



Calprotectin Rapid Test Cassette (Colloidal Gold) Instruction for Use

Lateral flow rapid test cassette for detection of human calprotectin in stool samples.

PRODUCT NAME

Calprotectin Rapid Test Cassette (Colloidal Gold)

SPECIFICATION

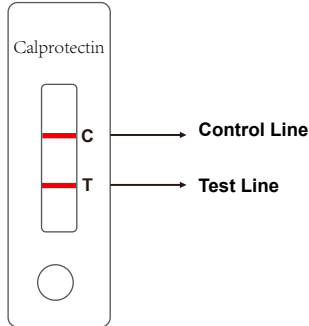
50 tests/kit, 40 tests/kit, 20 test/kit, 10 test/kit

INTENDED USE

This kit is an immunochromatographic assay for rapid quantitative determination of human calprotectin in feces. It is for in vitro diagnostics use only.

TEST PRINCIPLE

This calprotectin Rapid Test kit contains a fecal collection tube and a test cassette. Fecal specimen is collected in the collection tube containing sample extraction buffer and then added to the test device. When the sample is added to sample pad, it moves through the conjugate pad and mobilizes colloid gold conjugated anti-human calprotectin antibody. The mixture moves along the membrane by capillary action and reacts with another anti-human calprotectin antibody that is coated on the test region. If calprotectin is present of 50ng/g stool or greater, the result is the formation of a colored band in the test region. If there is no calprotectin in the sample, the test area will remain colorless. The sample continues to move to the control area where Goat anti-mouse IgG antibody will capture colloid gold antibody conjugate to form a pink to purple color, indicating the test is working and the result is valid.



MAIN COMPONENTS

Materials Provided

Components	50 tests/kit	40 tests/kit	20 test/kit	10 test/kit
Cassettes	50 cassettes with dependent sealed foil pouch	40 cassettes with dependent sealed foil pouch	20 cassette with dependent sealed foil pouch	10 cassette with dependent sealed foil pouch
specimen vial with buffer	50tubes	40tubes	20tubes	10tubes
Transfer tube	50 pcs	40 pcs	20pcs	10pcs
Package insert	1 pcs	1 pcs	1 pcs	1 pcs

Main ingredients of test cassettes:

It is composed of absorbent paper, nitrocellulose membrane, gold label pad, filter membrane and sample pad. The nitrocellulose membrane quality control line was coated with goat anti-mouse IgG polyclonal antibody, the detection line was coated with mouse anti-calprotectin monoclonal antibody 2, and the

gold label pad was coated with colloidal gold-labeled mouse anti-calprotectin monoclonal antibody 1.

Main ingredients of Sample Diluent Solution:

0.02 ml/L phosphate buffer

Reagents of different batch numbers cannot be used interchangeably.

MATERIALS REQUIRED BUT NOT PROVIDED

Timer

for timing use

PRECAUTIONS FOR USERS

- For in-vitro diagnostic use only.
- Handle all specimens as if they contain infectious agents. When the assay procedure is completed, dispose of specimens carefully after autoclaving for at least one hour. Alternatively, treat with a 0.5 or 1% solution of sodium hypochlorite for one hour before disposal.
- Wear protective clothing (laboratory coats and disposable gloves) when assaying samples.
- Do not eat, drink or smoke in areas where specimens and kit reagents are handled.
- Avoid contact between hands and eyes or nose during specimen collection and testing.

SPECIMEN COLLECTION

- Collect a random sample of feces in a clean, dry container.
- Trying not to spill the buffer, unscrew and remove the white color cap with attached sampling stick from the collection tube.
- Insert the sampling stick into the feces about 15 mm a few times.
- If necessary, remove excess of feces from the stick by gently wiping it with an absorbent tissue.
- Reinsert the stick into the tube and tighten the cap thoroughly.
- For liquid sample, add 100 µl of stool using an appropriate pipette into the vial via the green cap site.

