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CE

IVD

Rapid-VIDITEST

Calprotectin

One Step Calprotectin Card Test.

Instruction manual

INTENDED USE:

The Rapid-VIDITEST Calprotectin test is a rapid chromatographic immunoassay (non-invasive assay) for the qualitative detection of calprotectin in human feces specimens, which might be useful for the diagnosis of inflammatory gastrointestinal disorders. Only for laboratory use.

INTRODUCTION:

Calprotectin is a calcium-containing protein that makes up 5% of the total protein and 60% of the cytosolic protein of neutrophil. It has bacteriostatic and fungistatic properties and is found in feces at levels six times higher than that in plasma. That fecal biomarker is useful to assess the activity of inflammatory bowel disease (IBD). IBD includes Crohn's Disease (CD) and Ulcerative Colitis (UC) and are associated with elevated neutrophils.
This fecal calprotectin assay is useful in differentiating organic (IBD) from functional gastrointestinal disease (IBS: Intestinal Bowel Syndrome). It is a simple, non-invasive biomarker that is especially useful in children, who may require general anesthesia for colonoscopy.
And this fecal calprotectin detection can predict relapse.

PRINCIPLE:

The Rapid-VIDITEST Calprotectin is a qualitative immunoassay for the detection of calprotectin in feces samples. The membrane is pre-coated with monoclonal antibodies against calprotectin on the test lines region. During testing, the sample reacts with the particles coated with anti-human calprotectin antibodies which were pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. In the case of a positive result the specific antibodies present on the membrane will react with the mixture conjugate and generate colored line. A green colored band always appears in the control line and serves as verification that sufficient volume was added, that proper flow was obtained and as an internal control for the reagents.

MATERALS PROVIDED:

- Card tests
- Instructions for use
- Specimen collection vial with buffer

MATERIALS REQUIRED BUT NO PROVIDED:

- Specimen collection container
- Disposable gloves
- Timer

SPECIMEN COLLECTION AND PREPARATION:

Collect sufficient quantity of feces (1-2 g or mL for liquid sample). Stool samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-8ºC/36-46.4ºF) for 7 days prior to testing. For longer storage (maximum 6 months), the specimen must be kept frozen at –20ºC/-4ºF. In this case, the sample will be totally thawed, and brought to room temperature before testing.

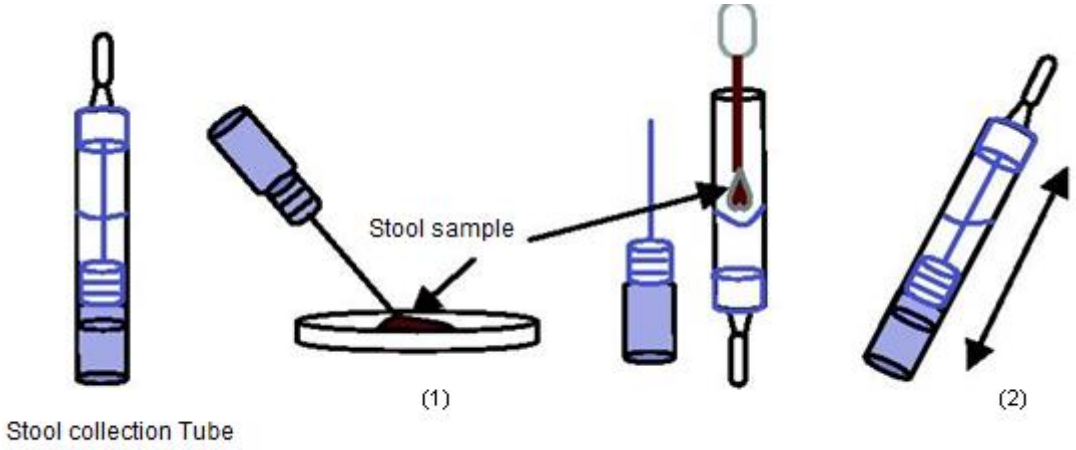
PROCEDURES:

To process the collected stool samples:

Use a separate vial for each sample.

1. Unscrew the cap of the vial and introduce the stick four times into the fecal specimen to pick up the sample (1). Close the vial with the buffer and stool sample. This vial with the sample can be storage during 7 days (2-8ºC/36-46.4ºF) .
2. Shake the vial in order to assure good sample dispersion (2).

