



Fecal Lactoferrin Test

Effective July 7, 2015, Laboratory Alliance of Central New York will begin offering a “Fecal Lactoferrin Test”. This test screens for the presence of lactoferrin which, when positive, is a reliable indicator for the presence of leukocytes in stool specimens. The “Fecal Lactoferrin Test” will be replacing the microscopic examination for fecal leukocytes because studies have shown that the lactoferrin test is much more reliable than microscopy in identifying patients with inflammatory versus non-inflammatory bowel disease due to infection or other causes.

Clinical Significance

Diarrheal diseases can be classified into inflammatory and non-inflammatory categories. Non-inflammatory diarrheas include those caused by viruses and certain bacterial pathogens that are generally treated with simple oral hydration. Inflammatory diarrheas, on the other hand, tend to be more serious and may require more extensive testing and/or treatment. Infectious causes of inflammatory diarrhea are due to various enteric pathogens such as *Shigella*, *Salmonella*, *Campylobacter jejuni*, and *Clostridium difficile*. Non-infectious causes of inflammatory bowel disease include ulcerative colitis and Crohn’s disease, both of which are highly inflammatory and are diagnosed by ruling out infectious agents and other potential causes of bowel inflammation. In all inflammatory bowel infections or diseases, fecal leukocytes are found in large numbers.

Microscopic examination of a stained fecal smear has been used for many years as a diagnostic tool for the detection of intestinal inflammation. The typical procedure requires fresh stool (tested within 1 hour of collection or refrigerated for up to 4 hours). However, the detection of fecal leukocytes by microscopy has several disadvantages: 1) microscopy is not standardized and is dependent upon subjective interpretation; 2) due to the rapid deterioration of leukocytes in feces, specimens must be examined soon after collection; and, 3) some enteric pathogens, such as *C. difficile*, produce toxins that rapidly lyse leukocytes and other cells. As a result, leukocytes may not be detected microscopically even though the patient is experiencing severe bowel inflammation.

The fecal lactoferrin test employs the use of a lateral flow immunochromatographic technology that detects the presence of lactoferrin, a glycoprotein component of granules found in leukocytes. Lactoferrin is very stable and is not degraded by toxins produced by pathogens such as *C. difficile*. As such, unpreserved stool specimens can be stored for up to two weeks before testing making the fecal lactoferrin test much more sensitive than microscopy because it does not require intact fecal leukocytes for test

positivity. Despite its advantages over microscopy, the fecal lactoferrin test has two limitations.

1. This test should not be performed on hospitalized patients admitted more than 3 days. Studies have demonstrated that fecal leukocyte/lactoferrin testing does not reliably distinguish infectious from noninfectious gastroenteritis in this patient group and may give misleading results.
2. Human breast milk contains very high levels of lactoferrin and infants whose diet includes breast milk will have a positive fecal lactoferrin test. If intestinal inflammation is suspected in a breast-milk fed infant, the stool should be examined for leukocytes by microscopy.

Test Name:	Fecal Lactoferrin or Lactoferrin, Fecal
Test Code:	LACTO
Method:	Lateral flow enzyme immunoassay
Specimen Requirements:	Fecal specimen in clean airtight container with NO preservatives
Unacceptable Specimens:	Specimens collected in transport media, have been preserved in 10% formalin or other fixatives
Storage and Transport:	Transport at ambient or 2-8° C and stored up to 1 week
Schedule of Testing:	Daily
CPT Code:	83630
Billing Code:	4010505

For questions or concerns regarding this test, please contact Anne Chamberlain, MT(ASCP)SH, Hematology Manager, at 315-410-7048.

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