Calprotectin FIA Rapid Test Device

Catalogue No.: FI2-CAL-001

(Human Faeces)

A rapid test for the quantitative detection of Calprotectin in human faecal specimens with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000). For professional in vitro diagnostic use only.

INTENDED USE

The Biopanda Calprotectin FIA Rapid Test Device is intended for *in vitro* quantitative detection of Calprotectin in human faecal specimens. Measurement of Calprotectin is used as an aid in the assessment of intestinal inflammation.

SUMMARY

Calprotectin is a 24 kDa dimer of calcium binding proteins S100A8 and S100A9.[1] The complex accounts for up to 60% of the soluble protein content of the neutrophil cytosol.[2] Calprotectin becomes available in the intestinal lumen via leukocyte shedding, active secretion, cell disturbance, and cell death.[3] This results in elevated faecal calprotectin levels, which can be detected in the stool.[3] Elevated faecal calprotectin levels therefore indicate migration of neutrophils into the intestinal mucosa, which occurs during intestinal inflammation.[4] Faecal calprotectin has been used to detect intestinal inflammation and can serve as a marker for inflammatory bowel diseases.[5] Calprotectin is useful as a marker, as it is resistant to enzymatic degradation, and can be easily measured in faeces.[6]

PRINCIPLE

The Calprotectin FIA Rapid Test Device detects Calprotectin based on Fluorescence Immunoassay. The sample moves through the strip from the sample pad to the absorbent pad. The Calprotectin in the specimen will be combined with the anti-Calprotectin antibody-1 that has been conjugated with fluorescence microspheres and the combination will be captured by anti-Calprotectin antibody-2 coated on the membrane. The more Calprotectin in the specimen, the more fluorescent microspheres will be captured on the membrane. The concentration of Calprotectin in the sample is inversely related to the intensity of the fluorescent signal captured on the T line. According to the fluorescence intensity of the test and the standard curve, the concentration of Calprotectin in the specimen can be calculated and reported by the Fluorescence Immunoassay Device (BR-FIA-2000).

REAGENTS

The test includes anti-Calprotectin antibody-1 coated fluorescent micro-spheres and anti-Calprotectin antibody-2 coated on the membrane.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. This test contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
4. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
5. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. Do not interchange or mix reagents or ID cards from different lots.
7. Humidity and temperature can adversely affect results.
8. Used testing materials should be discarded in accordance with local regulations.
9. Read the entire procedure carefully prior to any testing.
10. The Biopanda Calprotectin FIA Rapid Test Device should only be used with the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000) by approved medical professionals.

STORAGE AND STABILITY

1. The kit should be stored at 4-30°C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. **Do not freeze.**
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

KIT COMPONENTS

Materials Provided:

- 25 x foil wrapped Calprotectin FIA Rapid Test Devices
- 25 x Specimen collection tubes with buffer solution
- 1 x ID card (Calprotectin)
- Package Insert

Materials required but not provided:

- Specimen Collection Containers
- Timer
- Pipette
- Biopanda Fluorescence Immunoassay Device (BR-FIA-2000)

SPECIMEN COLLECTION AND PREPARATION

Specimen Collection

Collect sufficient quantity of faeces (1-2 mL or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present).

Specimen Storage and Shipping

Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8 °C if not tested within 6 hours. For long term storage, specimens should be kept below -20 °C. If specimens are to be shipped, these should be packed in compliance with local regulations covering the transportation of etiological agents.

Preparation

Before performing the test, please bring the specimen to room temperature (15-30 °C). Frozen specimens must be completely thawed and mixed well prior to testing.

DIRECTIONS FOR USE

Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for the complete instructions on use of the test. The test should be conducted at room temperature. Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.

Note: There are two test modes for the Biopanda Fluorescence Immunoassay Device: Standard Test mode and Quick Test mode. *Standard Test* mode is a 'set and forget' method where the test will automatically be read after 15 minutes. *Quick* Test mode provides an instant result but the user must monitor the 15 minute test time themselves. It is suitable when running multiple tests concurrently.

Refer to the Biopanda Fluorescence Immunoassay Device Operation Manual for further details.

