

Rule out inflammatory bowel diseases safely and efficiently

EliA Calprotectin 2 – second generation automated fecal calprotectin test for a fast turnaround of results



Provide early diagnostic guidance in a fast and cost-efficient manner

Rule out IBD safely and efficiently

The very high sensitivity of EliA[™] Calprotectin 2 for IBD together with its superb negative predictive value (Table 1) make the test an ideal tool to rule out inflammatory bowel diseases (IBD).

A negative test result makes a non-inflammatory, functional bowel disease (FBD) very likely. As first-line test fecal calprotectin can help to reduce the number of avoidable endoscopies by 50%¹.

	Negative predictive value (NPV)
EliA Calprotectin 2 98.0 %	96.9%

Table 1: Sensitivity and NPV of EIA Calprotectin 2. Internal study using 182 stool samples (99 IBD, 83 IBS or other functional bowel disorders).

Differentiate IBD from functional bowel diseases

EliA Calprotectin 2 is specifically detecting intestinal inflammation with very high sensitivity. Since the majority of functional bowel diseases will give a negative result, the test is very helpful in differential diagnosis of gastrointestinal disorders, distinguishing the rare inflammatory bowel diseases from the much more frequent functional bowel disorders (Figure 1).

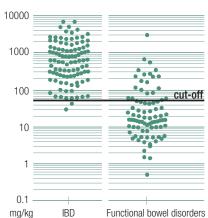


Figure 1: Performance of EliA Calprotectin 2 in 182 stool samples (99 IBD, 83 IBS or other functional bowel disorders). Cut-off for positivity: 50 mg/kg (internal study).

Provide early diagnostic guidance

The excellent clinical performance of EliA Calprotectin 2 provides early diagnostic guidance for the physician. Its outstanding sensitivity helps detect more IBD patients. Its high specificity helps in reducing avoidable endoscopic procedures. EliA Calprotectin 2 is best in class in all key performance indicators (Figure 2).

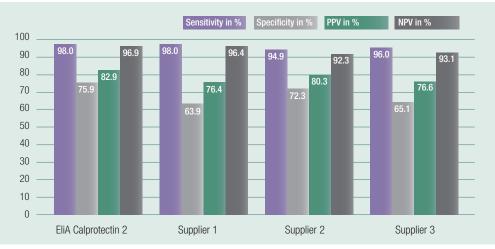


Figure 2: Clinical performance of EliA Calprotectin 2 compared to other suppliers' tests. Internal study using 182 stool samples (99 IBD, 83 IBS, and other functional bowel disorders).

Increase efficiency through flexibility and automation

EliA Calprotectin 2 is a second generation fecal calprotectin test which even outperforms its successful precursor EliA Calprotectin.

The significantly improved sensitivity and NPV of EliA Calprotectin 2 means that IBD can be ruled out with more certainty – a significant improvement in clinical utility (Table 2).

	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
EliA Calprotectin 2	98.0	75.9	82.9	96.9
EliA Calprotectin	88.9	79.5	83.8	85.7

Table 2: Clinical performance of EliA Calprotectin 2 compared to EliA Calprotectin. Internal study using 182 stool samples (99 IBD, 83 IBS or other functional bowel disorders).

Stool extraction is a time consuming process which is difficult to integrate into the tight schedules of laboratory routine.

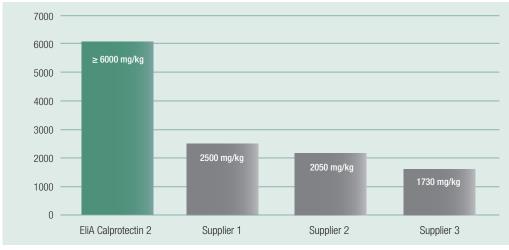
The longer stool extract stability of EliA Calprotectin 2 (three days at room temperature) provides more flexibility to the lab, enabling convenient separation of stool extraction and testing (Table 3).

Temperature	Room temperature	4°C	-20°C
Stool extract stability	3 days	7 days	3 months

 Table 3: Stability of EliA Calprotectin 2 stool extracts at different storage temperatures (internal evaluation study).

EliA Calprotectin 2 has the highest measuring range available (\geq 6000 mg/kg), which minimizes the need for further dilution of highly positive samples and repeated testing (Figure 3).

Together with the fully automated testing on Phadia[®] Laboratory Systems (Phadia 250/2500/5000) this cuts down operational costs, simplifies planning, and increases efficiency.



Second generation test for superior performance

Add flexibility to your lab routine

Save costs through increased efficiency

Figure 3: Measuring range of EliA Calprotectin 2 compared to other suppliers' tests according to manufacturers' directions for use.

Fecal calprotectin testing of high clinical value and easy integration into existing workflow

Your advantages with EliA Calprotectin 2:

- Ruling out IBD safely and efficiently
- Clear differentiation between IBD and IBS and other functional bowel disorders
- Early diagnostic guidance
- Second generation test for superior performance
- Adds flexibility to your lab routine
- Completely automated and efficient testing, reducing the workload for your lab personnel
- Improves service quality and ensures a quick delivery of results
- Add-on to the EliA gastro panel on Phadia Laboratory Systems

EliA Calprotectin 2 offers a complete solution: from stool extraction to automated sample measurement.

Technical data:			
Dilution	1:200		
Cut-off / measuring range	negative	positive	measuring range
	≤ 50 mg/kg	> 50 mg/kg	$3.8 - \ge 6000 \text{ mg/kg}$
Ordering information	Package size	Article No.	
EliA Calprotectin 2 Well	4 x 16 wells	14-6748-01	

Please note that the EliA Calprotectin 2 test requires dedicated reagents. For detailed information please refer to the test's directions for use.

Reference:

1 Mindemark M, Larsson A (2012). Ruling out IBD: Estimation of the possible economic effects of pre-endoscopic screening with F-calprotectin. Clin Biochem 45 (7-8): 552-5

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