Calprotectin Rapid Test Kit
Instructions For Use

PRODUCT NAME

FRENOVO Calprotectin Rapid Test Kit

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

FRENOVO Calprotectin Rapid Test Kit is a rapid chromatographic immunoassay for the semi-quantitative detection of Calprotectin in feces.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

Calprotectin, first described in 1980, is aprotein found in the cytosol of neutrophils and macrophages composed of two subunits S100A8 and S100A9. It is released extracellularly in times of cell stress or damage and can be detected within feces and thus can be used as a sensitive marker of intestinal inflammation. It is stable in feces for up to seven days at room temperature and has a homogenous distribution in feces, properties which lend it to testing spot fecal samples.

The inflammatory bowel diseases (IBD), Crohn's disease and ulcerative colitis, are chronic relapsing, remitting disorders. Diagnosis along with assessment of disease activity and prognosis present challenges to managing clinicians. Fecal biomarkers, such as fecal calprotectin, are a non-invasive method which can be used to aid the sedecisions. Fecalprotectin has been shown to be useful in the diagnosis of IBD, correlates with cosal disease activity and can help to predict response to treatment or relapse. With growing evidence supporting its use, over the last decade this fecal biomarker has significantly changed the way IBD is managed.

FRENOVO Calprotectin Rapid Test Kit detects Calprotectin through visual interpretation of color development on the internal strip. Anti- Calprotectin antibodies are immobilized on the test region of the membrane. During testing, the specimen reacts with anti-Calprotectin antibodies conjugated to colored particles and precoated on the sample pad of the test. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If no test line appears, it indicates that the Calprotectin level in the specimen is below 50ug/g. If only the test line 2 (T2) appears, it indicates that the Calprotectin level in the specimen is between 50-200ug/g. If all the test lines (T1, T2) appear, it indicates that the Calprotectin level is above 200ug/g. The appearance of control line serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

KIT COMPONENTS

Each kit contains:

1. Test devices: 20 pieces test devices individually pouched.
2. Sample collection tubes: 20 pieces tubes and 1.0 ml collection solution in each tube.
3. Instructions For Use: 1 piece attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Biohazard disposal waste container.
- Disposable gloves and/or protective clothing.

WARNINGS

1. Read the Instructions For Use completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. The kit is for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. The kit is for professional use only.
2. The Instructions For Use instructions must be followed to ensure optimum test performance.
3. The kit is intended for *in vitro* diagnostic use.
4. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.

Safety Precautions

1. Standard precautions for handling infectious agents should be observed when using this kit.
2. Wear protective clothing such as lab coat, safety glasses and disposable gloves when handling specimens and assay reagents.
3. Wash hands thoroughly after use.
4. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Bio safety Precautions

Appropriate bio safety practices should be used when handling specimens and reagents. These precautions include, but are not limited to the following:

1. Do not smoke, eat, drink, apply cosmetics or handle contact lenses in areas in which specimens are handled.
2. Dispose of all specimens, used devices and tubes as though they are capable of transmitting infection. The preferred methods of disposal are by autoclave at 121°C for a minimum of 60 minutes or by incineration. Disposable materials may be incinerated. Liquid waste may be mixed with appropriate chemical disinfectants. A solution of 10% bleach is recommended. Allow 60 minutes for effective decontamination. NOTE: Do not autoclave solutions containing bleach.
3. When disposing of sample collection tubes, avoid contact with acid to prevent liberation of a toxic gas.
4. All spills should be wiped thoroughly using a suitable disinfectant such as a sodium hypochlorite solution.
5. Use a separate tube and device for each specimen tested.

Handling Precautions

1. Do not use if the kit box safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not mix sample collection tubes/test devices from different kit lots.
5. Do not use the kit past the expiration date (this date is printed on the kit box).
6. Adequate lighting is required to read the test results.
7. The result should be read immediately after the end of the 10 minutes incubation time following the addition of collected specimen. Do not read results beyond 15 minutes.

STORAGE INSTRUCTIONS

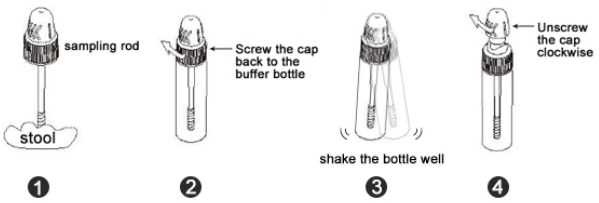
1. The kit should be stored between 2-30°C and the shelf life is 24 months.
2. The kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date. The kit expiry date is not impacted once the extraction Solution has been opened. Do not use kit components beyond overall kit expiry date.
3. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
4. Do not freeze the kit.

