



***New CALPROTECTIN  
LACTOFERRIN combo  
Rapid Test***

**CerTest Biotec**  
[www.certest.es](http://www.certest.es)



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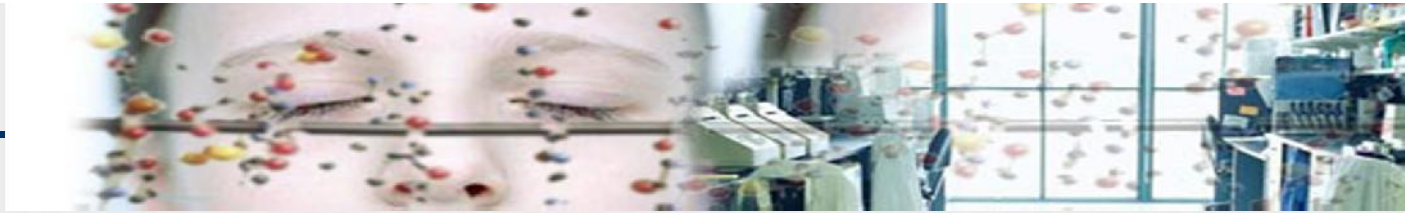




# Calprotectin

- ❑ Calprotectin is a calcium and zinc binding protein with bacteriostatic and fungistatic properties.
- ❑ It is found in abundance in neutrophils and it is extremely stable.
  - ✚ Measurement of faecal Calprotectin would represent a surrogate marker of neutrophil influx into the bowel lumen and in turn, act as a marker of intestinal inflammation.
- ❑ Calprotectin, when elevated in faeces, is a proven biomarker for organic, inflammatory bowel diseases (IBD) such as Ulcerative Colitis (UC) and Crohn's Disease (CD).
- ❑ Increased values of faecal Calprotectin are found in:
  - ✚ Inflammatory bowel disease
  - ✚ Colonic cancer
  - ✚ Non-steroidal anti-inflammatory drug treatment
  - ✚ Strongly associated with colorectal inflammation
- ❑ Calprotectin is an excellent marker for the presence and severity of gastrointestinal inflammation in adults and children with inflammatory bowel disease.
- ❑ Its sensitivity is twice that of fecal occult blood for the identification of colorectal adenoma or carcinoma.





# Calprotectin

- ❑ Its stability against the bacteria degradation is the main advantage against other markers as Lactoferrin.
  - ✚ Stable in faeces for several days after excretion.
  - ✚ It is resistant to enzymatic degradation and can be easily measured in faeces.
  - ✚ It is not decomposed by fecal bacterial microflora, being present up to 5 days for stool stored at room temperature or more than 6 months when frozen.
  
- ❑ Fecal Calprotectin:
  - ✚ Correlates well with endoscopy and histological grading of diseases activity in ulcerative colitis.
  - ✚ It is more sensitive than endoscopy in inflammatory bowel disease.
  
- ❑ Fecal Calprotectin may be able to predict relapse in inflammatory bowel disease before this becomes apparent clinically.
  
- ❑ Patients suffering from IBS (Irritable bowel syndrome) do not have increased fecal Calprotectin values.
  
- ❑ The test is particularly suitable in **paediatric** practice as it is non-invasive.





# Lactoferrin

- ❑ Glycoprotein found in many body fluids as well as in granules of neutrophil granulocytes.
  - ✚ Lactoferrin is a sensitive and specific marker in identifying intestinal inflammation.
- ❑ Fecal lactoferrin levels quickly increase after influx of neutrophils into intestinal lumen during inflammation.
  - ✚ Elevated levels of lactoferrin released from faecal leucocytes as a marker of intestinal inflammation
- ❑ Lactoferrin faecal concentration is increased in patients with active inflammatory bowel disease (IBD).
- ❑ Fecal lactoferrin levels may rise significantly prior to a clinically evident relapse and may be a good marker to predict subsequent IBD flares.
- ❑ Fecal Lactoferrin is sensitive and specific for detecting inflammation in chronic IBD.
- ❑ Fecal lactoferrin is a non-invasive biomarker that is elevated in Crohn's disease compared to irritable bowel syndrome.
- ❑ Lactoferrin as being an early and preclinical indicator of relapse.
  - ✚ Good marker to predict IBD flares.





# Calprotectin / Lactoferrin. Why?

- ❑ Mucosal inflammation may be detected through faecal biomarkers.
- ❑ Faecal Calprotectin and Lactoferrin are promising non-invasive biomarkers for intestinal inflammation, presenting abdominal pain and diarrhoea.
  - ✚ Patients suffering from IBS do not have increased faecal Calprotectin values.
  - ✚ Once symptoms appear, they resemble those of other conditions of functional origin (IBS).
  - ✚ Useful in predicting **relapse**.
- ❑ Children with clinical suspicion of IBD should have faecal Calprotectin measured in addition to lactoferrin if clinical IBD persists.
- ❑ Non-invasive test may prove useful in screening for inflammation in patients presenting abdominal pain and diarrhoea.
- ❑ Crohn's disease and ulcerative colitis are incurable serious chronic diseases of the intestinal tract.
  - ✚ Symptoms are distressing, embarrassing and debilitating.
  - ✚ Once symptoms appear they resemble those of other conditions of functional origin (IBS), which make it very difficult for doctors to correctly diagnose.





