Lactoferrin MonlabTest®
MO-804011 20 TESTS
One Step Lactoferrin Test Device

A rapid, one step test for the qualitative detection of human lactoferrin in human feces. For professional in vitro diagnostic use only.

INTENDED USE
The Lactoferrin MonlabTest® is a rapid chromatographic immunoassay for the qualitative detection of human Lactoferrin in faecal samples that may reflect intestinal inflammation in inflammatory bowel disease (IBD).

SYNTHESIS
Lactoferrin (Lf) is a glycoprotein that is produced by neutrophils, mononuclear phagocytes and epithelial cells and is contained in the secretory fluids such as saliva and breast milk. Its function is to block bacterial growth by limiting the availability of iron and this effect is enhanced by the presence of specific secretory IgA antibodies directed against bacteria. Lactoferrin also has a bacteriocidal effect by causing direct damage to cell membranes in cooperation with lisozyme. When inflammation develops in the gastrointestinal tract, neutrophils and phagocytic cells migrate to the inflammatory focus and release the granules containing Lactoferrin. Lactoferrin is stable in feces and is easily detected for immunochemical methods.

This marker is elevated in patients with inflammatory bowel disease. Inflammatory bowel disease (IBD), including ulcerative colitis (UC) and Crohn disease (CD), represent a spectrum of diseases characterized by an idiopathic and chronic inflammation affecting the gastrointestinal (GI) tract. Pediatric and adult patients with IBD may present with a variety of clinical symptoms (including abdominal pain and diarrhea) that can be non-specific.

The Lactoferrin MonlabTest® is a non-invasive assay used as a way to differentiate patients with inflammatory (invasive bacterial infection, IBD, etc.) from those with non-inflammatory (viral, toxigenic, etc.) gastrointestinal illness.

PRINCIPLE
The Lactoferrin MonlabTest® is a qualitative immunochromatographic assay for the determination of human lactoferrin in faecal samples. The membrane is pre-coated with antibodies on the test band (result region), against human lactoferrin.

During testing, the sample is allowed to react with the coloured conjugate (anti-human lactoferrin antibodies-red microspheres) pre-dried on the test. The mixture then moves upward on the membrane by capillary action. As the sample flows through the test membrane, the coloured particles migrate. In the case of a positive result the specific antibodies present on the membrane will capture the coloured conjugate. A coloured band will be visible, depend on the lactoferrin content of the sample. This band is used to interpret the result.

The mixture continues to move across the membrane to the immobilized antibody placed in the control band region; this RED coloured band always appears. The presence of this red band serves as 1) verification that sufficient volume is added, 2) that proper flow obtained and 3) as an internal control for the reagents.

PRECAUTIONS
- For professional in vitro diagnostic use only.
- Do not use after expiration date.
- The test should remain in the sealed pouch until use.
- Do not test the id if pouch is damaged.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test should be discarded in a proper biohazard container after testing.
- The test must be carried out within 2 hours of opening the sealed bag.

STORAGE AND STABILITY
Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30°C/36-86°F). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze.

MATERIALS PROVIDED
- 20 Tests
- Instructions for use
- 20 specimen collection vial with buffer

MATERIALS REQUIRED BUT NO PROVIDED
- Specimen collection container
- Disposable gloves
- Timer

SPECIMEN COLLECTION AND PREPARATION
Collect sufficient quantity of feces (1-2 g or mL for liquid sample). Stool samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-4°C/36-40°F) for 5 days prior to testing. For longer storage the specimen must be kept frozen at -20°C/-4°F. In this case, the sample will be totally thawed, and brought to room temperature before testing.

PROCEDURES
To process the collected stool samples (see illustration 1):
Use a separate specimen collection vial for each sample. Unscrew the cap of the vial and introduce the stick three times into the faecal specimen to pick up a little sample. Close the vial with the buffer and stool sample. Shake the vial in order to assure good sample dispersion. Test Procedure (see illustration 2)
Allow the tests, stool samples and buffer to reach to room temperature (15-30ºC/59-86ºF) prior to testing. Do not open pouches until ready to perform the assay.
1. Remove the Lactoferrin MonlabTest® from its sealed pouch and use it as soon as possible.
2. Shake the specimen collection vial to assure good sample dispersion. Break off the cap of the vial.
3. Use a separate device for each sample. Dispense 4 drops into the specimen well (S). Start the timer.
4. Read the result at 10 minutes after dispensing the sample.

