Diagnostics for Digestive Health Management
Faecal Testing

The Patient Pathway

Alpha Laboratories has been at the forefront of faecal testing in the UK for nearly 20 years. This was initially as the market leader for guaiac-based faecal occult blood testing. Tender wins for bowel screening in all four UK countries followed, as each launched its own screening programme.

Continuing to provide leading edge products, Alpha Laboratories is currently introducing the first faecal immunochemical testing (FIT) method for screening, having been awarded the contract for quantitative FIT as the frontline test in the Scottish Bowel Screening Programme. England will also be moving to a quantitative FIT method in the near future.

In addition, we are now actively working with NICE to incorporate FIT into the pathway for patients with suspected lower GI cancer.

This will ultimately lead to an improvement in the patient care pathway and a reduction in colonoscopy referrals, similar to that experienced with the introduction of calprotectin.

With extensive experience in faecal diagnostic indicators Alpha Laboratories has championed calprotectin testing for more than a decade and supported the NICE review (DG 11) of calprotectin for differentiation between IBS and IBD.

As calprotectin testing has developed, the BUHLMANN assay range has continued to evolve. This has enabled us to work in partnership with clinics and laboratories, providing solutions for improved patient care and management, throughout the pathway for both screening and monitoring.
Elevated faecal calprotectin is a well proven biomarker for Inflammatory Bowel Disease (IBD) such as Ulcerative Colitis and Crohn’s Disease and can be used to easily and cost-effectively differentiate between these conditions and Irritable Bowel Syndrome (IBS). Since the publication of the NICE guidelines (DG11) in October 2013, supporting the use of calprotectin to differentiate between IBD and IBS, the level of calprotectin testing in UK laboratories has significantly increased:

- As a screening test to help clinicians make informed decisions:
  - Investigate for other causes of symptoms, e.g. IBS, Food allergies
  - Possible infection, NSAIDS, mild diverticulitis
  - Refer for further evaluation

- To monitor IBD positive patients to assist in better patient management
  - Predicting flares
  - Predicting post-operative relapse
  - Predicting response to therapy

Calprotectin can be used more extensively than just for an initial IBS/IBD screen test. Numerous publications suggest that regular monitoring of IBD patients can help to predict, flares, response to therapy or post-operative relapse. Calprotectin concentrations can start to rise before the clinical symptoms become apparent, offering the opportunity for intervention therapy.

Alpha Laboratories offers a wide range of calprotectin sample preparation and test formats, all from BÜHLMANN Laboratories AG. BÜHLMANN has specialised in calprotectin assays for more than 10 years and has the broadest range of faecal calprotectin assays available. These are scalable and flexible allowing hospitals to evolve their calprotectin service in line with changing demands. All the BÜHLMANN assays give quantitative measurements and are standardised together to give consistent results and cut-off values allowing for the smooth transition between assay technologies.

For more information visit: [www.calprotectin.co.uk](http://www.calprotectin.co.uk)
Faecal Testing

Faecal Calprotectin Sample Extraction

A choice of devices are available, to simplify and assist the pre-analytical faecal extraction process. These are dedicated, specially designed products to minimise operator contact with the sample, whilst optimising extraction of calprotectin.

CALEX® Cap Calprotectin Stool Extraction Device

CALEX® Cap is a stool extraction device providing rapid, clean and consistent sample preparation every time. The CALEX contains a measured amount of BÜHLMANN extraction buffer and is for exclusive use with all BÜHLMANN calprotectin assays.

The CALEX extraction device improves laboratory workflow and efficiency by eliminating the need for sample weighing, pipetting or decanting and enables direct loading of the extraction device onto many ELISA processors and routine biochemistry analysers.

- Ease of use for laboratory personnel and patients
- Delivers a precise amount of faecal sample
- Application as a primary tube for many ELISA robots and routine biochemistry analysers
- Optimised sample dilution for maximum efficiency in stool extraction
- Extract stability of 3 days at room temperature allowing batching to suit the laboratory routine
- 95kPa postal compliant
- UN3373 and IATA 650 compliant for transport by air

The Calex Cap improves the pre-analytical sample handling, with reduced hands on time and simplified procedure as there is no need to weigh out samples or dilute before use.

