pouch-anal anastomosis.** 2004. Gastroenterology 126. 1280-1286.

S. Kane, W. Sandborn, P. Rufo, A. Zholudev, J. Boone, D. Lyerly, M. Camilleri, and S. Hanauer.

Fecal lactoferrin is a sensitive and specific marker in identifying intestinal inflammation.

2003. Am J Gastroenterol 98:6. 1309-1314.

# What support services are available for lactoferrin tests?

# Utilize the benefits of on-site product support and technical consultants

An established network of product consultants can provide technical training and operational support of enteric diagnostics for routine use in your laboratory.

Dedicated to facilitating the implementation of new assays, these consultants will offer effective training to help speed up the validation process of a new test for use.

Expertise is offered on the evaluation and review of data from a laboratory perspective.

Our product support team is dedicated to helping achieve efficiency and excellence in clinical practice.

Contact us **TODAY** and save staff time with on-site training and validation of the *IBD-SCAN®* or *IBD EZ VUE®* tests in your lab.



# Contact our distributor, Alere, with questions or to order your lactoferrin test kit by phone or online.

#### **Alere Customer Service**

Phone: 1-877-441-7440 (if calling from U.S.)

1-321-441-7200 (if calling from outside U.S.)

Online: www.alere.com

#### IBD-SCAN®

Highly Complex 96 Test Kit

Order Number: 30351 CPT® Code: 83631

#### IBD EZ VUE®

Moderately Complex 25 Test Kit

Order Number: 30353 CPT® Code: 83630

Actual reimbursement may vary. Alere cannot guarantee or promise coverage or payment for any particular item or service from any payer or health benefit plan. It is the individual provider's responsibility to determine appropriate coding for a particular service. Made in the U.S.A.

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