

Calprotectin Rapid Test Kit

Instruction for use

【Product Name】 Calprotectin Rapid Test Kit

【REF】 A10066001B, A10066001C, A10066001D, A10066001E

【Specification】 1 test/kit, 5 tests/kit, 10 tests/kit, 25 tests/kit

【Intended Use】

The Calprotectin Rapid Test Kit is a colloidal gold immunochromatography intended for the qualitative detection of the Calprotectin (Cal) in human feces. The test is intended *in vitro* qualitative determination of Calprotectin (Cal) in human fecal samples.

【Summary】

Calprotectin, first isolated in 1980 from neutrophil and monocytes, is an important inflammatory protein found in human tissues, body fluids and cells. It is a heterozygous calcium-binding protein, because of its anti-protease activity, can be in the intestinal lumen and the environment for a long time to remain stable and not destroyed by various enzymes and bacteria. Inflammatory bowel disease, colorectal cancer and irritable bowel syndrome are common diseases of the digestive tract, more and more clinical researches have shown the value of faecal calprotectin in the diagnosis and differential diagnosis of IBD, colorectal cancer and IBS.

【Test Principle】

The test is a sandwich immunoassay of double antibodies. If there are Calprotectin in the sample, it will be combined with colloidal gold labeled mouse anti-Calprotectin antibody, form a complex. Under the action of chromatography, the complex flows on the nitrocellulose membrane. Then, the complex will combine to another Calprotectin antibody (T line) coated on the nitrocellulose membrane. The control line (C line) must appear in the control area of the rod for the result to be valid. A line will appear in the test line area, indicating a positive result.

【Main Components】

Materials Provided:

Specification Material	1 test/kit	5 tests/kit	10 tests/kit	25 tests/kit
Test Cassette	1	5	10	25
Sample Diluent	1	5	10	25
Instruction for Use	1	1	1	1

Materials Required but Not Provided:

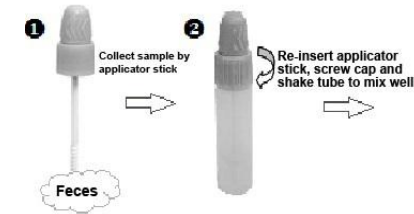
- 1.Timer
- 2.Pipette
- 3.Biohazard disposal container
- 4.Any necessary personal protective equipment

【Storage Conditions and Validity】

- 1.This product should be stored in a dark and dry place at 2~30°C.The validity period of the kit is 24 months.
- 2.After unpacking the aluminum foil bag of the test cassette, It should be used in the specified environment (Temperature 2-35°C, Humidity 40%-90%) within 1 hour.
- 3.Please see label for the information about the date of manufacture and shelf life.

【Samples Collection Handling】

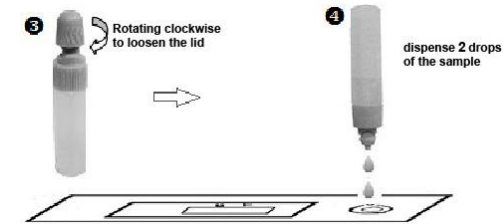
1. This kit is used to detect human feces samples. Other samples may not get accurate results.
2. Remove the applicator stick from the sample collection tube. Insert and turn the stick into the feces sample 5-6 times at different sites (fully covering the spiral groove on the applicator stick).
3. Re-insert the applicator stick into the sample collection tube, screw the cap and shake the tube vigorously to mix the sample well.
4. Testing should be performed immediately after the feces have been collected. If the feces cannot be processed immediately, it may be held at 2 ~ 8 °C for up to 48 hours.



【Test Method】



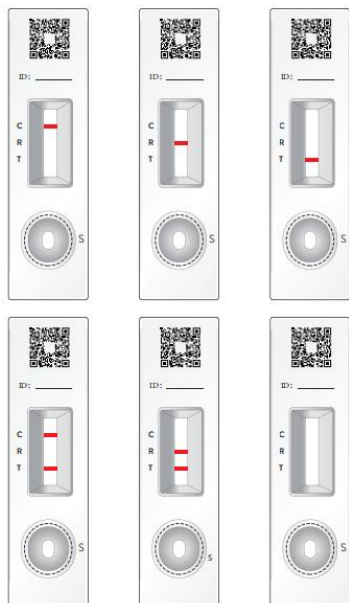
Note: Please read the Instruction for Use carefully before use. The test should be operated in room temperature.

- 1.Read package insert carefully before testing. Bring all test cassettes and samples to room temperature (10-30 °C). Do not open pouches until ready to perform the assay.
2. Remove the test cassette from the foil pouch and place on a clean dry surface.
3. Rotating clockwise to loosen the lid of sample collection tube cap.
4. Invert the sample collection tube and dispense 2 drops of sample which has been mixed evenly and without bubble into the sample well on the cassette, start timing.
5. Interpret the test results at 15 minutes. Do not interpret the results after 20 minutes.



