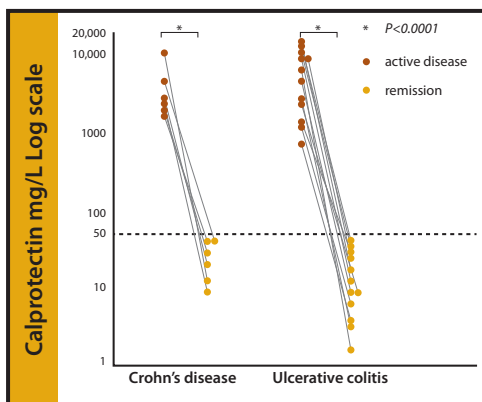




Insight

Differentiate between Irritable Bowel Syndrome (IBS) and Inflammatory Bowel Disease (IBD) with a non-invasive marker of inflammation¹

Fecal calprotectin levels correlate well with disease activity²



Adapted from Roseth, Scand J Gastroenterol 1992

QUANTA Lite Calprotectin can provide insight into diagnosis as well as disease activity levels for IBD patients

- Fecal calprotectin can be used to support the differential diagnosis between organic and functional gastrointestinal disease³
- The use of fecal calprotectin can help in the selection of patients in need of endoscopy⁴
- QUANTA Lite Calprotectin can help identify relapse in patients with inflammatory bowel disease⁵

QUANTA Lite® Calprotectin

Clinical Performance Characteristics¹

Sensitive

- QUANTA Lite Calprotectin achieves 96.9% sensitivity (n=98 Crohn's Disease and Ulcerative Colitis Patients)
- High sensitivity helps guide decision-making when selecting patients for endoscopy
- The use of a polyclonal antibody allows for the recognition of multiple calprotectin epitopes reducing possible false negatives

Specific

- QUANTA Lite Calprotectin achieves 85.0% specificity (n=40 Irritable bowel syndrome, recurrent abdominal pain, other diseases)
- Fecal Calprotectin is more specific for intestinal inflammation than traditional serum markers such as CRP⁶
- Optimized dynamic range allows for disease activity insight without sacrificing diagnostic accuracy

Clinical Performance of QUANTA Lite Calprotectin Assay (n=138)

		IBD		Total
		Positive	Negative	
QUANTA Lite® Calprotectin	Positive	95	6	101
	Negative	3	34	37
	Total	98	40	138
Sensitivity		96.9%		95% CI (91.3% - 99.4%)
Specificity		85.0%		95% CI (70.2% - 94.3%)
PPV		94.1%		95% CI (87.5% - 97.8%)
NPV		91.9%		95% CI (78.1% - 98.3%)

QUANTA Lite Calprotectin results in this analysis considered negative below 50 mg/kg.

A full range of tests for lower gastrointestinal tract disorders

Product Ordering Information	IgA	IgG	Screen (IgA/IgG)
QUANTA Lite Calprotectin		704770	
QUANTA Lite ASCA	708870	708865	
QUANTA Lite Gliadin II (DGP)	704525	704520	704545
QUANTA Lite h-tTG (Human Tissue Transglutaminase)	708760	708755	704570
QUANTA Lite R h-tTG (Recombinant Human Tissue Transglutaminase)	704605	704610	
QUANTA Lite h-tTG/DGP Screen			704575
QUANTA Lite Gliadin	708655	708650	
QUANTA Lite F-Actin	704500		

References:

1. QUANTA Lite Calprotectin directional insert.
2. Roseth, A. et al. Assessment of the neutrophil dominating protein calprotectin in feces. A methodologic study. Scand J Gastroenterol. 1992 Sep;27(9):793-8.
3. Carroccio, A. et al. Diagnostic accuracy of fecal calprotectin assay in distinguishing organic causes of chronic diarrhea from irritable bowel syndrome: a prospective study in adults and children. Clin Chem 2003;49:861-7.
4. Bunn, S. et al. Fecal calprotectin: validation as a noninvasive measure of bowel inflammation in childhood inflammatory bowel disease. J Pediatric Gastroenterology Nutrition 2001;33:14-22.
5. Diamanti, A. Clinical role of calprotectin assay in determining histological relapses in children affected by inflammatory bowel diseases. Inflamm Bowel Dis 2008;14:1229-35.
6. Vermeire, S. et al. Laboratory Markers in IBD: useful, magic or unnecessary toys? Gut. Mar 2006; 55(3) 426-431.

www.inovadx.com

San Diego, CA 92131 USA
PH: +1-858-586-9900 US Toll Free: 1-800-545-9495 FAX: +1-858-586-9911

QUANTA Lite is a registered trademark of Inova Diagnostics, Inc. © 2015 Inova Diagnostics, Inc. All rights reserved.

690402 February 2015 Rev. 3



**Inova
Diagnostics**
A Werfen Company