MAYO CLINIC LABORATORIES

Test Definition: LCTF

Lactoferrin, Feces

Overview

Useful For

Evaluating patients suspected of having a gastrointestinal inflammatory process

Distinguishing inflammatory bowel disease from irritable bowel syndrome, when used in conjunction with other diagnostic modalities, including endoscopy, histology, and imaging

Testing Algorithm

For information see Inflammatory Bowel Disease Diagnostic Testing Algorithm.

Special Instructions

- Inflammatory Bowel Disease Diagnostic Testing Algorithm

Method Name

Enzyme-Linked Immunosorbent Assay (ELISA)

NY State Available

Yes

Specimen

Specimen Type

Fecal

Shipping Instructions

Preferred shipping temperature is frozen. **Refrigerated or thawed specimens received more than 72 hours after collection will be rejected**.

Specimen Required

Supplies: Stool container, Small (Random), 4 oz (T288)
Container/Tube: Stool container
Specimen Volume: 5 g
Collection Instructions:
1. Collect a fresh random fecal specimen, no preservatives.
2. If specimen is sent refrigerate, send immediately after collection.
3. If specimen cannot be sent immediately, freeze specimen and send frozen.

Additional Information:
1. Separate specimens must be submitted when multiple tests are ordered, with the exception of ELASF / Pancreatic Elastase, Feces and CALPR / Calprotectin, Feces. If only a single specimen is collected, it must be split prior to transport.
2. Testing cannot be added on to a previously collected specimen.

Forms

If not ordering electronically, complete, print, and send Gastroenterology and Hepatology Test Request (T728) with the specimen.

Specimen Minimum Volume

1 g

Reject Due To

Specimens collected from diapers	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Fecal	Frozen (preferred)	7 days	
	Ambient	72 hours	
	Refrigerated	72 hours	

Clinical & Interpretive

Clinical Information

Lactoferrin is an iron-binding glycoprotein belonging to the transferrin family. Lactoferrin is primarily stored in the secondary granules of neutrophils as well as monocytes, macrophages and epithelial cells.(1,2) Lactoferrin has multiple roles in host defense with antimicrobial, anti-inflammatory, and immunomodulatory properties and is released through active secretion from living cells rather than cell death.(3) Lactoferrin reversibly binds ferric (Fe[3+]) iron,(2) inhibiting the growth of iron-dependent bacterial species.

Fecal lactoferrin is a stable biomarker, resistant to proteolysis and environmental degradation for several days, making it suitable for non-invasive assessment of intestinal inflammation. Fecal lactoferrin is the most specific (96.5%) biomarker to distinguish irritable bowel syndrome (IBS) from inflammatory bowel disease (IBD), and nearly as sensitive (81.5%) as fecal calprotectin (85%).(4) In cases where the calprotectin result is borderline, fecal lactoferrin results may provide additional context for clinicians in the diagnosis and monitoring of IBD. Measurement of fecal lactoferrin and fecal calprotectin may reduce the need for invasive procedures like colonoscopy for the monitoring of IBD patients. The American Gastroenterological Association includes both fecal calprotectin and lactoferrin in their recommendations for the application of biomarkers in the management of ulcerative colitis.(5)

Because lactoferrin is a non-specific inflammatory biomarker, elevated concentrations can also be found in patients with celiac disease, colorectal cancer, gastrointestinal surgery, and gastrointestinal infections such as *Clostridioides difficile*.(5) Increased concentrations of fecal lactoferrin are not diagnostic for IBD and must be interpreted along with clinical symptoms and endoscopic findings.(4)

Reference Values

< or =4.4 mcg/g (Normal)
>4.4 mcg/g (Abnormal)
Reference values apply to all ages.

Interpretation

Lactoferrin concentrations at or below 4.4 mcg/g are not suggestive of an active inflammatory process within the gastrointestinal system. For patients experiencing gastrointestinal symptoms, consider further evaluation for functional gastrointestinal disorders.

Fecal lactoferrin concentrations above 4.4 mcg/g are suggestive of an active inflammatory process within the gastrointestinal system. Additional diagnostic testing to determine the etiology of the inflammation is suggested.

Cautions

Elevations in fecal lactoferrin are not diagnostic for inflammatory bowel disease (IBD), and normal fecal lactoferrin concentrations do not exclude the possibility of IBD. Diagnosis of IBD should be based on clinical evaluation, endoscopy, histology, and imaging studies.

Elevations in fecal lactoferrin may be observed in other disease states associated with neutrophilic inflammation of the gastrointestinal system, including celiac disease, colorectal cancer, and gastrointestinal infections.

Falsely decreased concentrations of fecal lactoferrin may be observed in patients with neutropenia or granulocytopenia.

Due to the lack of homogenous distribution of lactoferrin in fecal material, variability in results may be seen when patients are monitored over time, particularly in samples with high lactoferrin concentrations.

Bovine lactoferrin (found in dairy products) has a different molecular structure from human lactoferrin and is not detected in this assay. However, nursing infants and those taking human lactoferrin supplements may risk false-positive results.(5)

Clinical Reference

1. Kell DB, Heyden EL, Pretorius E. The biology of lactoferrin, an iron-binding protein that can help defend against viruses and bacteria. Front Immunol. 2020;11:1221
2. Liu N, Feng G, Zhang X, et al. The functional role of lactoferrin in intestine mucosal immune system and inflammatory bowel disease. Front Nutr. 2021;8:759507
3. Cao X, Ren Y, Lu Q, et al. Lactoferrin: A glycoprotein that plays an active role in human health. Front Nutr. 2023;9:1018336
4. LACTOFERRIN SCAN. Package insert. TechLab; RMS #91-351-02-TL, 07/2021
5. Singh S, Ananthakrishnan AN, Nguyen NH, et al. AGA Clinical Practice Guideline on the role of biomarkers for the management of ulcerative colitis. Gastroenterology. 2023;164(3):344-372

Performance

Method Description

The TechLab LACTOFERRIN SCAN assay is a quantitative enzyme-linked immunosorbent assay for measuring concentrations of human lactoferrin in feces. Briefly, polyclonal capture antibodies specific to human lactoferrin are immobilized on a 96-well plate. Calibrators, controls, and diluted patient samples are added to the wells of the plate. If present, lactoferrin will bind to the capture antibodies on the plate. After 37 degrees C incubation and washing, enzyme-labeled antibody conjugate is added. After another incubation and plate washing, a substrate solution is added and the plate is incubated. At the end of the assay, acidic stop solution is added to halt color development, turning the solution from blue to yellow. The absorbance of the color produced by the substrate is proportional to the amount of lactoferrin in the patient sample. Lastly, the control and patient results are calculated based on a curve generated from the kit calibrators and the dilution of the sample.(Package insert: Lactoferrin SCAN. TechLab; 07/2021)

PDF Report
No

Day(s) Performed
Wednesday

Report Available
3 to 8 days

Specimen Retention Time
Extracted feces: 7 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Superior Drive

Fees & Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification
This test has been modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information
83631

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
LCTF	Lactoferrin, F	In Process

Test Definition: LCTF

Lactoferrin, Feces

Result ID	Test Result Name	Result LOINC® Value
LCTF	Lactoferrin, F	In Process