ZOAN™

Calprotectin Test Kit

User Instruction Guide

【PREPARATION】

1. Follow the below steps for preparation.
2. Ensure the test kit is at room temperature for at least 30 minutes prior to use.
3. A timing device (clock, phone or timer) is required but not provided.

Step 1

▶ 1a Wash hands before and after the test, either using soap and water or hand sanitizer.

▶ 1b Make sure hands are dry before starting.

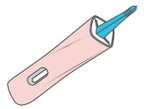
Step 2

▶ Read the instructions for use carefully before using the ZOAN™ calprotectin test kit.

Step 3

▶ 3a Check the expiration date on the label of foil pouch and extraction buffer cap.

▶ 3b Do not use if it is beyond expiration date or if it is damaged.



Test Device

Extraction Buffer cap

Step 4

▶ 4a Open the test device foil pouch.

▶ 4b Place the test device and extraction buffer cap on a dry and clean surface.

▶ 4c Check the result window and specimen well on the test device.

【OPERATION PROCEDURE】

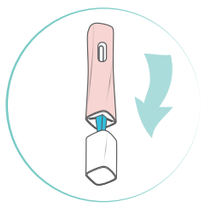
Sample stool should be fresh

Step 5

▶ 5a Put the clean collection paper in the toilet before sample collection;

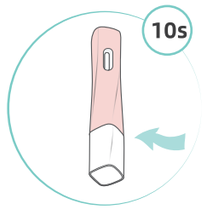
▶ 5b Make sure no water to the sample;

▶ 5c Use the test device (tip part) to fully collect sample on the clean collection paper, back and forth ;



Step 6

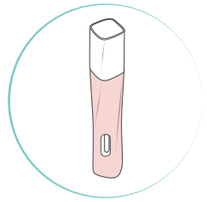
▶ 6a Insert the test device into the extraction buffer cap downward;



Step 7

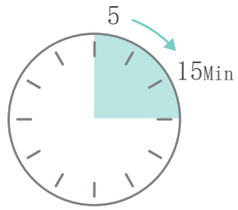
▶ 7a Make sure the test device and extraction buffer cap are fully screwed so that the sample can be completely extracted;

▶ 7b Wait for 10 seconds;



Step 8

▶ 8a Put the test device vertically on the flat surface with extraction buffer cap up;



Step 9

▶ 9a Wait for 5-15 minutes to read the results ;

▶ 9b Do not read results after 15 minutes .

【Q&A】

Q: What is fecal calprotectin?

A: Fecal calprotectin is a biochemical measurement of the protein calprotectin in the stool. Elevated fecal
calprotectin indicates the migration of neutrophils to the intestinal mucosa,which occurs during intestinal

Q: What is purpose to test fecal calprotectin?

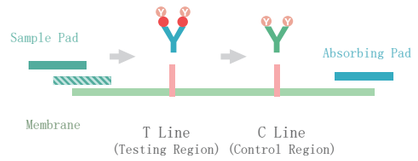
A: Detection of calprotectin in human stool samples can be used for detecting diarrhea in children and auxiliary diagnosis of inflammatory bowel disease.

Inflammatory bowel disease includes ulcerative colitis and Crohn's disease.Calprotectin in feces is sensitive to active Crohn's disease, At the same time, it has a good correlation with ulcerative colitis and its stages, and is an important indicator for screening inflammatory bowel disease and indicating the degree of disease recovery. At the same time,fecal calprotectin is positively correlated with the severity of inflammatory bowel disease in children, and can be used as an important marker for early diagnosis and condition monitoring ofinflammatory bowel disease in children.

Q: The principle of calprotectin detection?

A:Applying colloidal gold test technology, thecal-protectin rapid test uses immunochemical methodology to detect calprotectin levels in human feces sample.

Example of
Positive case



When the stool sample contains antigens of calprotectin, it will react with with the colloidal gold-anti-body-coupling, then become colloidal gold antibody conjugate. The colloidal gold antibody conjugate migrates upward on the membrane chromatographi-cally by capillary action to react with pre-coat-ed calprotectin-antibody, then combined to a mix-ture, which will generate a colored Test line (T).

If the sample does not have calprotectin, the testing region will not generate any colored Test line.
Colloidal gold-antibody-coupling migrates upward on the membrane chromatographically to the con-trol line region, it will react with pre-coated IgG-antibody,then combined to a mixture, which will generate a colored Control line (C).

The control line should generate a red colored line when testing. This indicates the test strip is

Q: Besides inflammatory bowel disease, what other conditions can cause calprotectin in stool?

