# Lactoferrin Rapid Test Cassette (Feces)
## Package Insert

| REF OLF-602 | English |
|---|---|

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

**【INTENDED USE】**

The Lactoferrin Rapid Test Cassette (Feces) is a rapid chromatographic immunoassay for the qualitative detection of lactoferrin in human feces, for the diagnosis of inflammatory gastrointestinal disorders.

**【SUMMARY】**

Inflammatory bowel disease (IBD) involves a large clinical spectrum of disease presentations from mild to severe symptoms in relation to different disease locations and the extent from possible rectal to upper intestinal involvement. In pediatric patients, early diagnosis of IBD is of great relevance and essential for best outcome. Induction of remission by specific therapy aims to improve the patient's symptoms, to maintain or restore the quality of life as soon as possible, and to prevent complications of the disease[1,2,3]. Human lactoferrin, a neutrophil derived glycoprotein, can be measured in feces and whole gut lavage as an indicator of intestinal inflammation in both IBD and infectious gastroenteritis. Recent studies have shown fecal lactoferrin (FL) as a sensitive biomarker for pediatric IBD. In addition, this biomarker can serve as an aid for guiding the diagnostic and therapeutic process for both pediatric and adult IBD.

**【PRINCIPLE】**

The Lactoferrin Rapid Test Cassette (Feces) is a qualitative, lateral flow immunoassay for the detection of lactoferrin in human feces. The membrane is precoated with anti-lactoferrin antibody on the test line region of the test. During testing, lactoferrin, if present in the specimen reacts with anti-lactoferrin antibody conjugated with colored particle. The mixture migrates upward on the membrane by capillary action to react with anti-lactoferrin antibody on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

**【REAGENTS】**

The test contains mouse anti-lactoferrin antibody particles and mouse anti-lactoferrin antibody coated on the membrane.

**【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 eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

**【STORAGE AND STABILITY】**

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

**【SPECIMEN COLLECTION AND PREPARATION】**

1. The fecal specimen must be collected in a clean, dry, waterproof container containing no detergents, preservatives or transport media.
2. Bring the necessary reagents to room temperature before use.
3. If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

**【MATERIALS】**

**Materials Provided**

- Test Cassettes
- Specimen Collection Tubes with extraction buffer
- Package Insert

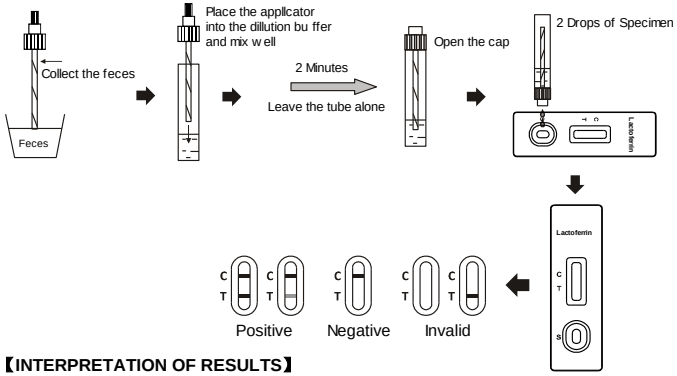
**Materials Required But Not Provided**

- Specimen Collection Containers
- Timer
- Droppers

**【DIRECTIONS FOR USE】**

**Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.**

1. Collection of fecal specimens:
   Collect sufficient quantity of feces (1-2 mL or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present). Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8℃ if not tested within 6 hours. For long term storage, specimens should be kept below -20℃.
2. Processing of fecal specimens:
   • For Solid Specimens:
   Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection applicator into the fecal specimen in at least **3 different sites to collect approximately 50 mg of feces** (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.
   • For Liquid Specimens:
   Hold the dropper vertically, aspirate fecal specimens, and then transfer **2 drops (approximately 80μL)** into the specimen collection tube containing the extraction buffer.
3. Tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Leave the tube alone for 2 minutes.
4. Bring the pouch to room temperature before opening it. Remove the test cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
5. Hold the specimen collection tube upright and open the cap onto the specimen collection tube. Invert the specimen collection tube and transfer **2 full drops of the extracted specimen (approximately 80μL)** to the specimen well (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
6. Read results at **5 minutes** after dispensing the specimen. Do not read results after 10 minutes.
7. **Note:** If the specimen does not migrate (presence of particles), centrifuge the extracted specimens contained in the extraction buffer vial. Collect 80μL of supernatant, dispense into the specimen well (S) of a new test cassette and start afresh following the instructions mentioned above.