【Interpretation of Test Results】

Diagram	Interpretation of Results
	<p>Two red stripes appear in the control area(C,R), but there are no red stripes in the detection area(T).</p> <p>Calprotectin concentration < 15µg/g</p> <p>Indicating that the calprotectin in the sample is at a normal level</p>
	<p>Two red bands appear in the control area(C,R), while the color intensity in the detection area(T) is weaker than that in the control area(R).</p> <p>Calprotectin concentration 15µg/g~60µg/g</p> <p>Suggest that calprotectin may be at normal levels or there may be a risk of irritable bowel syndrome</p>

<p>Two red bands appear at the position of the control area(C,R), and the color intensity of the detection area (T) is consistent with that of the control area(R).</p> 	<p>Calprotectin concentration=60µg/g Suggest possible risk of enteritis disease</p>
<p>Two red bands appear in the control area(C,R), while the color intensity in the detection area(T) is darker than that in the control area(R).</p> 	<p>Calprotectin concentration >60µg/g Suggest possible risk of enteritis disease</p>
	<p>The results indicate that it is invalid The possible cause is incorrect operation process or the reagent has deteriorated and damaged. If the invalid results are retested, they should be strictly operated according to the instructions when retesting. If the result is invalid again, you should consult a doctor or a test center.</p>

【Reporting of Results】

Positive test:

If any Positive, there is possible risk of enteritis disease. Please carefully compare the above test results this time to more accurately determine and contact your doctor or local health department immediately.

Negative test:

Negative test results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions, including infection control decisions, particularly in the presence of clinical signs and symptoms consistent with enteritis disease. It is recommended that these results be confirmed by other methods, if necessary, for patient management Control.

Invalid:

If the control line C or R is not visible, the result is invalid. An invalid result may have been caused by the

incorrect execution of the test. Please perform a new test with a new sample and a new test cassette. If the result is invalid again, you should consult a doctor or a test center.

【Limitation of The Test】

1. The kit can be used for the detection of human feces samples.The reliability of the determination of this substance in other types of samples has not been fully confirmed.
2. The kit will only indicate the presence of Calprotectin in the specimen and should not be used as the sole criteria for the diagnosis of enteritis disease.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of enteritis disease.
5. Other factors may interfere with Anbio Calprotectin Rapid Test Kit and may cause erroneous results. These include technical or procedural errors, as well as additional substances in feces specimens.

【Performance Characteristics】

1. The clinical performance of Calprotectin Rapid Test Kit was evaluated in comparison to Calprotectin test using clinical specimens. The results are shown in the following tables.

Calprotectin Rapid Test Kit	Commercial Calprotectin test				Total
	Negative	"+"Positive	"++"Positive	"+++"Positive	
Negative	33	0	0	0	33
"+"Positive	1	65	1	0	67
"++"Positive	0	1	50	0	51
"+++"Positive	0	0	0	6	6
Total	34	66	51	6	157
Negative Compliance Rate	97.06% (84.67%~99.93%)				
"+"Positive Compliance Rate	98.48% (91.84%~99.96%)				
"++"Positive Compliance Rate	98.04% (89.55%~99.95%)				
"+++"Positive Compliance Rate	100.00% (54.07%~100.00%)				
Overall Accuracy	98.09% (94.52%~99.60%)				

2. Limitation of Detection (LoD)

The LoD of Calprotectin Rapid Test Kit is 60 µg/g.

3. **Interfering substances:**The Concentrations of triglycerides 40mmol/L,hemoglobin 2g/L,rheumatoid factor 1000IU/mL,bilirubin 350µmol/L and HAMA 600ng/mL have no effect on the test results.

















【Precautions】

1. After opening the package, the kit should be ready for use as soon as possible and avoid placing it in a high temperature (over 30°C) and high humidity environment for a long time.
2. All samples and test cassettes after use should be considered potentially dangerous and should be treated as infectious materials, and the waste should be disposed of in accordance with the regulations of the hospital or environmental protection department.
3. The test strips with any color lines before the test should not be used and the cassettes with damaged packaging bags or invalid seals should not be used.
4. The kit is for in vitro diagnostic use only.The kit is for single-use,please do not use the product after it expires.
5. Do not mix components from different kit lots.

【Bibliography】

1. Roseth AG, et al. Fecal calprotectin levels and gut inflammation in patients with ulcerative colitis. Digestion. 1999;60(6):607-14.
2. Bunn SK, et al. Fecal calprotectin: validation as a noninvasive measure of bowel inflammation in childhood inflammatory bowel disease. J Pediatr Gastroenterol Nutr. 2001;33(1):14-22.

【Index of Symbols】

	In vitro diagnostic medical device		Do not re-use
	Authorized representative in the European Community/ European Union		Consult instructions for use or consult electronic instructions for use
	Caution		Manufacturer
	Temperature limit		Batch code
	Use-by date		Keep dry
	Keep away from sunlight		Catalog number
	Date of manufacture		Contains sufficient for <n> tests
	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		Do not use if package is damaged and consult instructions for use

【Basic Information】

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