

eCassetTM Calprotectin Rapid Test Kit

REF KT-112

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

This kit is an immunochromatographic assay for rapid qualitative 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 antihuman 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 $50\mu g/g$ 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.

REAGENTS AND MATERIALS

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•	Calprotectin Cassette	REF 30823	20
•	Sampling Tube	REF 30824	20
•	Instruction for use	REF 31039	1

Rapid Cassette Test Reader (EPC – 100): (optional-inquire)

PRECAUTION FOR USERS

- 1. 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

- 1. 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.
- 3. 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.
- 5. Reinsert the stick into the tube and tighten the cap thoroughly.
- 6. For liquid sample, add 100 μ l of stool using an appropriate pipette into the vial via the green cap site.

STORAGE OF TEST KIT

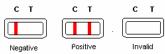
The calprotectin kit can be stored at any temperature between 2-30°C. **Do not freeze**. The stability of the kit under these storage conditions is 18 months. Use up the reagents as soon as possible after the kit is unpacked.

TEST PROCEDURE

- Step 1. Mix and dissolve stool sample completely by shaking or votexing.
- Step 2. Unscrew the natural colored cap on top of the green cap. Add 2 drops to the sample well of the test cassette.
- Step 3. Incubate the test at room temperature and read the test result between

5-10 minutes.

INTERPRETATION OF RESULTS



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

Positive: 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.

LIMITATIONS OF THE ASSAY

As with all diagnostic, a definitive clinical diagnosis should not be based on the result of a single test, but only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE

Sensitivity

The analytical sensitivity of the calprotectin test is $50\mu g/g$ stool. Sample containing less than $25\mu g/g$ 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

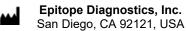
Interference testing:

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:

 Acetan 	ninophen	20 mg/dl
 Acetyls 	salicyclic Acid	20 mg/dl
 Ampic 	llin	40 mg/dl
 Ascorb 	oic Acid	40 mg/dl
 Atropir 	ne	40 mg/dl
 Caffeir 	ie	40 mg/dl
 Gentisi 	ic acid	40 mg/dl
Glucos	é	2000 mg/d
Human	n Albumin	2000mg/dl

REFERENCES

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W	Manufacturer	IVD	For in vitro diagnostic use only
EC REP	Authorized representative	[i	Consult instructions for use
Ση	Contains sufficient for <n> tests</n>	*	Keep dry
REF	Catalogue Code	X	Temperature limitation
LOT	Lot Number	23	Use by
DIL	Sample diluent	5,07,66	