PHARMA *Southern Africa*

CALPROTECTIN' ALERT®
Ref. 63084/ZA

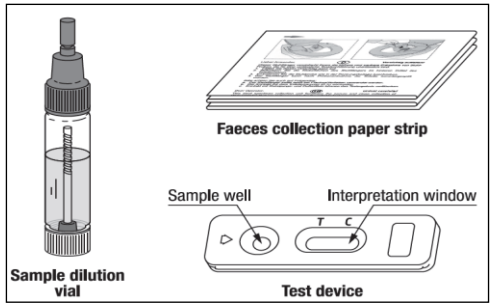
Self-diagnostic test for the detection of faecal Calprotectin associated to intestinal inflammation

GENERAL POINTS

Calprotectin is a major protein found in the inflammatory cells such as neutrophil granulocytes. The incidence of inflammatory bowel disease is increasing and elevated levels of faecal calprotectin indicate the migration of neutrophils into the gut lumen. The calprotectin which is recognized as having a bacteriostatic and mycostatic activity is released and further secreted with stool. As the protein is resistant to degradation it has become a marker of choice to detect inflammatory bowel diseases such as Crohn's diseases or ulcerative colitis (which may need further surgery) and to discriminate them from the irritable bowel syndrome (which does not need invasive endoscopic procedures).
The CALPROTECTIN' ALERT® is a fast and convenient immunological test for the detection of calprotectin in faeces when its concentration is exceeding 50 µg of calprotectin per gram of faeces.

PRESENTATION

The box contains the material necessary to perform a test:
- 1 sealed aluminium pouch containing:
1 test device and 1 desiccant pouch
Only open the protection pouch after having collected the faeces sample. The desiccant bag should be discarded.
- 1 faeces collection paper strip.
- 1 sample dilution vial containing 3.5 mL of extraction solution.
- 1 leaflet.



PRECAUTIONS

1. This test is exclusively intended to *in vitro* diagnostic. External use only. DO NOT SWALLOW.
2. Carefully read the instructions before performing the test. **The test is reliable assuming the instructions are carefully respected. Strictly respect the indicated number of drops of diluted sample to be added in the sample well of the test device and the reading time of result.**
3. Store at +4°C to +30°C. Do not freeze the test.
4. Do not use after the expiry date indicated on the label and the pouch. Do not use the test if the protective aluminium pouch is damaged.
5. Do not re-use the CALPROTECTIN' ALERT®
6. Keep out of the reach of children.
7. After use, all the components can be discarded in a dustbin.

PROCEDURE

Before performing the test, a stool sample must be collected as indicated hereunder:

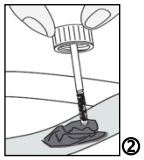
A- Sample collection

1. Wash your hands with soap and rinse with clear water.

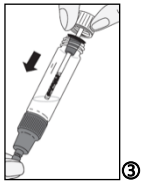
2. The faeces should be collected using the special paper strip supplied in the box ①.

3. Unscrew the **white cap** of the sample dilution vial having the collection tip attached on it.

4. Collect the stool sample dipping the tip in 3 different places of the same stool sample.②



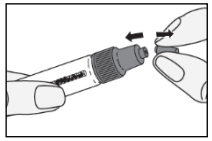
5. Put the white cap containing the faeces sample back in place onto the dilution vial and screw it firmly. ③
Shake the dilution vial for 10 seconds to resuspend the faeces sample into the diluent.

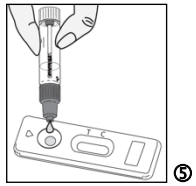


B- Test procedure

1. Open the protective pouch using the notches and take out the test device. Discard the small desiccant bag.

2. Break the **purple** tip of the dilution vial ④; holding the dilution vial vertically, squeeze it to add 5 drops of diluted faeces sample into the sample well (▷) ⑤. Avoid air bubbles.



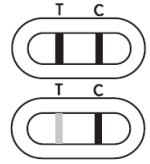


3. Read the result of the test 10 minutes after addition of the sample on the test device. Do not interpret after 15 minutes.

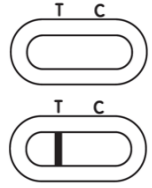
RESULT INTERPRETATION

1. Negative result
Only one coloured band appears on the control zone (C). The sample does not contain calprotectin or the concentration is lower than 50 µg/gr faeces.