A: Current research shows that taking non-steroidal anti-inflammatory drugs and colon tumors can increase the level of calprotectin.

Q:During operation of test, is there a high risk of leaking or peculiar smell?

A:No. The sampler is designed fully sealed. This can allow the extra liquid to go to the waste buffer thoroughly.In addition, Zoan™ also has function of odor removal, which can avoid peculiar

Q: Who should have a calprotectin test?

A: Patients with inflammatory bowel disease and pediatric inflammatory bowel disease can be tested for calprotectin for early diagnosis and to indicate the degree of disease recovery.

Q:What should I do if I get an invalid result?

A:Manual operating error may cause invalid result.

It is suggested to use a new one to re-test.

CE IVD

ZOAN™

EN
ENGLISH

Calprotectin

Calprotectin Test Kit
(Colloidal Gold Method)
Instructions for Use

Version: A/0

REF : HP-FC-1/HP-FC-2/HP-FC-5/HP-FC-7/HP-FC-20/HP-FC-25

Manufacturer

Shijiazhuang Hipro Biotechnology Co.,Ltd.
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Tel: +86 400-019-1606

EC REP Riomavix Sociedad Limitada

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【PRODUCT NAME】

Calprotectin Test Kit (Colloidal Gold Method)

【INTENDED USE】

This product is used for in-vitro test for the qualitative detection of calprotectin in feces. This test is used for auxiliary diagnosis for inflammatory bowel disease.
Calprotectin is a calcium-containing protein derived from neutrophils and macrophages. Its expression is tissue- and cell-specific, and it can be used as a marker of acute inflammatory cell activation, and its properties are relatively stable.

Inflammatory bowel disease includes ulcerative colitis and Crohn's disease. Calprotectin in feces is sensitive to active Crohn's disease, and has a good correlation with ulcerative colitis and its stage. Inflammatory bowel disease and an important indicator of the degree of recovery from the disease. At the same time, fecal calprotectin is positively correlated
with the severity of inflammatory bowel disease in children,and can be used as an important marker for early diagnosis and condition monitoring of

【PRINCIPLE】

Applying colloidal gold test technology, the calprotectin rapid test uses immunochemical methodology to detect calprotectin levels in human feces sample.

When the stool sample contains antigens of calprotectin, it will react with with the colloidal gold-antibody-coupling, then become colloidal gold antibody conjugate. The colloidal gold antibody conjugate migrates upward on the membrane chromatographically by capillary action to react with pre-coated calprotectin-antibody, then combined to a mixture,
which will generate a colored Test line (T).

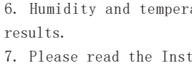
If the sample does not have calprotectin, the testing region will not generate any colored Test line.

Colloidal gold-antibody-coupling migrates upward on the membrane chromatographically to the control line region, it will react with pre-coated IgG-antibody, then combined to a mixture,which will generate a colored Control line (C).

【MATERIALS PROVIDED-Pen Shape】

Components	1 Kit	2 Kits	5 Kits	7 Kits	20 Kits	25 Kits
REF	HP-FC-1	HP-FC-2	HP-FC-5	HP-FC-7	HP-FC-20	HP-FC-25
Test Device	1	2	5	7	20	25
Extraction Buffer Cap	1	2	5	7	20	25
Clean Collection Paper	1	2	5	7	20	25
Instructions for Use	1	1	1	1	1	1

Test Device



Extraction Buffer Cap

Clean Collection Paper

Instructions for Use

【MATERIALS REQUIRED BUT NOT PROVIDED】

• Clock, timer or stopwatch

【STORAGE AND STABILITY】

- Store in a dry place at 2-30° C . Do not freeze or damp the test kit.
- Please use it within 1 hour after opening the inner sealing pouch.
- Validity: 24 months.
- Please refer to the label for LOT number and expiration date.

【WARNINGS AND PRECAUTIONS】

1. For in vitro diagnostic use only.
2. Do not use after expiration date.
3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
4. Observe established precautions against microbiological hazards throughout the testing and follow the standard procedures for proper disposal of specimens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
6. Humidity and temperature can adversely affect results.
7. Please read the Instructions for Use seriously before using the kit.
8. Do not use the kit with an obviously damaged package.
9. Do not reuse any kit components.
10. Do not use with multiple specimens.
11. Avoid menstrual period,haemorrhoid bleeding and blood urine while collecting samples.

