

## eCasset™ 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 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 50µg/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

- 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

- 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 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 vortexing.
- 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 50µg/g stool. Sample containing less than 25µg/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
▪ Gentisic acid	40 mg/dl
▪ Glucose	2000 mg/dl
▪ Human Albumin	2000mg/dl

### REFERENCES

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	Manufacturer	IVD	For in vitro diagnostic use only
EC REP	Authorized representative		Consult instructions for use
	Contains sufficient for <n> tests		Keep dry
REF	Catalogue Code		Temperature limitation
LOT	Lot Number		Use by
DIL	Sample diluent		