CALEX® Cap compared to 1:50 manual extraction

Passing-Bablock over the complete ELISA range 10-1800μg/g

Rapid, clean and consistent sample preparation is achieved every time for evaluation of faecal calprotectin.

<table>
<thead>
<tr>
<th>CALEX Cap</th>
<th>Calprotectin Stool Extraction Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product code</td>
<td>Description</td>
</tr>
<tr>
<td>B-CALEX-C50</td>
<td>CALEX Cap Device</td>
</tr>
<tr>
<td>B-CALEX-C200</td>
<td>CALEX Cap Device</td>
</tr>
<tr>
<td>B-CALEX-C500</td>
<td>CALEX Cap Device</td>
</tr>
<tr>
<td></td>
<td>Pack Size</td>
</tr>
<tr>
<td></td>
<td>50 tubes</td>
</tr>
<tr>
<td></td>
<td>200 tubes</td>
</tr>
<tr>
<td></td>
<td>500 tubes</td>
</tr>
</tbody>
</table>

BÜHLMANN Laboratories
Faecal Testing

**CALEX® Valve**

Simplified procedure for use by patients or in clinics for evaluation of faecal calprotectin levels using the IBDoc™ or Quantum Blue™ system. The unique lever design accurately dispenses the required volume of extracted sample without the need for calibrated pipettes.

<table>
<thead>
<tr>
<th>CALEX Valve</th>
<th>Product code</th>
<th>Description</th>
<th>Pack Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>B-CALEX-V25</td>
<td>CALEX Valve Device</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>BÜHLMANN Laboratories</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Smart-Prep**

This sample preparation device is supplied without buffer and therefore can be used for various diagnostic tests.

<table>
<thead>
<tr>
<th>Smart-Prep Faecal Extraction Device</th>
<th>Product code</th>
<th>Description</th>
<th>Pack Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>B-CAL-RD</td>
<td>Smart-Prep Faecal Sample Preparation Kit</td>
<td>50 tubes</td>
<td></td>
</tr>
<tr>
<td>BÜHLMANN Laboratories</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Faecal Sample Collection

- Easy-to-use, hygienic, stool collection paper
- Flushable and biodegradable
- Simple instructions for use
- Convenient for patients
- Less risk of sample contamination

Demonstration video available at: [www.alphalabs.co.uk/fecol](http://www.alphalabs.co.uk/fecol)

### Fe-CoL® Faeces Collection Device

- Fe-CoL® Faecal Collection Papers

<table>
<thead>
<tr>
<th>Fe-CoL® Faecal Collection Papers</th>
<th>Product code</th>
<th>Description</th>
<th>Pack Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>FC2010</td>
<td>Fe-CoL® Faecal Collection Paper with Instructions for Use (IFU)</td>
<td>1000</td>
<td></td>
</tr>
<tr>
<td>FC2030</td>
<td>Fe-CoL® Faecal Collection Paper in Dispenser Box of 50</td>
<td>5 x 50</td>
<td></td>
</tr>
<tr>
<td>FC2040</td>
<td>Mini Collection Kit: Fe-CoL with IFU, gloves and cardboard applicators</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>FC2050</td>
<td>Basic Collection Kit: Fe-CoL with IFU, Sample container, SpeciSafe transport container and UN labelled mailing envelope</td>
<td>40</td>
<td></td>
</tr>
<tr>
<td>FC2060</td>
<td>Premium Collection Kit: Fe-CoL with IFU, gloves, Sample container, SpeciSafe transport container, biohazard bag and UN labelled mailing envelope</td>
<td>40</td>
<td></td>
</tr>
</tbody>
</table>

Alpha Laboratories Ltd. See Website for more information and details
Faecal Testing

Managing chronic conditions through patient self-testing has become common place, and it is now possible for sufferers of inflammatory bowel disease (IBD) to manage their conditions at home. New sophisticated technology enables patients to perform quantitative calprotectin tests themselves and then use their smartphones to read the results.