Calprotectin Test Kit Instruction Guide

BEFORE YOU BEGIN

Cautions :
1.Follow the below steps for preparation.
2.Ensure the test kit is at room temperature for at least 30 minutes prior to use.
3.A timing device (clock, phone or timer) is requested but not provided

1a Wash hands before and after the test, either using soap and water or hand sanitizer

1b Make sure hands are dry before starting

Test Device

Extraction Buffer Cap

Clean Collection Paper

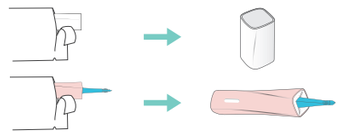
Instructions for Use

2a Take all the items out of the test box and lay them on a well-cleaned flat surface. Identify each item in the test kit.

2b Read the instructions for use carefully before using the ZOAN™ Calprotectin test kit.

2c Check the expiration date on the label of test device foil pouch and extraction buffer cap.

2d Do not use if it is beyond expiration date or if it is



3a Open the test device and extraction buffer cap foil pouch and place them on the dry and clean surface.

3b Check the result window and specimen well on the test device.

TEST PROCEDURE

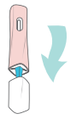
Sample stool should be fresh

4a Unfold the clean collection paper and put it on the toilet before sample collection.

4b Make sure no water to the collection paper or sample.

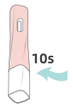
4c Use the test device (tip part) to fully collect sample

TEST PROCEDURE



5a Insert the test device with collected sample into the extraction buffer cap as the direction shown.

5b Make sure the test device and buffer cap are tightly and fully screwed to



5c let the sample and buffer completely mix.

Put the test device on a dry, clean and flat surface with buffer cap

6a Invert the test device with buffer cap up.

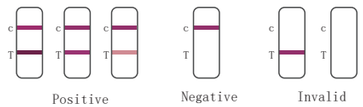
6b Place the test device on a flat and clean

6c surface.

Wait and read the results at 5 minutes (no longer than 15 minutes) .

6d Dispose the waste test device into the trash

INTERPRETATION OF RESULTS



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

*NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of hemoglobin present in the specimen. Therefore, any shade in the test region indicates positive result.

NEGATIVE: One colored line appears in the control region (C). No apparent red or pink line appears in the test 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 device. If the problem persists, discontinue using the test kit

! The user should not take any decision of medical relevance without first consulting his or her medical practitioner.

【LIMITATIONS】

1. The ZOAN™Calprotectin Test is for in vitro diagnostic use only.
2. This ZOAN™Calprotectin Test is a qualitative detection reagent and cannot determine the quantity of calprotectin in the sample.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician, such as symptoms, medical history etc.
4. Other clinical tests are required if questionable
results are obtained.

【QUALITY CONTROL】

An internal procedure control has been incorporated into the test to ensure proper kit performance and reliability. The use of an external control is recommended to verify proper kit performance. Quality control samples should be tested according to quality control requirements

【HAZARDOUS INGREDIENTS】

The Extraction buffer contains potentially harmful chemicals (see table below). If the test solution contacts the skin or eye, flush with copious amounts of water.

Chemical Name	Harms (GHS Code) for each ingredient	Concentration
Disodium Hydrogen Phosphate Dodecahydrate	Harmful if swallowed (H302) Cause skin irritation(H315) Cause serious eye damage (H318)	0.58%
ProClin® 300	Harmful if swallowed (H302) Harmful if inhaled (H332) Causes severe skin burns and eye damage (H314) May cause an allergic skin reaction (H317)	0.05%
Sodium dihydrogen phosphate dihydrate	Harmful if swallowed (H302) Cause skin irritation(H315) Cause serious eye damage (H318)	0.03%

【PERFORMANCE】

LoD: The lowest LoD should be ≤400ng/mL

Positive Percent Agreement (PPA)
The PPA should be ≥90%

Negative Percent Agreement (NPA)
The NPA should be ≥90%

Other
◆ Strip width: ≥2.5MM
◆ Liquid flow speed: ≥10mm/min

【SYMBOLS】

	Use-By date		Consult Instructions for use
LOT	Batch code		Do not freeze
	Manufacturer		Biological risks
	Keep Away from Sunlight	Σ	Contains su cient for <n> tests
	Temperature Limit		Do not use if package is damaged
IVD	In Vitro Diagnostic Medical device		Date of manufacture
CE	CE Mark		Do Not Reuse
EC REP	Authorized Representative in the European Community		

【Approval date and date of revision 】

Approval Date: Jul.15, 2022

CE IVD

展开尺寸：400*260mm　　正反印刷；横向5折，竖向1折；　　材质：70G双胶纸