# Calprotectin / Lactoferrin. Why?

- ❑ Good biomarkers (Calprotectin / Lactoferrin) in measuring disease activity and predict early relapse in patients with Inflammatory Bowel Disease.
- ❑ IBS (functional disease) does not have an inflammatory component and can be treated by changes in lifestyle and diet.
  - ✚ Irritable Bowel Syndrome does not require colonoscopy and/or treatment regime.
- ❑ IBS is probably one of the most frequent causes of chronic diarrhoea in adults affecting 6-22% of the general population in industrialized countries with an annual incidence ranging from 6% to 9%.
- ❑ In routine clinical practice, gastroenterologists are often faced with the diagnostic difficulty of differentiating between patients with IBS and those with intestinal pathology IBD.
- ❑ 30% of all visits to gastroenterologists are due to symptoms of IBS.
  - ✚ IBS affects over 30 million people in Europe and results in over 2 million yearly visits to physicians.
- ❑ Useful during follow-up of patients with already diagnosed colorectal disease.





# Calprotectin / Lactoferrin

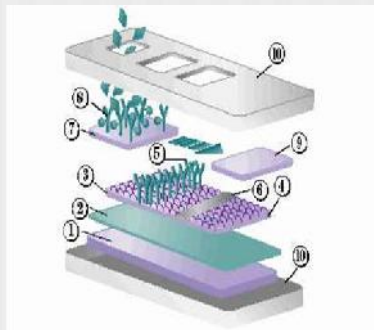
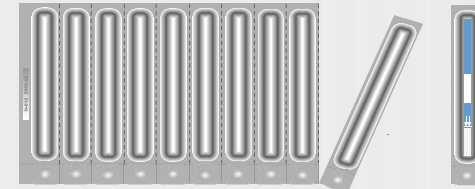
Calprotectin	Lactoferrin	
+	+	No irritable bowel syndrome (IBS). Intestinal inflammation (ulcerative colitis/Crohn's disease). Enteric infection. Early relapse.
+	-	Intestinal inflammation (ulcerative colitis, Crohn's disease). Colonic inflammation. Colorectal adenoma or carcinoma. No enteric pathogen infection. Effect of non-steroidal anti-inflammatory drug (NSAID)
-	+	Intestinal inflammation (ulcerative colitis, Crohn's disease). Relapse and IBD flares. Enteric infection E. coli, Shigellosis or C. difficile toxin.
-	-	No IBD. No enteric infection. IBS if symptoms persists.





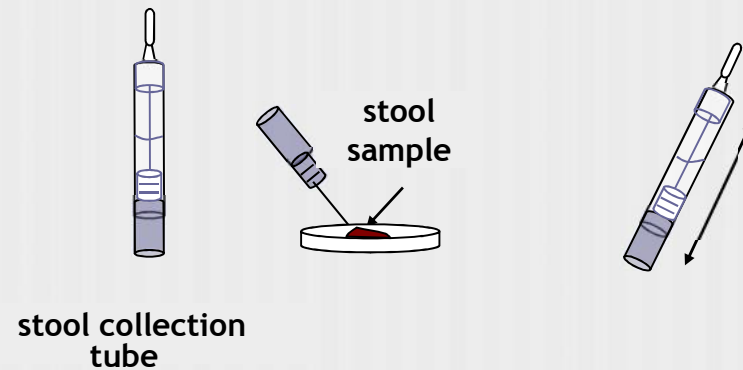
# Product: rapid test

- ❑ Rapid test for the detection of **Calprotectin** and **Lactoferrin** protein in stool samples.
- ❑ Technique: immunocromatographic assay.
- ❑ Format: Card, Blister and Tube.