The CALEX® Valve allows patients to process their own samples without the need for vortex mixing, centrifuging or pipetting. The valve at the base of the device dispenses a precise amount of liquid onto the lateral flow test device. After 12 minutes the calprotectin assay result is read using the smartphone CalApp and the data is transmitted to the clinician via a secure web portal.

- First CE marked Calprotectin Home Test
- Quantitative Rapid Test
- Consistent results with other BÜHLMANN Calprotectin assays: - Quantum Blue® - fCAL® ELISA
- Calibrated for use with 20 smartphones including: Apple, Samsung, LG, Sony and HTC

Customised, patient centric approach for management of disease and therapy.

<table>
<thead>
<tr>
<th>Product code</th>
<th>Description</th>
<th>Pack Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>LF·IBDOC8</td>
<td>IBDoc Home Test Kts</td>
<td>8</td>
</tr>
<tr>
<td>BI·IBDOC</td>
<td>IBDoc Starter Pack</td>
<td>Each</td>
</tr>
</tbody>
</table>

BÜHLMANN Laboratories
Faecal Testing

Quantum Blue®: Quantitative Rapid Calprotectin Test

The Quantum Blue® fCAL rapid tests combine the ease and speed of lateral flow technology (using a highly specific monoclonal antibody to calprotectin), with full quantitation by means of a small, dedicated telephone sized reading device.

The Quantum Blue® reader analyses the signal intensity from the test and control line to give a quantitative value and is standardised with the BÜHLMANN fCAL™ ELISA.

This diagnostic tool enables a rapid gatekeeper strategy based on calprotectin levels in patient stool samples to support the physician’s decision on whether to prepare patients for colonoscopy or to treat them for the symptoms associated with Irritable Bowel Syndrome (IBS) and other gastric conditions.

This test is suitable when true quantitation is required but in a low sample throughput or Point-of-Care environment.

Why Use Quantum Blue Calprotectin?

- Provides a quantitative measurement of calprotectin in faecal samples
- Simple and rapid extraction and test process
- Results in 12 minutes
- Compact benchtop reader
- Excellent correlation with the fCAL ELISA
- 3 analytical ranges available for screening or monitoring applications: 30-300 µg/g, 100-1800 µg/g or 30-1000 µg/g calprotectin in faecal samples
- High and low control included in the kits
- Based on established lateral flow technology

Quantum Blue® fCAL Assays

<table>
<thead>
<tr>
<th>Product code</th>
<th>Description</th>
<th>Pack Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>LF-CAL25</td>
<td>Quantum Blue® fCAL 30-300 µg/g</td>
<td>25 tests</td>
</tr>
<tr>
<td>LF-CHR25</td>
<td>Quantum Blue® fCAL high range 100-1800 µg/g</td>
<td>25 tests</td>
</tr>
<tr>
<td>LF-CALE25</td>
<td>Quantum Blue® fCAL extended range 30-1000 µg/g</td>
<td>25 tests</td>
</tr>
<tr>
<td>BI-POCTR-ABS</td>
<td>Quantum Blue® Reader</td>
<td>1 unit</td>
</tr>
</tbody>
</table>

BÜHLMANN Laboratories

Correlation of the Quantum Blue Calprotectin Test and the BÜHLMANN fCAL™ ELISA (EK-CAL)

"The introduction of the Quantum Blue test into the Department has been very easy. Staff like using the system and the extraction step is made as easy and straightforward as possible with the Smart Prep stool extraction device."
Faecal Testing

Calprotectin ELISA: Quantitative High Throughput Test

The BÜHLMANN fCAL® is the UK market-leading calprotectin ELISA. It provides quantitative determination of faecal calprotectin in high sample throughput environments. The format is a microtitre plate based assay that can be performed manually or on an automated ELISA system to reduce hands-on time. The BÜHLMANN fCAL® ELISA also has an extended range protocol for use in monitoring patient therapy and mucosal healing. This reduces the need for further dilution and repeated assay.

