

Faecal Calprotectin testing with Phadia Laboratory Systems®

A fully automated, cost-effective approach to diagnostic guidance in patients with GI symptoms

WHAT IS FAECAL CALPROTECTIN?

Calprotectin is a calcium- and zinc-binding protein found in high levels in neutrophils; it is resistant to enzyme activity and stays active in faeces for almost a week at room temperature. **Elevated faecal calprotectin ($\geq 50 \mu\text{g/g}$) is indicative of inflammatory bowel disease (IBD); normal levels of faecal calprotectin are indicative of non-inflammatory functional bowel disease, e.g. irritable bowel syndrome (IBS).**¹

WHY SHOULD YOU EVALUATE A FULLY AUTOMATED FAECAL CALPROTECTIN TEST?

Distinction of IBS from IBD on clinical grounds is not always possible. Diagnostic blood tests for inflammation (erythrocyte sedimentation rate and C-reactive protein) may be abnormal because of other, non-gastrointestinal conditions, and can conversely be normal in people with IBD. Until recently, invasive and unpleasant endoscopies requiring sedation have been used to distinguish between IBD and IBS, with over 60% of colonoscopies in younger patients returning 'normal' and therefore being deemed unnecessary.²

NICE guidelines now recommend faecal calprotectin testing as a clinical option for diagnosis of IBD/IBS.

NICE issued new guidelines on 2nd October 2013 recommending faecal calprotectin testing as a clinical option for the differential diagnosis of IBD or IBS.²⁻⁵ Although it can take time for clinicians to implement new guidelines, the potential cost savings achieved by preventing unnecessary investigative endoscopies (approximately £180,000 per 100,000 population)⁶ increases the likelihood of implementation by clinical commissioning groups (CCGs). In addition, the NIHR Health

Technology Adoption Programme is undertaking work on behalf of NICE to encourage the introduction of faecal calprotectin testing in clinical diagnostic pathways. With a high number of people presenting with GI symptoms, it is reasonable to anticipate a significant increase in the number of test requests. Furthermore, it is likely that clinicians will start requesting a panel of tests that will most likely include coeliac disease tests and faecal calprotectin. As such, an efficient, fully automated instrument that can run both samples as they arrive, improving efficiency and reducing costs could assist in managing this anticipated increase in workload.*

EliA™ Calprotectin – the first fully automated faecal calprotectin test.

Individual laboratories will need to consider the potential impact on workload and whether or not their present kit is suited to handling a significant increase in the number of requests. **Laboratories may choose to utilise the expertise of specialists like Karen Garratt, Thermo Fisher Scientific Application Specialist for EliA™ Calprotectin, to evaluate new kits;** and considering the anticipated increase in workload, it may be wise to reflect sooner rather than later.

EliA™ Calprotectin demonstrates excellent performance with high predictive values.

WHY SHOULD YOU USE ELIA™ CALPROTECTIN?

EliA™ Calprotectin can be run on Phadia Laboratory Systems and demonstrates excellent performance with high predictive values (PPV 0.96; NPV 0.95) and sensitivity and specificity values of 97.7% and 89.8% respectively.⁷

A range of Phadia Laboratory Systems has been designed to suit your needs

Phadia Laboratory Systems:

- Designed to run allergy and autoimmunity assays simultaneously with no risk of contamination, providing up to 3,750 results per week
- Process samples as and when they arrive, eliminating the need to batch*. This allows your laboratory to manage increased test requests while still offering fast turnaround and quality service
- Can investigate coeliac disease (EliA™ Celikey®, IgA and IgG) at the same time as faecal calprotectin
- Have low hands-on time
- Have high inter- and intra-laboratory reproducibility

*With exception of Phadia 100

HOW CAN THERMO FISHER HELP YOU?

High quality support services

Thermo Fisher provides a high quality support service for Phadia Laboratory Systems which includes:

- **Autoimmunity application laboratory** offering re-testing of samples to resolve any unclear results
- Remote system monitoring and fault identification via **Phadia Lab Community**
- **On-site technical support** for fast resolution of technical issues
- **Immediate training** and system support
- **Remote collection** of Instrument log files

The benefits of a comprehensive support service include reduced instrument downtime, improved productivity, better quality of service and peace of mind.

EliA Calprotectin – saving time and delivering cost-effective results that guide clinical decisions.

References

1. O'Malley J. *The Digest* 2013.
2. National Institute for Health and Care Excellence October 2013. Faecal calprotectin diagnostic tests for inflammatory diseases of the bowel [Diagnostics guidance no. 11] London: National Institute for Health and Care Excellence.
3. National Institute for Health and Care Excellence. NICE pathways- Crohn's disease, 2013 Available from: <http://pathways.nice.org.uk/pathways/crohns-disease>.
4. National Institute for Health and Care Excellence. NICE pathways – ulcerative colitis, 2013 Available from: <http://pathways.nice.org.uk/pathways/ulcerative-colitis>.
5. National Institute for Health and Care Excellence. NICE pathways – irritable bowel syndrome in adults, 2013 Available from: <http://pathways.nice.org.uk/pathways/irritable-bowel-syndrome-in-adults>
6. Harvey Walsh. Analysis of NHS Hospital Episode Statistics. Runcom, Cheshire: Harvey Walsh, 2013. Available from: www.harveywalsh.co.uk.
7. Internal clinical study

Clinical education package

An EliA™ Calprotectin educational package has been created to educate clinicians on the availability of faecal calprotectin testing, helping labs to drive their business by championing excellence in clinical practice.

On-site scientific application specialist

Thermo Fisher Scientific Application Specialist Karen Garratt is dedicated to facilitating the introduction of faecal calprotectin testing with EliA™ Calprotectin.

The implementation of a new assay into routine use requires staff time to plan and perform evaluations and review the data obtained, which delays implementation of the assay – not ideal when an increase in requests is expected.

Having worked previously as a Senior Biomedical Scientist, Karen can appreciate the benefits of support from a laboratory perspective.

Karen can help you:

- run the evaluation
- source samples
- train staff in the extraction procedure
- identify the need for additional or upgraded instruments

She can also offer any other assistance required to speed up the process of bringing EliA Calprotectin into routine use in your laboratory.

If you would like to discuss further how Karen can support the evaluation and implementation of EliA™ Calprotectin testing in your laboratory, please find her contact details below:

Karen Garratt
Application Specialist
01908 769110 – Office
+44 (0) 7775816801 – Mobile
karen.garratt@thermofisher.com
www.thermoscientific.com/phadia



Karen Garratt