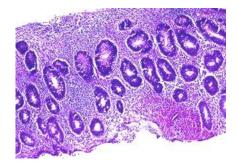
Calprotectin RAPID TEST



Rapid one step test for the qualitative detection of **Calprotectin** in human faeces





1. What is CALPROTECTIN?

Calprotectin is a calcium and zinc binding protein that has bacteriostatic and fungistatic properties. It is resistant to enzymatic degradation, and can be easily measured in faeces.

The main diseases that cause an increased excretion of faecal calprotectin are inflammatory bowel diseases (i.e.: Crohn's disease, ulcerative colitis...) and neoplasms (cancer).

The levels of this protein are markedly elevated in infectious and inflammatory conditions, including inflammatory bowel disease (IBD). Elevated concentrations of fecal calprotectin have been demonstrated in numerous studies of patients with IBD. Fecal calprotectin correlates well with histological inflammation as detected by colonoscopy with biopsies and has been shown successfully to predict relapses and detect pouchitis in patients with IBD.

Fecal calprotectin has been shown to consistently differentiate IBD from irritable bowel syndrome because it has excellent negative predictive value in ruling out IBD in undiagnosed, symptomatic patients. Fecal calprotectin also may be useful in determining whether clinical symptoms in patients with known IBD are caused by disease flares or noninflammatory complications/underlying irritable bowel syndrome and in providing objective evidence of response to treatment. For that reasons, measurement of faecal calprotectin as a biochemical test for inflammatory bowel disease could replace the need for invasive colonoscopy or radio-labelled white cell scanning in many clinical scenarios

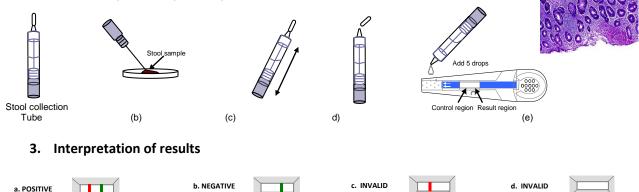
2. What is *H&R Calprotectin* test?

The *H&R Calprotectin* test is a one step coloured chromatographic immunoassay for the qualitative determination of human calprotectin in stool samples that reflects gastrointestinal inflammation caused by several pathologies (inflammatory bowel disease, colorectal cancer and some enteropathies).

H&R Calprotectin test offers a highly sensitive, simple and non-invasive assay to estimate intestinal inflammatory activity, to monitor treatment response and to predict risk of relapse.

3. How is H&R Calprotectin test performed?

- a. Collect sufficient quantity of faeces
- b. Unscrew the cap of the vial and introduce the stick into the faecal specimen to pick up enough sample
- c. Introduce the stick with the sample into the vial and shake it in order to assure good sample dispersion
- d. Break off the tip of the vial and open the pouche to take the H&R Calprotectin test device.
- e. Dispense 5 drops or 150 μ L into the cassette and wait 10 minutes for the result.



4. Performance Data

<u>Sensitivity</u>: A sample containing calprotectin at concentration equal to or higher than $50\mu g/g$ faeces produces positive results when using *H&R* Calprotectin test.

The detection of human calprotectin with *H&R* Calprotectin test showed >94% of sensitivity correlation compared to another commercial immunoassay (Calprest[®] Eurospital).

<u>Specificity</u>: The detection of human calprotectin with *H&R* Calprotectin test showed 93% of specificity correlation compared to another commercial immunoassay (Calprest[®] Eurospital).

Vegal Farmacéutica, S.L.

Vía de las Dos Castillas 9C Portal 2 3ºC 28224 Pozuelo de Alarcón – Madrid (ESPAÑA) T.: +34 91 799 09 10 F.: +34 91 351 10 84 E-mail: mgonzalez@hrconsulting.org www.h-rdiagnostics.com