Why Use BÜHLMANN fCAL® ELISA?
- Measurable range is 10-600 µg/g or 30-1800 µg/g: same test kit, different protocol
- All reagents are ready to use (except wash buffer)
- Reliable results over the entire range
- Total assay time is 75 minutes
- Easily automated on ELISA processors
- CE marked protocol available for the DS2® and DSX®
- The kit includes all calibrators and quality controls ready to use
- A simple and well documented assay

How Does It Work?
The BÜHLMANN fCAL® ELISA kit is designed for the quantitative determination of human calprotectin concentrations in stool samples.

After a short extraction procedure, the test allows for the selective antibody measurement of calprotectin antigen by sandwich ELISA. The capture monoclonal antibody coated on the microtitre plate is highly specific for calprotectin heterodimeric and polymeric complexes (4-5) respectively.

Clinical Evidence

A study at the University Hospital Basel, Switzerland, proves calprotectin concentrations measured with the BÜHLMANN Calprotectin ELISA correlate highly with clinical results and the current gold standard of colonoscopy. 405 symptomatic patients were included.

With a sensitivity of 84% and a specificity of 95% the BÜHLMANN calprotectin ELISA confirmed the nature of the pathology behind the symptoms, and showed an excellent negative predictive value of 93%. In this study, the performance of the BÜHLMANN monoclonal ELISA was superior to polyclonal calprotectin determinations (Figure 1) and to lactoferrin measurements (not shown). The cut off used was 50 µg/g calprotectin in faeces.

Calprotectin ELISA

<table>
<thead>
<tr>
<th>Product code</th>
<th>Description</th>
<th>Pack Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>EK-CAL</td>
<td>fCAL ELISA single plate</td>
<td>96 wells</td>
</tr>
<tr>
<td>EK-CAL2</td>
<td>fCAL ELISA two plates</td>
<td>192 wells</td>
</tr>
<tr>
<td>EK-CAL2-WEX</td>
<td>fCAL ELISA two plates without buffer</td>
<td>192 wells</td>
</tr>
</tbody>
</table>

BÜHLMANN Laboratories

Figure 1: ROC analysis of the ability of BÜHLMANN Calprotectin ELISA and of a polyclonal ELISA to discriminate between patients with CD and IBS. From Lehmann. et al. (in prep).
Faecal Testing

BÜHLMANN fCAL® turbo

The BÜHLMANN fCAL® turbo is a quantitative random access calprotectin assay that combines speed, quality and flexibility. The wide assay range (20 - 8000µg/g) provides sensitivity at the low end for differentiation between IBS and IBD patients, whilst also giving an actual value to monitor IBD positive patients at the high end.

With the ability to run on many standard clinical chemistry analysers (see http://www.alphalabs.co.uk/kk-cal for the most up to date list of analyser protocols available), there is no requirement for additional equipment saving expense on capital purchase, service contracts and valuable laboratory space.

Why Use BÜHLMANN fCAL® turbo?

- Fastest calprotectin test with results in 10 minutes
- Wide initial test range (20 - 2000µg/g) keeps dilutions to a minimum
- Automatic on-board dilution for samples >2000µg/g to give reportable results up to 8000µg/g
- CALEX extraction device simplifies sample preparation and is loaded directly onto the analyser streamlining the workflow
- Sample preparation device, controls and calibrators are in stable, ready to use format
- Excellent linearity across the assay range
- Excellent correlation with other BÜHLMANN assays

