AUSTRALIAN Clinicalabs

MEDICARE-Rebatable

Calprotectin Testing

Clinical utility for the diagnosis and management of IBD

Clinical Benefits

Faecal calprotectin concentration is a safe and reliable non-invasive test for inflammation of the bowel wall that can:

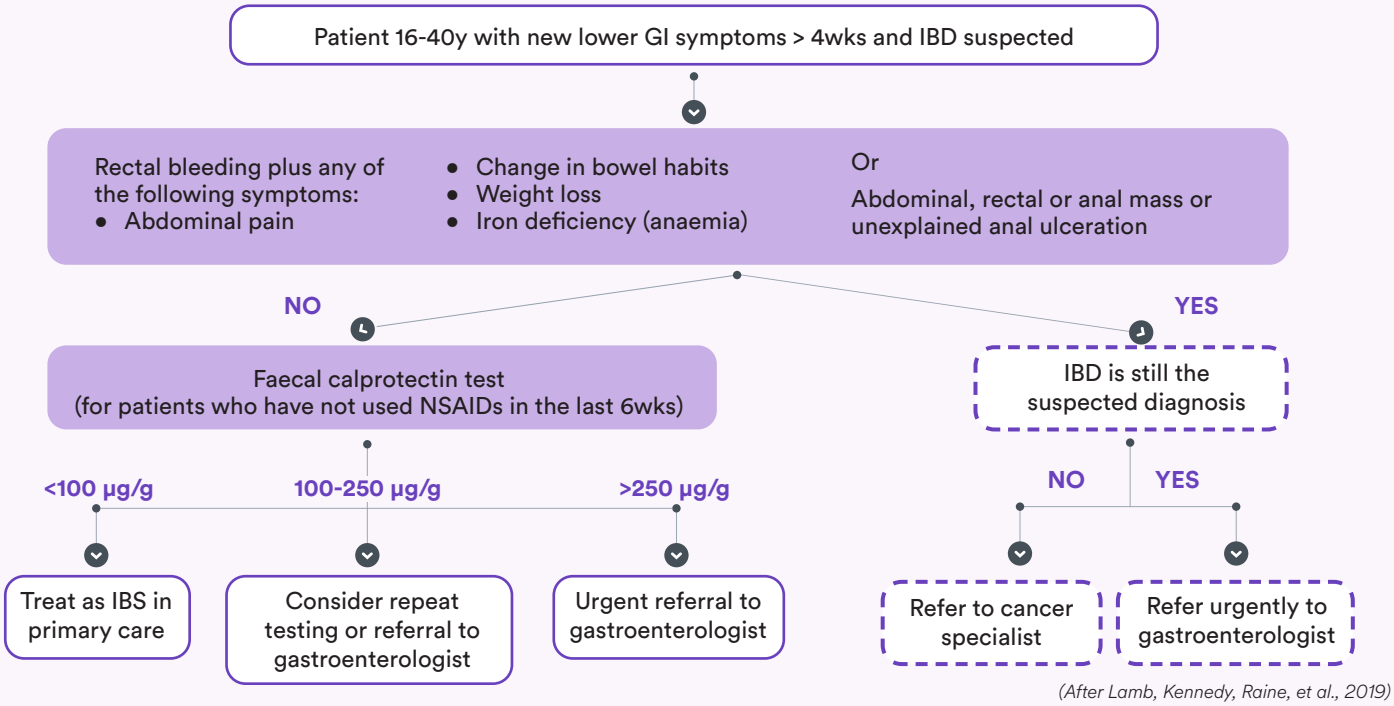
- **Help distinguish between patients with IBD and IBS.**
- **Determine disease activity and risk of relapse in IBD patients, and assess the level of mucosal healing.**
- **Help identify patients with abdominal symptoms who may require further investigative procedures and reduce the number of endoscopies performed for the diagnosis of diarrhoeal disease and monitoring of IBD.**

Clinical Labs' faecal calprotectin test is a highly sensitive marker for evaluating inflammation in the gastrointestinal tract. It offers a simple, reliable, and non-invasive method for distinguishing between Inflammatory Bowel Disease (IBD) and Irritable Bowel Syndrome (IBS).

Calprotectin plays a regulatory role in the inflammatory process. Faecal calprotectin levels are significantly elevated in patients with IBD and correlate well with endoscopic and histological assessment of disease activity. Patients with IBS do not exhibit increased faecal calprotectin values. Calprotectin testing can also aid in monitoring IBD disease activity, assessing the risk of IBD relapse, and evaluating the response of IBD to therapy.

Note: Calprotectin is not specific to IBD, as it is variably increased in other causes of gut wall inflammation and various gastrointestinal malignancies. Additionally, ingestion of some common drugs can also elevate calprotectin levels. Therefore, interpretation must be done in the clinical context.