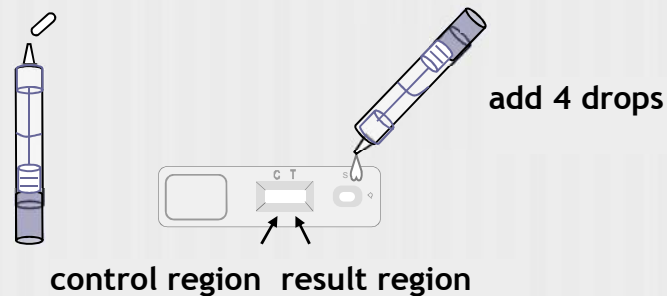




# CerTest test performance

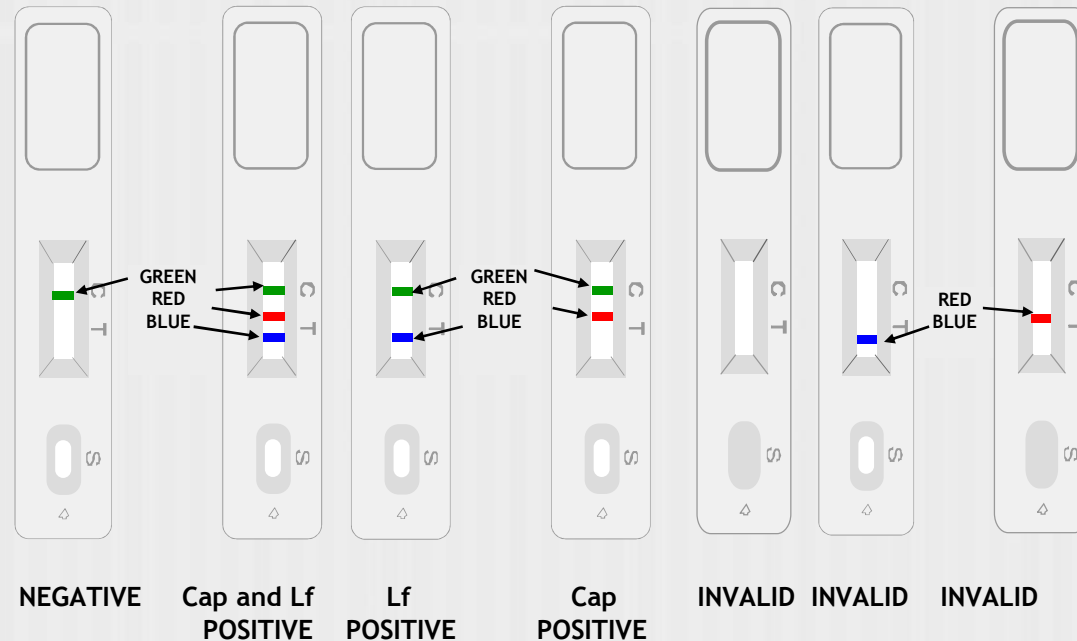


- Qualitative immunocromatographic assay to determine **Calprotectin** and **Lactoferrin** protein in stool samples.





## Results

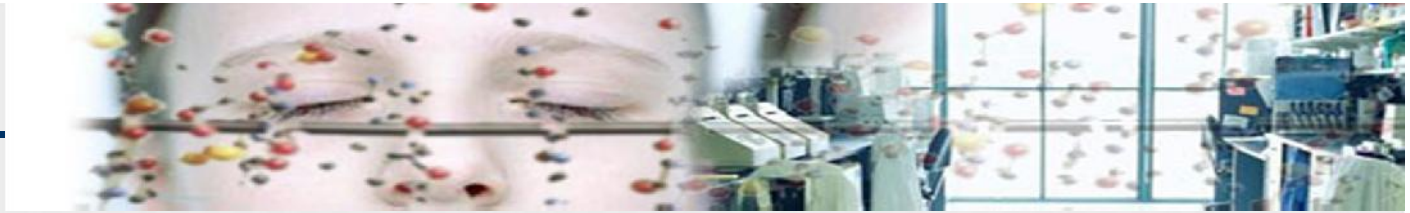


- ❑ **NEGATIVE:** only one GREEN band appearing. Neither Calprotectin nor Lactoferrin protein presence. No IBD.
- ❑ **Cap and Lf+:** in addition to the GREEN control band, the RED (Cap test line) and BLUE (Lf test line) band are also appearing.
- ❑ **Lf+:** in addition to the GREEN control band, the BLUE one (Lf test line) is also appearing.
- ❑ **Cap+:** in addition to the GREEN control band, the RED one (Cap test line) is also appearing.
- ❑ **INVALID:** total absence of the control coloured band (GREEN) regardless the appearance or not of the result lines (RED/BLUE).

Reasons for control failure:

- ✚ Insufficient specimen volume
- ✚ Incorrect procedural techniques
- ✚ Reagents deterioration





# Conclusions

- ❑ One-step Calprotectin and Lactoferrin screening: simple, inexpensive and non-invasive.
- ❑ The fecal markers Calprotectin and Lactoferrin are able to differentiate active IBD from inactive IBD as well as from IBS.
  - ✚ Replaces the needs for invasive endoscopy.
  - ✚ Test of considerable value in the paediatric population in which diagnosis of IBD may be difficult and a delay to diagnosis is common.
- ❑ Screening Calprotectin and Lactoferrin also aid to signal whether the symptoms are the result of:
  - ✚ an inflammatory bacterial infection
  - ✚ an IBD flare
  - ✚ indication whether a patient has responded to treatment to eradicate an infection.
- ❑ A combination of the two markers increase the diagnostic accuracy with reference to endoscopic inflammation in **Ulcerative Colitis** and **Crohn's disease**.
- ❑ Key to follow-up:
  - ✚ Shigella
  - ✚ Salmonella species
  - ✚ C. jejuni
  - ✚ C. difficile





*!! Thanks for your attention !!*



Differentiating  
**IBD & IBS**

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