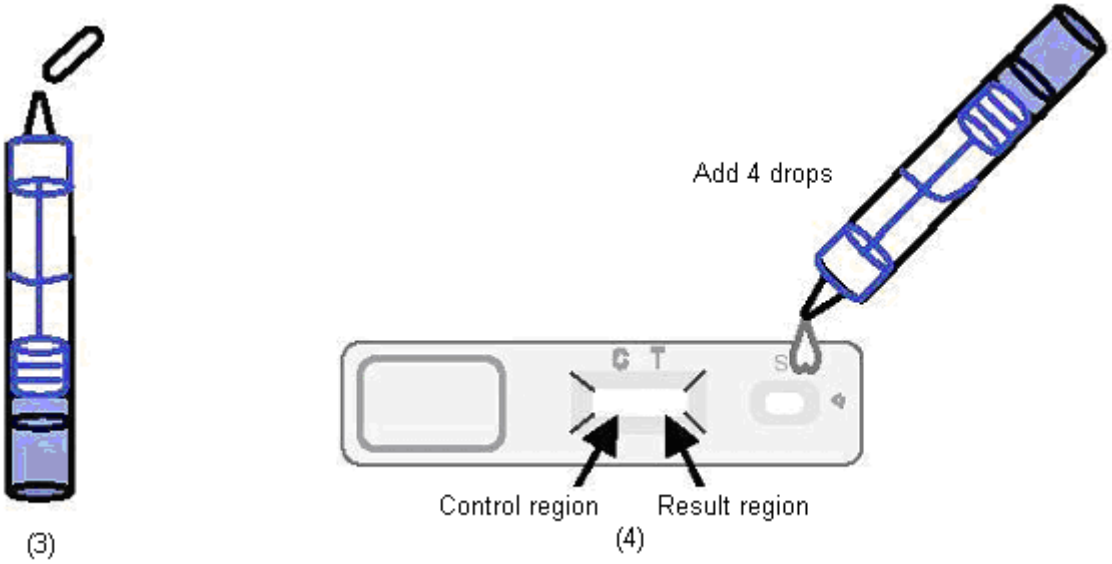
For liquid stool samples, aspirate the fecal specimen with a dropper and add approx. 15 uL into the specimen collection vial with buffer.



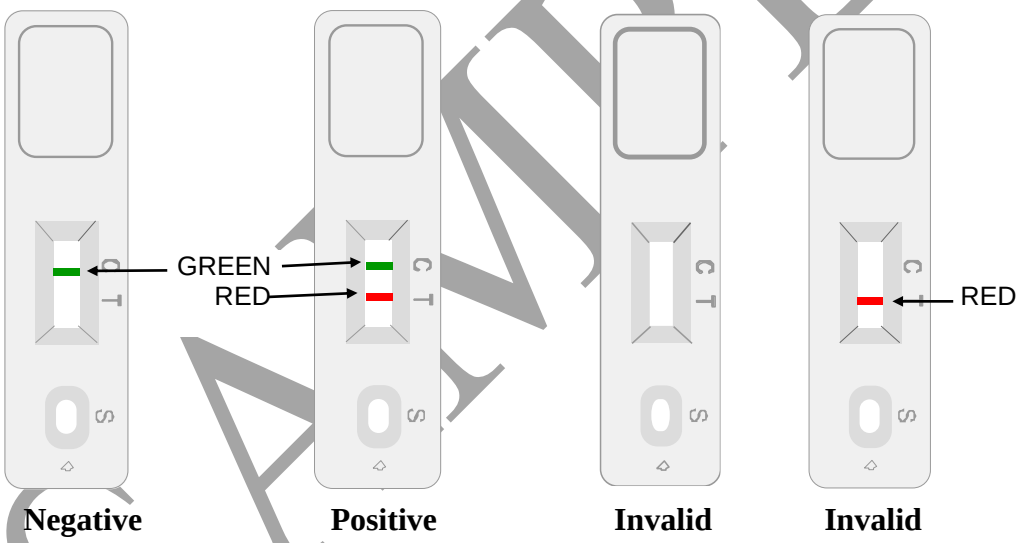
Test Procedure:

Allow the tests, stool samples and buffer to reach to room temperature (15-30ºC/59-86ºF) prior to testing. Do not open the pouch until ready to perform the assay.

1. Remove the Rapid-VIDITEST Calprotectin from its sealed pouch and use it as soon as possible. Place in a clean and flat surface.
2. Shake the specimen collection vial to assure good sample dispersion. Break off the tip of the vial (3).
3. Use a separate device for each sample. Dispense 4 drops into the specimen well (S) (4). Start the timer.
4. Read the result at **10 minutes** after dispensing the sample.