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Turn on the Analyser. Then according to the user requirement, select "Standard test" or "Quick test" mode.
2. Take out the ID card and insert it into the Analyser port.
3. To process faecal specimens:

   For Solid Specimens:

   Unscrew the cap of the specimen collection tube， then randomly stab the specimen collection applicator into the faecal specimen in **at least 3 different sites** to collect approximately **50 mg** of faeces (equivalent to 1/4 of a pea). Do not scoop the faecal specimen.

   For Liquid Specimens:

   Pipette **80 µL** of faeces into the specimen collection tube containing the buffer.

   Tighten the cap onto the specimen collection tube and then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Let the tube sit for 2 minutes.
4. Remove the test Device from the sealed foil pouch and place it on a clean, level surface. The Device should be used within one hour of opening.
5. Hold the specimen collection tube upright and open the cap onto the specimen collection tube. Invert the specimen collection tube and **discard**

2 drops of the extracted specimen (approximately 80 µL), then transfer **2 full drops of the extracted specimen (approximately 80 µL)** to the specimen well of the test device and then start the timer. Avoid trapping air bubbles in the specimen well.

6. Test results should be read at **15 minutes** with the use of the Biopanda Fluorescence Immunoassay Device (BR-FIA-2000).

INTERPRETATION OF RESULTS

The result of the Calprotectin FIA Rapid Test Device is calculated by the Fluorescence Immunoassay Device (BR-FIA-2000) and displayed on the screen. For additional information, please refer to the user manual of Fluorescence Immunoassay Device.
The assay range of Calprotectin Test is 1-1000 µg/g.

QUALITY CONTROL

Each Calprotectin FIA Rapid Test Device contains an internal control that satisfies routine quality control requirements. This internal control is performed each time a patient specimen is tested. This control indicates that the test device was inserted and read properly by the Biopanda Fluorescence Immunoassay Device. An invalid result from the internal control causes an "N/A" message on the Analyser. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS OF THE TEST

1. The Calprotectin FIA Rapid Test Device should be used only with the analyzer.
2. The test should preferably be performed on freshly collected samples. For stored specimens, please refer to specimen storage.
3. The Calprotectin FIA Rapid Test Device is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of Calprotectin. It should not be used as the sole criteria for clinical result. If the result is abnormal, other clinical findings and alternative test methods are recommended to reach proper medical treatments.
4. The test may yield low results due to Calprotectin epitopes being covered by some unknown components. Low results may also be obtained due to instability or degradation of Calprotectin antigen with time and temperature.
5. Other factors interfering with the test and causing erroneous results include technical/procedural errors, degradation of the test components as well as presence of interfering substances in the test samples.
6. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

EXPECTED RESULTS

Concentrations	Clinical Reference
< 50 µg/g	Negative
≥ 50 µg/g	Positive

Each laboratory should determine the applicability of the reference range through experiments and establish its own reference value range if necessary to ensure that it can correctly reflect the situation of a particular population.

PERFORMANCE CHARACTERISTICS

1. **Method comparison**
   For 96 specimens, the test results of Calprotectin FIA Rapid Test Device were consistent with commercial Calprotectin test kits and the correlation coefficient (R2) is 0.942.
2. **Accuracy**
   The test deviation is ≤ ±15%.
3. **Assay Range**
   Assay Range is 1-1000 µg/g.
4. **Precision**
   Intra-lot precision
   Within-run precision has been determined by using 10 replicates of 2 different concentrations of Calprotectin control. C.V. is ≤ 15%.
   Inter-lot precision
   Between-run precision has been determined by using 10 replicates for each of three lots using 2 different concentrations of Calprotectin control. C.V. is ≤15%.

REFERENCES

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SYMBOLS USED

The following symbols are used on the packaging and labelling. They are presented here along with their meaning.

	Manufacturer		Expiration date
	Do not re-use test	IVD	*in vitro* diagnostic medical device
	Consult instructions for use	LOT	Batch code
	Storage temperature	Σ	Contains sufficient for <*n*> tests
REF	Catalogue number		Do not use if package is damaged

Thank you for purchasing Biopanda's Calprotectin FIA Rapid Test Device. Please read this manual carefully before operating to ensure proper use.

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