**【INTERPRETATION OF RESULTS】**

(Please refer to the illustration above)

**POSITIVE**:* **Two colored lines appear.** One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

***NOTE**: The intensity of the color in the test line region (T) will vary depending on the concentration of lactoferrin present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

**NEGATIVE**: **One colored line appears in the control line region (C).** No line appears in the test line region (T).

**INVALID: Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

**【QUALITY CONTROL】**

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal valid procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

**【LIMITATIONS】**

1. The Lactoferrin Rapid Test Cassette (Feces) is for in vitro diagnostic use only.
2. The Lactoferrin Rapid Test Cassette (Feces) will only indicate the presence of lactoferrin, the detail concentration of lactoferrin was not confirmed with the rapid test.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. Other clinically available tests are required if questionable results are obtained.

**【EXPECTED VALUES】**

The Lactoferrin Rapid Test Cassette (Feces) has been compared with a commercially available Lactoferrin Rapid Test, demonstrating an overall accuracy of 98%.

**【PERFORMANCE CHARACTERISTICS】**

**Detection Limitation**

The Lactoferrin Rapid Test Cassette (Feces) can detect human Lactoferrin as low as 100ng/ml.

**Sensitivity and Specificity**

The Lactoferrin Rapid Test Cassette (Feces) was compared with a commercially available Lactoferrin Rapid Test; the results indicate that Lactoferrin Rapid Test Cassette (Feces) has an overall accuracy of >98%.

| Method | | Commercially Available Rapid Test | | Total Results |
|---|---|---|---|---|
| Lactoferrin Rapid Test Cassette (Feces) | Results | Positive | Negative | |
| | Positive | 41 | 2 | 43 |
| | Negative | 1 | 118 | 119 |
| Total Results | | 42 | 120 | 162 |

Relative Sensitivity: 97.6% (95%CI*: 87.4%-99.9%) *Confidence Interval
Relative Specificity: 98.3% (95%CI*: 94.1%-99.8%)
Overall Accuracy: 98.1% (95%CI*: 94.7%-99.6%)

**Precision**

**Intra-Assay**

Within-run precision has been determined by using 3 replicates of these specimens: negative, 100ng/ml, 500ng/ml and 10μg/ml Lactoferrin specimens. The specimens were correctly identified >99% of the time.

**Inter-Assay**

Between-run precision has been determined by 3 independent assays on the same specimens: negative, 100ng/ml, 500ng/ml and 10μg/ml Lactoferrin specimens. Three different lots of the Lactoferrin Rapid Test Cassette (Feces) have been tested using these specimens. The specimens were correctly identified >99% of the time.

**【BIBLIOGRAPHY】**


1. Sánchez L, Calvo M, Brock JH (May 1992). "Biological role of lactoferrin". Archives of Disease in Childhood. 67 (5): 657–61.
2. Levin RE, Kalidas S, Gopinadhan P, Pometto A (2006). Food biotechnology. Boca Raton, FL: CRC/Taylor & Francis. p. 1028.
3. Pursel VG (1998). "Modification of Production Traits". In Clark AJ. Animal Breeding: Technology for the 21st Century (Modern Genetics). Boca Raton: CRC. p. 191.


**Index of Symbols**

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| | Attention, see instructions for use | Σ | Tests per kit | EC REP | Authorized Representative |
| IVD | For in vitro diagnostic use only | | Use by | 2 | Do not reuse |
| 2°C 30°C | Store between 2-30°C | LOT | Lot Number | REF | Catalog # |
| | Do not use if package is damaged | | Manufacturer | | Consult Instructions For Use |


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