

A rapid test for the quantitative detection of Calprotectin in human feces specimen that can be performed with the use of JusChek ACRO LF Reader.
For professional in vitro diagnostic use only.

INTENDED USE

The Calprotectin Rapid Test Cassette (Feces) is a rapid chromatographic immunoassay for the quantitative detection of Calprotectin in human feces specimen which might be useful for the diagnosis of inflammatory gastrointestinal disorders that can be performed with the use of JusChek ACRO LF Reader.

SUMMARY

Calprotectin is a 24 kDa dimer of calcium binding proteins S100A8 and S100A9.^[1] The complex accounts for up to 60% of the soluble protein content of the neutrophil cytosol.^[2] Calprotectin becomes available in the intestinal lumen via leukocyte shedding,^[3] active secretion,^[2] cell disturbance, and cell death.^[3] This results in elevated faecal calprotectin levels, which can be detected in the stool.^[3] Elevated faecal calprotectin levels therefore indicate migration of neutrophils into the intestinal mucosa, which occurs during intestinal inflammation.^[4] Faecal calprotectin has been used to detect intestinal inflammation, and can serve as a marker for inflammatory bowel diseases.^[5] Calprotectin is useful as a marker, as it is resistant to enzymatic degradation, and can be easily measured in faeces.^[6]

PRINCIPLE

The Calprotectin Rapid Test Cassette (Feces) is a quantitative, lateral flow immunoassay for the detection of Calprotectin in human feces specimen. The membrane is pre-coated with anti-Calprotectin antibody on the test line region of the test. During testing, the specimen reacts with the particle coated with Calprotectin antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-Calprotectin 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 anti-Calprotectin antibody particles and anti-Calprotectin antibody coated on the membrane.

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- For use exclusively with the JusChek ACRO LF Reader. Do not interpret test results visually.
- The test cassette 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 materials 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

- The feces specimen must be collected in clean, dry, waterproof container containing no detergents, preservatives or transport media.
- Bring the necessary reagents to room temperature before use.

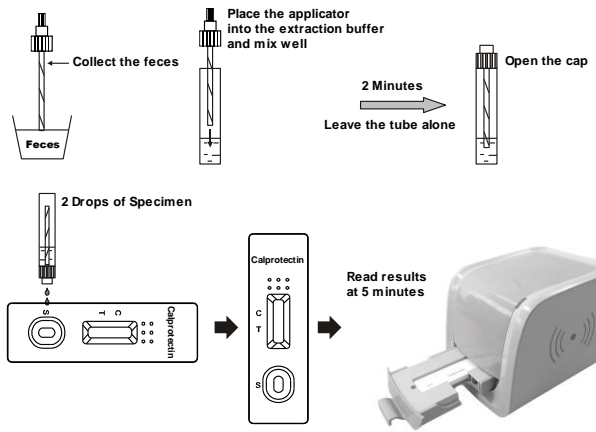
MATERIALS

- | Materials Provided | |
|-------------------------------------|--|
| • Test Cassettes | • Specimen collection tubes with extraction buffer |
| • Package Insert | • QR code card |
| Materials Required But Not Provided | |
| • Specimen collection containers | • Timer |
| • JusChek ACRO LF Reader | • Droppers |

DIRECTIONS FOR USE

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

- To collect 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°C if not tested within 6 hours. For long term storage, specimens should be kept below -20°C.
- To process 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.
- 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.
- Exact QR Code from the QR code card for specific information of the test. Use only QR code card provided inside the test kits.
- 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.
- Hold the specimen collection tube upright and open the cap of 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.
- Wait for the colored line(s) to appear. **The result should be read with JusChek ACRO LF Reader at 5 minutes.**
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.
- Do not interpret test results visually.
Note: For JusChek ACRO LF Reader installation, start up and complete instructions refer to JusChek ACRO LF Reader User Manual. Operator must consult the JusChek ACRO LF Reader User Manual prior to use and become familiar with the processes and quality control procedures.



INTERPRETATION OF RESULTS

Results read by JusChek ACRO LF Reader

The result for Calprotectin is determined by JusChek ACRO LF Reader. Result could be exported to excel or PDF.

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

- The Calprotectin Rapid Test Cassette (Feces) is for in vitro diagnostic use only.
- As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
- Other clinically available tests are required if questionable results are obtained.
- The results of JusChek ACRO LF Reader are only for the analysis of the results on the rapid tests. It should not be used as criteria for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

PERFORMANCE CHARACTERISTICS

Correlation analysis

The ELISA value as independent variables and the test value of JusChek ACRO LF Reader as the dependent variable, calculating correlation. Results show good correlation that the JusChek ACRO LF Reader and ELISA the overall correlation is $r = 0.906$.

JusChek ACRO LF Reader	n	r	p
0-500ng/ml	166	0.923	0.000
500-2000ng/ml	9	0.911	0.000
2000-5000ng/ml	7	0.901	0.000
5000-10000ng/ml	3	0.889	0.000
0-10000ng/ml	185	0.906	0.000

Calprotectin ng/ml $\times 0.36 =$ Calprotectin ug/g, Calprotectin ug/g $\times 2.78 =$ Calprotectin ng/ml.

Sensitivity

The Calprotectin Rapid Test Cassette detects Calprotectin at a concentration of 140ng/ml or 50 ug/g or greater.

Precision Intra-Assay

Within-run precision has been determined by using 15 replicates of three specimens: 140ng/ml, 500ng/ml and 10µg/ml positive specimens. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same three specimens: 140ng/ml, 500ng/ml and 10µg/ml positive specimens. Three different lots of the Calprotectin Rapid Test Cassette (Feces) have been tested using these specimens. The specimens were correctly identified >99% of the time.

BIBLIOGRAPHY

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Index of Symbols

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

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