Use of faecal calprotectin test in primary care



(After Lamb, Kennedy, Raine, et al., 2019)

Reference intervals

Most healthy adults will have a faecal calprotectin concentration of <10 µg/g faeces. However, as the faecal calprotectin concentration in adults is known to increase with age, reference intervals (RIs) are usually established to account for miscellaneous factors, including age. These RIs should not be used for longitudinal monitoring, as patients should become their own reference.

Based on the expected values from literature reports and the manufacturer's recommendation, Clinical Labs has adopted the following RIs for faecal calprotectin concentration in adult patients with clinically suspected IBD (please see the following page).

Please note: Adult RIs do not apply to children, especially <4 yo.

0-50 µg/gram	IBD unlikely but not excluded.
50-100 µg/gram	IBD likely; other inflammatory conditions, including but not limited to infection, Coeliac disease and Diverticular disease, cannot be excluded.
100 µg/gram	Almost exclusively IBD. Other severe inflammatory diseases not excluded.

Factors and conditions associated with elevated faecal calprotectin levels

Infectious

- Bacterial dysentery
- *C. difficile*
- Giardia lamblia
- *Helicobacter pylori* gastritis
- HIV
- Infectious diarrhea
- Small intestinal bacterial overgrowth
- Viral gastroenteritis

Inflammatory conditions

- Inflammatory bowel disease
- Autoimmune enteropathy
- Cirrhosis
- Cystic fibrosis
- Diverticulitis
- Eosinophilic colitis/ enteritis
- Gastroesophageal reflux disease
- Juvenile polyp
- Microscopic colitis
- Pancreatitis
- Peptic ulcer
- Pouchitis
- Untreated coeliac disease

Neoplasms

- Colonic and gastric polyps
- Colorectal cancer
- Gastric carcinoma
- Intestinal lymphoma
- Intestinal polyposis
- Pancreatic cancer

Drugs

- NSAIDs
- PPI

Other

- Age <5y
- Graft rejection (small bowel)
- Immune Deficiency
- Protein-losing enteropathy
- Radiotherapy
- Untreated food allergy

NSAIDs (Nonsteroidal anti-inflammatory drugs); PPIs (Proton pump inhibitors) (After Bressler, Panaccione, Fedorak, & Seidman, 2015)

Specimen collection, transport and storage

The time between defaecation might affect the faecal calprotectin concentration; therefore, the first stool of the day is recommended. Stool specimens should be collected into a clean, airtight container without preservative and stored at 2-8°C. The sample must be received at the laboratory within 24hrs of collection. Stool specimens that are liquid or very solid may be technically unsuitable.

Medicare eligibility for calprotectin testing

66522: Faecal calprotectin test for the diagnosis of inflammatory bowel disease, if all the following apply: the patient is under 50 years of age; the patient has gastrointestinal symptoms suggestive of inflammatory or functional bowel disease of more than 6 weeks' duration; infectious causes have been excluded; the likelihood of malignancy has been assessed as low; no relevant clinical alarms are present.

66523: Faecal calprotectin test for the diagnosis of inflammatory bowel disease, if all the following apply: the results of a service to which item 66522 applies were inconclusive for the patient (that is, the results showed a faecal calprotectin level of more than 50 g/g but not more than 100 g/g); the patient has ongoing gastrointestinal symptoms suggestive of inflammatory or functional bowel disease; the service is requested by a specialist or consultant physician practising as a specialist gastroenterologist; the request indicates that an endoscopic examination is not initially required; no relevant clinical alarms are present.

66525: Faecal calprotectin test for the management of a symptomatic patient with diagnosed inflammatory bowel disease, requested by or on behalf of a specialist or consultant physician.

References

Bressler, B., Panaccione, R., Fedorak, R. N., & Seidman, E. G. (2015). Clinicians' guide to the use of fecal calprotectin to identify and monitor disease activity in inflammatory bowel disease. *Can J Gastroenterol Hepatol., 29*(7), 369-372.

Lamb, C. A., Kennedy, N. A., Raine, T., & et al. (2019, September 27). British Society of Gastroenterology consensus guidelines on the management of inflammatory bowel disease in adults. Gut, 68, s1-s106. Retrieved from http://dx.doi.org/10.1136/gutjnl-2019-318484

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Associate Professor Smyth is a graduate of the University of Western Australia and a Fellow of, and current State Councillor of the RCPA. Associate Professor Smyth designed and implemented the Pathology programme for the School of Medicine at the University of Notre Dame Australia, Fremantle, where she is a founding member of, and Associate Professor in the School of Medicine. She has a Graduate Certificate in University Teaching, qualifying her to supervise candidates for higher degrees as well as teaching undergraduate students. She is most interested in autoimmunity but has extensive experience including autoimmunity, transplantation, immune deficiency and allergy. Her publications are predominantly in the field of Bone Marrow Transplantation. Dr Smyth joined St John of God Pathology (now Australian Clinical Labs) in 2016.

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