



Chuangxingwell



## Calprotectin (CALP) Rapid Test Kit Package Insert



A rapid, one step test for the qualitative detection of Calprotectin in human feces specimen.

For professional in vitro diagnostic use only.

### 【INTENDED USE】

The Calprotectin (CALP) Rapid Test Kit (Feces) is a rapid chromatographic immunoassay for the qualitative detection of Calprotectin in human feces specimen which might be useful for the diagnosis of inflammatory gastrointestinal disorders.

### 【SUMMARY】

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

### 【PRINCIPLE】

The Calprotectin (CALP) Rapid Test Kit (Feces) is a qualitative, 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 an 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.
- 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】

Store the test kit at 2-30°C with a valid period of 24 months. The test kit is stable through the expiration date printed on the sealed pouch. The test kit must remain in the sealed pouch until use. Use the test kit within 1 hour once the foil pouch is opened. DO NOT FREEZE. Do not use beyond the expiration date.

### 【SPECIMEN COLLECTION AND PREPARATION】

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

### 【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. 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.

2. To process fecal specimens:

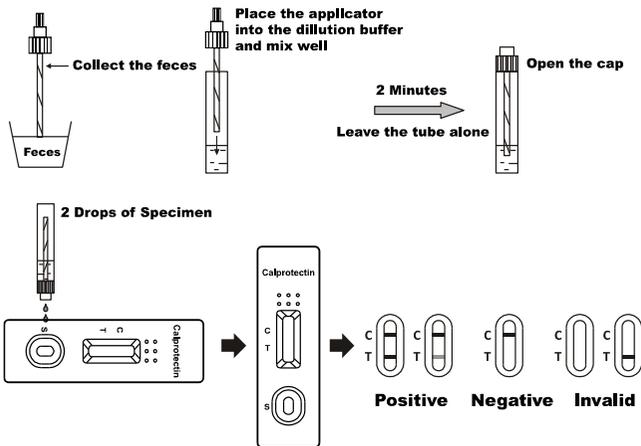
- For Solid Specimens:

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 80 µL) 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 80 µL) 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 80 µL 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 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 Calprotectin 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 Calprotectin (CALP) Rapid Test Kit (Feces) is for in vitro diagnostic use only.
2. The Calprotectin (CALP) Rapid Test Kit (Feces) will only indicate the presence of Calprotectin, the detail concentration of Calprotectin 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 Calprotectin (CALP) Rapid Test Kit (Feces) has been compared with another leading commercial rapid test. The correlation between this two system is 98.5%

### 【PERFORMANCE CHARACTERISTICS】

#### Accuracy

The Calprotectin (CALP) Rapid Test Kit (Feces) has been compared with another leading commercial rapid test using clinical specimens.

Method	Results	Other Rapid Test		Total Result
		Positive	Negative	
Calprotectin (CALP) Rapid Test Kit (Feces)	Positive	133	2	135
	Negative	3	198	201
Total Result		136	200	336

Relative sensitivity: 97.8% (95%CI\*: 93.7%~99.5%);

Relative specificity: 99.0% (95%CI\*: 96.4%~99.9%);

Accuracy: 98.5% (95%CI\*: 96.6%~99.5%).

\*Confidence Intervals

#### Sensitivity

The Calprotectin (CALP) Rapid Test Kit (Feces) can detect levels of Calprotectin as low as 50 µg/g or 140 ng/ml feces.

#### 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 (CALP) Rapid Test Kit (Feces) have been tested using these specimens. The specimens were correctly identified >99% of the time.

### 【BIBLIOGRAPHY】

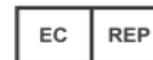
1. Brophy, Megan Brunjes; Nolan, Elizabeth M. (16 January 2015). "Manganese and Microbial Pathogenesis: Sequestration by the Mammalian Immune System and Utilization by Microorganisms". ACS Chemical Biology. 10: 150116125412006.
2. Striz, I; Trebichavsky, I (2004). "Calprotectin - a pleiotropic molecule in acute and chronic inflammation.". Physiological research / Academia Scientiarum Bohemoslovaca. 53 (3): 245-53.
3. Lehmann, F. S.; Burri, E.; Beglinger, C. (13 October 2014). "The role and utility of faecal markers in inflammatory bowel disease". Therapeutic Advances in Gastroenterology. 8 (1): 23-36.
4. Gupta, Ramesh (2014). Biomarkers in toxicology. San Diego, CA: Academic Press. pp. 272-273. ISBN 9780124046498
5. Marshall, William Marshall.; Lapsley, Marta; Day, Andrew; Ayling, Ruth (2014). Clinical Biochemistry: Metabolic and Clinical Aspects (3 ed.). Elsevier Health Sciences, 2014. ISBN 9780702054785.
6. Tibble J, Teahon K, Thjodleifsson B, Roseth A, Sigthorsson G, Bridger S, Foster R, Sherwood R, Fagerhol M, Bjarnason I (2000). "A simple method for assessing intestinal inflammation in Crohn's disease". Gut. 47 (4): 506-13.

### Index of Symbols

	Caution		In Vitro Diagnostic Medical Device		Do Not Use if Package is Damaged
	Manufacturer		Batch Code		Contains Sufficient for <n> Tests
	CE Marking		Catalogue Number		Authorized representative in the European Community
	Keep Dry		Use-By Date		Keep Away From Sunlight
	Temperature Limit		Do Not Re-use		Date of Manufacture



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