<table>
<thead>
<tr>
<th>fCAL® turbo</th>
<th>Description</th>
<th>Pack Size*</th>
</tr>
</thead>
<tbody>
<tr>
<td>KK-CAL</td>
<td>fCAL turbo kit (reagents, controls and calibrators)</td>
<td>~200</td>
</tr>
<tr>
<td>B-KCAL-RSET</td>
<td>fCAL turbo reagents</td>
<td>~200</td>
</tr>
<tr>
<td>B-KCAL-CASET</td>
<td>fCAL turbo calibrators</td>
<td>6 levels, 1 ml each</td>
</tr>
<tr>
<td>B-KCAL-CONSET</td>
<td>fCAL turbo controls</td>
<td>3 x 2 levels, 1 ml each</td>
</tr>
<tr>
<td>B-CAL-EX12</td>
<td>Extraction buffer</td>
<td>12 x 125ml</td>
</tr>
</tbody>
</table>

*BÜHLMANN Laboratories

*y = 1.1507x + 10.082
R² = 0.9544

Scatter Plot

fCAL turbo on the Siemens Advia 2400

fCAL turbo on the Roche Cobas 6000
Faecal Testing

Products for Pancreatic Insufficiency

Elastase is a pancreatic enzyme that degrades connective tissue. Pancreatic elastase does not undergo any significant degradation during intestinal transit. Therefore, measurement of Faecal Elastase can be used to diagnose or exclude pancreatic insufficiency associated with chronic pancreatitis, cystic fibrosis, carcinoma of the pancreas, Diabetes mellitus type 1, Schwachman-Diamond syndrome and other pancreatic diseases. BS-86-01 and BS-86-01-SK15 provide quantitative determination of Pancreatic Elastase levels in faecal samples and can be supplied with faecal extraction tubes.

<table>
<thead>
<tr>
<th>Pancreatic Insufficiency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product code</td>
</tr>
<tr>
<td>BS-86-01</td>
</tr>
<tr>
<td>BS-86-01-SK15</td>
</tr>
<tr>
<td>BS-00-03</td>
</tr>
</tbody>
</table>

Bioserv Diagnostics

Anti-TNFα Therapy Monitoring

Anti-TNFα drugs provide a major biotherapeutic breakthrough in the treatment of Chronic Inflammatory Rheumatism (CIR) such as Rheumatoid Arthritis, ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthritis. They are also used for the treatment of Inflammatory Bowel Diseases when patients do not respond to steroids. These biomarkers bind TNFα, blocking the action that is responsible for the inflammatory state.

However, not all patients undergoing such treatment respond well and among those that do, the level of response can vary between patients and within the same individual over time.

The BÜHLMANN Quantum Blue® Therapeutic Drug Monitoring Assays (TDM) are the first rapid test to measure trough drug levels in patients’ serum. They allow timely decision making for dose adjustments before the next infusion.

Why use Quantum Blue® TDM Assays?

- Single use assay
- No need to batch samples
- Assay time of 15 minutes
- Good correlation with ELISA methods
- Good linearity across the range
- Individually sealed cassette ensures quality
- High and low control included in the kit

Why use Quantum Blue® TDM Assays?

Quantum Blue® Anti-TNFα Monitoring

<table>
<thead>
<tr>
<th>Product code</th>
<th>Description</th>
<th>Pack Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>LF-TLF25</td>
<td>Trough level Infliximab 0.4-20 µg/ml</td>
<td>25 tests</td>
</tr>
<tr>
<td>LF-LAO25</td>
<td>Trough level Adalimumab 1-35 µg/ml</td>
<td>25 tests</td>
</tr>
</tbody>
</table>

BÜHLMANN Laboratories
Faecal Testing

Dynex DS2® ELISA Processor

The DS2® ELISA Processor from Dynex Technologies is a state-of-the-art, fully automated system that can process two 96-well microtitre plates simultaneously.

Key Features
- Reliable, cost-effective, and easy to use and maintain
- Quickly and easily processes up to two 96-well microplates and up to 12 different assays simultaneously
- Features the most advanced and user-friendly control system available
- Designed with full walk-away capability
- Sample ID-bar-code reading, chain-of-custody, and instrument self-diagnostics

A complete walk away system, the DS2 can execute all functions associated with ELISA assay processing including sample/reagent dilution and addition, plate incubation and shaking, wash steps and OD measurement.