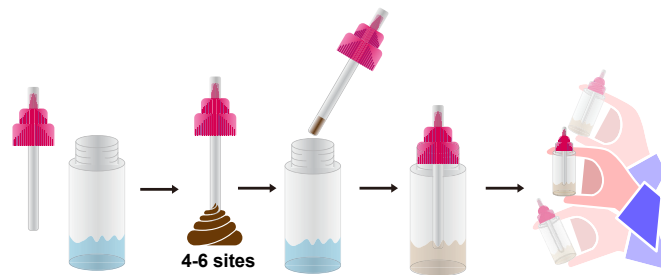
STORAGE OF TEST KIT

The calprotectin kit can be stored at any temperature between 4-30°C. Do not freeze. The stability of the kit under these storage conditions is 18 months. Use up the reagents as soon as possible after the kit is unpacked.

TEST PROCEDURE

Before performing the test, it is necessary to read the instructions and restore the test card, sample diluent and sample to 18-30°C. The detection method is as follows:

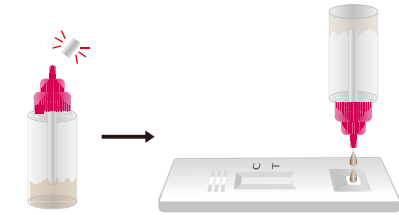
1. Open the packaging box, take out the sample dilution bottle, insert the fecal collection stick connected to the lid at several different positions of the sample randomly 4-6 times, take a sample of about 10-20m, and then insert the fecal collection stick into the dilution bottle; Or use a dropper to take a stool sample drop and add it to the sample dilution bottle; Tighten the cap and shake the dilution bottle to mix well.



2. Take out the test card from the aluminum foil bag, mark the test card on it, and place it on the horizontal work surface.

3. Remove the protective cap at the top of the sample diluent bottle, then break off the cap head, flip the dilution bottle, press lightly with your fingers, and add 2~3 drops of sample (about 80uL) to the sample filling hole of the test card.

4. Read the result within 5~10 minutes, and the result after 10 minutes is invalid.



INTERPRETATION OF RESULTS

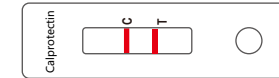
Negative Control

Only one colored band appears on the control region. No apparent band on the test region.



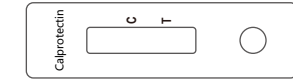
Positive Control:

In addition to a pink colored control band, a distinct pink colored band will also appear in the test region.



INVALID:

A total absence of color in both regions is an indication of procedure error and/or that test reagent deterioration has occurred.



The appearance of any burgundy color in the test bands, regardless of intensity, must be considered as presence of the band.

Samples with positive or reactive results should be confirmed with alternative testing method(s) such as ELISA or PCR and clinical findings before a diagnostic decision is made.

PERFORMANCE CHARACTERISTICS

Sensitivity:

The analytical sensitivity of the calprotectin test is 500ng/g stool. Sample containing less than 200 ng/g stool calprotectin would not show a test line.

Specificity:

The test is specific to human calprotectin. Samples containing the following substances both positive and negative controls with no effect on the test results.
















SUBSTANCES	CONCENTRATIONS
Bovine calprotectin	1 mg/ml
Goat calprotectin	1 mg/ml
Horse calprotectin	1 mg/ml
Pork calprotectin	1 mg/ml
Rabbit calprotectin	1 mg/ml

Interference testing:

The following substances were added to calprotectin free, 50 ng/g and 250 ng/g controls. No interference was found with any of the substances at the following concentrations:

- Acetaminophen 20 mg/dl
- Acetylsalicylic Acid 20 mg/dl
- Ampicillin 40 mg/dl
- Ascorbic Acid 40 mg/dl
- Atropine 40 mg/dl
- Caffeine 40 mg/dl
- Genticic acid 40 mg/dl
- Glucose 2000 mg/dlHuman
- Albumin 2000mg/dl

SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
	Batch code		In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don't use the product when the package is damaged		Keep dry
	Date of manufacture		Tests per kit
	CE Mark		Biological Risks
	Authorized representative in the European Community		