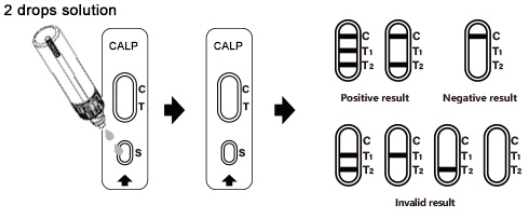
TEST PROCEDURE

Allow the test device, specimen, extraction solution to equilibrate to room temperature (15-30°C) prior to testing.

1. Loosen the sample collection tube, take out the sampling rod, insert the feces sample, pick up 50 mg fecal sample (equivalent to the size of match head) and then put the sampling rod back into the tube, and rotate it tighten and shake well.
2. Place the test cassette on a clean and level surface. Break the tip of the sample collection tube, abandon the first two drops and draw two drops (approximately 90ul) into the sample well then start the timer. Avoid trapping air bubbles in the sample well.
3. Wait for the colored line(s)to appear. The test result should be read at 10 minutes. Do not

interpret the result after 15 minutes.





INTERPRETATION OF RESULTS

Positive result: One color line appears in the control region(C). One or Two color lines appear in the test region(T) .

Test line(T)	Semi quantitative result
Only T2 appears	Calprotectin level is 50ug/g~200ug/g
T1 and T2 appear	Calprotectin level is >200ug/g

Negative result: One color line appears in the control region(C). No apparent purple line appears in the test region (T). Negative result showed:There was not CALP in the sample,or the content of CALP below the detectable range.

Test line (T)	Semi quantitative result
No line	Calprotectin level is below 50ug/g

Invalid result: Control line fails to appear. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The kit is for professional in vitro diagnostic use only. is for professional in vitro diagnostic use. The test should be used for the detection of calprotectin in human feces specimens only.
2. The kit will only indicate the semi-quantitative level of Calprotectin in the specimen and should not be used as the sole criteria for evaluating inflammatory conditions.
3. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician After all clinical and laboratory findings have been evaluated.
4. Calprotectin values near the cut-off level Test line 2(T2: 50ug/g) and Test line 1 (T1: 200ug/g), should be reported with caution as with all quantitative assays there exists some level of variation. Therefore, a T line with slightly higher intensity than T2can also represent a value slightly below 200ug/g. Similar observations may occur with values near 50ug/g. A repeat test or further quantitative test is recommended.
5. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended.

PERFORMANCE CHARACTERISTICS

Expected Values

FRENOVO Calprotectin Rapid Test Kit has been compared with Calprotectin ELISA test, demonstrating an overall accuracy of 95%.

Sensitivity and Specificity

Clinical study was performed to compare the results obtained by The kit and EIA. The results indicated that The kit has a high sensitivity and specificity as summarized below:

Method		**EIA**			**Total Results**
		Negative	**Positive**		
Calprotectin Rapid Test	**Result**	**0~50ug/g**	**50~200ug/g**	**>200ug/g**	
	0~50ug/g	86	0	0	86
	50~200ug/g	2	10	0	12
	>200ug/g	0	0	2	2
Total Results		88	10	2	100

Clinical sensitivity=100% (95%CI * 77.9% to 100%)
Clinical specificity=97.7% (95%CI * 92.0% to 99.7%)

Accuracy=98.0% (95%CI * 93.0% to 99.8%)

Interfering Substances

The following substances do not interfere with the test results at the indicated concentrations: lactoferrin at 3mg/ml, Adenovirus, Rotavirus, E.coli, helicobacter pylori and Salmonella.

INDEX OF SYBOML

IVD	In vitro diagnostic medical device		single-use,Please don't reuse it
	Use-by date		Consult instructions for use
	Cautions		Manufacturer
2°C	Temperature limit	LOT	Batch code
	Date of manufacture		Keep Dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged
CE	CE mark		Biological risks

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INSTRUCTION APPROVAL AND REVISION DATE

Approval Date:
Revision Date:
Date of Issue: