What is the Test?
• The PathFlow® Calprotectin is a lateral flow immunoassay for the detection of calprotectin – a potential indicator to aid in the correct diagnosis of inflammatory gastrointestinal disorders.

What is the Disease?
• Calprotectin (MRP-8/MRP-14 or S100A8/A9 heterocomplex) is named after the calcium-binding proteins it’s formed by.
• The expression of these proteins is largely confined to the intracellular fluid (cytosol) of neutrocytes and monocytes (white blood cells), accounting for approximately 60% of their total soluble proteins.
• During periods of inflammation, calprotectin is released from activated neutrocytes and can also be released upon cell damage/death.
• This release of calprotectin results in higher levels being present in-patient stools which can directly relate to the severity of inflammation.

Symptoms
• It’s widely accepted that a calprotectin result of <50 µg/g is negative – this doesn’t confirm health, just that the symptoms are unlikely to be caused by IBD.
• If symptoms persist but the calprotectin level is negative then other causes for the symptoms need to be investigated e.g. Irritable Bowel Syndrome (IBS), coeliac disease, food allergies or intolerances.

• Faecal calprotectin levels >200 µg/g are usually considered positive and require further investigations to be performed to determine the cause of these increased values.

Mortality/Morbidity – Clinical Implications
• Faecal calprotectin is an extremely useful and cost-effective marker to help differentiate between IBD (Inflammatory Bowel Disease) and IBS (Irritable Bowel Syndrome).
• Calprotectin results aid in determining following courses of action and treatment/diagnosis of bowel conditions; often preventing patients from undergoing unnecessary invasive procedures, such as colonoscopies.

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Why use PathFlow®

- Faecal calprotectin testing is recommended by NICE to aid distinguishing between inflammatory bowel diseases (such as Crohn’s disease/ulcerative colitis) and non-inflammatory bowel diseases (IBS).
- These conditions can cause similar symptoms; however, Crohn’s disease and ulcerative colitis can also lead to serious complications, so their differential diagnosis is imperative.
- Many people with irritable bowel syndrome have unnecessary invasive hospital investigations before their condition is diagnosed.
- PathFlow® Calprotectin allows for the potential of a differential diagnosis of IBS, without the need for such invasive investigations.

Performance vs. Rapid Test

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<tbody>
<tr>
<td>Sensitivity: 97.8%</td>
<td>Specificity: 99%</td>
<td>Accuracy: 98.5%</td>
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Ordering Information

<table>
<thead>
<tr>
<th>Code: M589CE</th>
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<tr>
<td>Description – PathFlow® Calprotectin</td>
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<tr>
<td>Size: 10 Test Kits</td>
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<td>Storage: 2°C-30°C</td>
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Procedure

Step 1. Bring the pouch to room temperature before opening it. Remove the test cassette from the foil pouch and use it within one hour. Collect sufficient quantity of faeces (1-2mL/1-2g). Optimum results will be obtained if the assay is performed within 6 hours.

Step 2. Solid specimens - Unscrew the cap of the specimen collection tube, then collect approximately 50mg of faeces. Liquid specimen - Hold the dropper vertically, aspirate faecal specimens, and then transfer 2 drops (approximately 80μL) into the specimen collection tube containing the extraction buffer.

Step 3. Tighten the cap onto the specimen collection tube, shake vigorously, leave for 2 minutes.

Step 4. Hold the specimen collection tube upright and open the cap of the specimen collection tube. Invert the specimen collection tube and transfer 2 full drops of the extracted specimen (approximately 80μL) to the specimen well (S) of the test cassette, then start the timer.

Step 5. The result should be read from 5 minutes.