Illustration 1
Pick up the sample
Mix the sample with the buffer

Illustration 2
Break the tip
Infection bowel diseases, circulating neutrophils migrate into the infected tissues and release many kinds of granules. Lactoferrin is associated with the secondary (specific) granules, which are released synchronously with other lysosomal proteins during phagocytosis. Thus, fecal lactoferrin is thought to be a marker of leukocyte activity in bowel infections. The increase in fecal leukocytes suggests an inflammatory response to bacterial infection, including Salmonella species, Shigella species, Campylobacter jejuni and Clostridium difficile, while in a majority of viral infections, appears to be an invasive inflammatory process with little neutrophil migration.

### Notes on the Interpretation of Results

The intensity of the red coloured band in the result region (T) will vary depending on the concentration of human lactoferrin in the specimen. However, neither the quantitative value, nor the rate of increase in lactoferrin can be determined by this qualitative test.

### Quality Control

Internal procedural controls are included in the test.

- A red line appearing in the control region (C) is an internal control. It confirms sufficient specimen volume and correct procedural technique.

### Limitations

1. The test must be carried out within 2 hours of opening the sealed bag.
2. An excess of stool sample could result in wrong results (brown bands appear or absence of the control coloured band).
3. Stool from patients with active inflammatory bowel diseases that usually involve significant neutrophilic inflammation of the intestine, such as Crohn’s disease and ulcerative colitis, would be positive for fecal lactoferrin. The Lactoferrin MonlabTest® could be sensitive for this diagnosis in patients with chronic diarrhea.
4. Positive results confirm the presence of human lactoferrin in fecal samples; nevertheless, it can be also due to several causes besides IBD. A positive result should be followed up with additional diagnostic procedures. Endoscopy and histology on biopsy specimens are the methods for detecting and quantifying bowel inflammation.
5. Negative results do not exclude inflammation, some diseases such as celiac sprue and microscopic colitis polyps that involve mainly monocellular inflammation.
6. Lactoferrin is a component of breast milk; the test will be positive in breast fed children and should not be used to evaluate neonates receiving breast milk.

### Expected Values

In infection bowel diseases, circulating neutrophils migrate into the infected tissues and release many kinds of granules. Lactoferrin is associated with the secondary (specific) granules, which are released synchronously with other lysosomal proteins during phagocytosis. Thus, fecal lactoferrin is thought to be a marker of leukocyte activity in bowel infections. The increase in fecal leukocytes suggests an inflammatory response to bacterial infection, including Salmonella species, Shigella species, Campylobacter jejuni and Clostridium difficile, while in a majority of viral infections, appears to be an invasive inflammatory process with little neutrophil migration.

### Performance Characteristics

**Sensitivity**

A sample containing lactoferrin at concentration equal to or higher than 10ug HLF/g feces produces positive results when using the Lactoferrin MonlabTest®.

Different lactoferrin dilutions were tested directly in the extraction buffer or spiked in a negative stool sample in accordance with the kit instructions to determine the detection limit of the test. The detection of human lactoferrin with the Lactoferrin MonlabTest® showed >99% of sensitivity compared to another commercial immunoassay.

**Specificity**

The detection of human lactoferrin with the Lactoferrin MonlabTest® showed 99% of specificity compared to another commercial immunoassay.

The Lactoferrin MonlabTest® is specific for human lactoferrin, showing no cross-reaction with bovine lactoferrin.

### References


### Symbols for IVD Components and Reagents

- **Manufacturer**
- **Don’t re-use**
- **Contains sufficient for <n> tests**
- **Catalogue Code**
- **Lot Number**
- **For in vitro diagnostic use only**
- **Consult instructions for use**
- **Keep dry**
- **Temperature limitation**
- **Use by**