2. Positive result
In addition of the control band (C), a clearly distinguishable band also appears on the test zone (T). The colour intensity of the lines may be different. The sample contains calprotectin at a concentration higher than 50 µg/gr faeces. You should consult a doctor.



3. Non valid result
If there is no distinct colour band visible in the control zone (C), the test is not valid. The test should be repeated using a new CALPROTECTIN' ALERT® and a new sample of faeces.



QUESTIONS AND ANSWERS

How does CALPROTECTIN' ALERT® work?
The incidence of inflammatory bowel disease (such as Crohn's disease and ulcerative colitis) is increasing and many people only with irritable bowel syndrome have unnecessary invasive hospital investigations before their condition is diagnosed. Testing faecal calprotectin, a marker of intestinal inflammation, will lead to the detection of most people with irritable bowel syndrome reducing the need of these investigations as well as their associated risk of such investigations. The CALPROTECTIN' ALERT® allows the detection of faecal calprotectin when exceeding 50µg/gr of faeces thanks to the use of two monoclonal antibodies. One is fixed on the membrane (test line) and another one is fixed on mobile red gold particles to allow the appearance of a red line when calprotectin is present in the sample.

When can this test be performed?
CALPROTECTIN' ALERT® test can be performed when persistent (4 weeks or more) or recurrent (2 episodes in 6 months or more) abdominal pain or diarrhea are occurring. Rectal bleeding, weight loss or anaemia may also increase the probability of intestinal inflammation. The test could be performed any time of the day.
The test cannot be performed on liquid stool. You should therefore consult your doctor before performing the test in case of liquid faeces (diarrhea etc.).

Can the result be incorrect?
The result is accurate as long as the instructions for use are carefully respected.
Nevertheless, the result can be incorrect if the CALPROTECTIN' ALERT® gets wet before performing the test, if faeces collecting steps are not correctly performed, if the sample is contaminated or if an incorrect number of drops is dispensed in the sample wells.

How to interpret the test if the colour and the intensity of the lines are different?
The colour and intensity of the lines have no importance for result interpretation. The lines should only be homogenous and clearly distinguishable.
The test should be considered as positive whatever the colour intensity of the test line (T), weak or strong.

What is the line that appears under the mark C (Control) for?
When this line appears, it only means that the test was performing well.

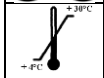
If I read the result after 15 minutes, will the result be reliable?
No. The test should be read after 10 minutes and before 15 minutes after having added the diluted sample. The results are reliable up to 15 minutes.

What do I have to do if the result is positive?
If the result is positive, it means that the calprotectin is exceeding 50 µg/gr of faeces and that you should consult a practitioner. Then the practitioner will decide whether additional investigations should be performed.

What do I have to do if the result is negative?
If the result is negative, it means that the calprotectin concentration is below 50 µg/gr of faeces and that you are likely not suffering of intestinal inflammation. However, it the symptoms persist, it is recommended to consult your doctor.

What is the accuracy of CALPROTECTIN' ALERT®?
The CALPROTECTIN' ALERT® is accurate. Evaluation report shows an overall result correlation of 95.4% ([90.38 –98.18] *) with reference method. Although this test is reliable, false positive or false negative results could be obtained.
**CI 95%: 95% confidence interval*

Information on calprotectin and its clinical significance:
https://www.larevuedupraticien.fr/article/maladies-inflammatoires-chroniques-de-lintestin-0
https://www.calprotectin.co.uk/about-calprotectin/information-for-patients/
https://www.mayocliniclabs.com/test-catalog/Clinical+and+Interpretive/63016

	Read the instructions before use	IVD	For *in vitro* diagnostic use		Do not reuse
	Store between +4°C and +30°C	LOT	Batch number		Expiry date
	Manufacturer				

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CHANGES DESCRIPTION
Changes type:

- N/A Not Applicable (creation)
- Technical change Addition, revision and/or removal of information related to the product.
- Administrative Implementation of non-technical changes noticeable to the end-user.

Changes type	Changes description
N/A	Creation

Note: Minor typographical, grammar, spelling and formatting changes are not reported in the change details.

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2023/01
CALPMCOT600401