INTERPRETATION OF RESULTS:



POSITIVE: Two lines appears across the central window, in the result line region (**red** test line marked with the letter T) and in the control line region (**green** control line marked with the letter C). A calprotectin positive result could be indicative of gastrointestinal inflammatory pathology is present.

NEGATIVE: Only one **green** band appears across the control line region marked with the letter C (control line). A negative results shows that neither active gastrointestinal inflammation is present.

INVALID: A total absence of the green control colored band regardless the appearance or not of the red test line. Note: Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit and contact your local distributor.

NOTES ON THE INTERPRETATION OF RESULTS:

The intensity of the red colored band in the result line region (T) will vary depending on the concentration of calprotectin in the specimen.

QUALITY CONTROL:

Internal procedural controls are included in the test:

- A green line appearing in the control line region (C). It confirms sufficient specimen volume and correct procedural technique.
- A clear background is an internal negative background control. If the test is working properly, the background in the result area should be clear and not interfere with the ability to read the result.

LIMITATIONS:

1. Rapid-VIDITEST Calprotectin will only indicate the presence of calprotectin in the specimen (qualitative detection) and should be used for the detection of calprotectin in feces specimens only. Neither the quantitative value nor the rate of increase in calprotectin concentration can be determined by this test.
2. An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
3. Some stool samples can decrease the intensity of the control line.
4. In the case of patients with active neutrophilic inflammatory bowel diseases such as Crohn's disease and Ulcerative Colitis, would be positive for fecal calprotectin. Rapid-VIDITEST Calprotectin Card could be used for patients with chronic diarrhea.
5. Positive results confirm the presence of calprotectin in fecal samples; nevertheless, it can be due to several causes, inflammatory bowel disease, colorectal cancer and some enteropathies). Positive results should be followed up with additional diagnostic procedures by a physician to determine the exact cause of inflammation.
6. Neonatal fecal calprotectin levels have been reported higher than normal children with a median of 167µg/g.

EXPECTED VALUES:

Higher levels of calprotectin in the stool are associated with an increased risk of relapse in patients with inflammatory bowel disease (IBD). Some studies established equal or higher 50µg hFCP/g faeces as cut-off value to allow detect adult patients with GI inflammatory problems.

PERFORMANCE CHARACTERISTICS:

Cut-off value

Cut-off value of test is 500 ng/mL (50 µg hCp/g feces) for human calprotectin.

Sensitivity and Specificity

It was performed an evaluation using Rapid-VIDITEST Calprotectin. The Rapid-VIDITEST Calprotectin was evaluated compared with a commercial immunoassay (Calprest®, Eurospital).

Sensitivity >94% and specificity 93%.

Cross-Reactivity

It was performed an evaluation to determine the cross reactivity of Calprotectin Device. There is not cross reactivity against other fecal markers occasionally present in feces.

- Bovine and pig hemoglobin
- Bovine and pig transferrin
- Bovine lactoferrin
- Human hemoglobin
- Human lactoferrin
- Human transferrin

STORAGE AND STABILITY:

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC/36-86ºF). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze.

PRECAUTIONS:

- For professional in vitro diagnostic use only.
- Do not use after expiration date.
- The test should remain in the sealed pouch until use.
- Do not use the test if pouch is damaged.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test should be discarded in a proper biohazard container after testing.
- The test must be carried out within 2 hours of opening the sealed bag.

REFERENCES:

1. VIEIRA, A. et al., "Inflammatory bowel disease activity assessed by fecal calprotectin and lactoferrin: correlation with laboratory parameters, clinical, endoscopic and histological indexes", BMC Research Notes 2009, 2:221.
2. HANAI, H. et al. «"Relationship Between Fecal Calprotectin, Intestinal Inflammation, and Peripheral Blood Neutrophils in Patients with Active Ulcerative Colitis" Digestive Diseases and Sciences, Sept. 2004, Vol 49, No 9, pp 1438-1443.
3. BONNIN TOMAS, A, et al. "Calprotectina fecal como marcador diferencia entre patología gastrointestinal orgánica y funcional". Rev. Esp. de Enf. Dig. 2007, Vol 99, No 12, pp. 689-693.

SYMBOLS FOR IVD COMPONENTS AND REAGENTS:

IVD	*In vitro* diagnostic device	LOT	Batch code
	Use by		Manufacturer

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