The DS2 is ideal for clinical laboratories that would like to enhance their processes through automation, but do not have the volume requirements to justify the investment in the larger more expensive systems.

Building on the renowned Dynex DSX® walk-away workstation, the DS2 System has all the power and performance of the higher-capacity DSX, but is designed for the needs of lower-throughput labs. With advanced automation and precise liquid-handling capabilities, the DS2 eliminates variations that occur with manual processes, ensuring the rigorous, repeatable analyses required in critical applications.

A CE marked application is available for the BÜHLMANN IFELISA assays run on the DS2.

Applications are also available for the Elastase ELISA (BS-86-01, BS-86-01-SK15).

Automated ELISA Instrumentation

<table>
<thead>
<tr>
<th>Product code</th>
<th>Description</th>
<th>Pack Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>62010</td>
<td>Dynex DS2 Automated 2-plate system</td>
<td>1</td>
</tr>
</tbody>
</table>

Consumables

<table>
<thead>
<tr>
<th>Product code</th>
<th>Description</th>
<th>Pack Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>62910</td>
<td>Deep well dilution strips</td>
<td>250 x 8 well</td>
</tr>
<tr>
<td>62930</td>
<td>Reagent Bottles - 15ml</td>
<td>10</td>
</tr>
<tr>
<td>65950</td>
<td>Reagent Bottles - 25ml</td>
<td>24</td>
</tr>
<tr>
<td>65910</td>
<td>Racked Sample Tips</td>
<td>4 x 108</td>
</tr>
<tr>
<td>65920</td>
<td>Reagent Tips</td>
<td>4 x 108</td>
</tr>
<tr>
<td>65940</td>
<td>Standard/Control Bottles</td>
<td>33</td>
</tr>
</tbody>
</table>

Helicobacter pylori (H. pylori) is a spiral bacterium and is associated with a variety of gastrointestinal diseases including gastritis, duodenal and gastric ulcers, non-ulcer dyspepsia, gastric adenocarcinoma and lymphoma. The organism is present in 95-98% of patients with duodenal ulcers and 60-90% of patients with gastric ulcers.

The Easy-Card H. pylori antigen test, designed for rapid detection of H. pylori antigen in stool samples, gives an answer in just 10 minutes. Sample processing is quick and simple using the dip stick sampling device and pre-filled buffer tube. The Easy-Card’s lateral flow technology means it is clear and easy to read. It also has an integral control to validate the assay. The sensitivity is 94% and specificity 99%.

Infectious Disease

<table>
<thead>
<tr>
<th>Product code</th>
<th>Description</th>
<th>Pack Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>14656</td>
<td>Easy-Card H. pylori Ag</td>
<td>20 tests</td>
</tr>
</tbody>
</table>

Infectious Diseases

Sentinel
Faecal Testing

Faecal Immunochemical Testing (FIT)

Guaiac-based Faecal Occult Blood Tests (gFOBT) have been used for many years identifying occult blood in symptomatic patients and in screening of the asymptomatic. However, it is now widely recognised that Faecal Immunochemical Testing (FIT) provides greater sensitivity and specificity for identifying haemoglobin in faeces. This has resulted in many laboratories eliminating gFOBT from their patient pathway, consequently creating an increase in referrals for colonoscopy in those presenting with lower abdominal symptoms. Since these symptoms overlap considerably in serious colorectal disease and benign and functional bowel disorders, it can be hard to triage patients in primary care and this can result in more patients being referred to secondary care.

Colonoscopy resources are under considerable pressure and, despite increasing referrals, disease detection remains low, as only about a third of symptomatic patients have an abnormality detected.

FIT are specific for human haemoglobin and hence dietary factors do not cause false positive or negative results. Moreover, FIT are about 100 times more sensitive than guaiac and hence more able to detect the presence of blood in stools.

FIT tests are now available in two formats from Alpha Laboratories. Qualitative and Quantitative

Qualitative FIT

The Qualitative FIT method is a lateral flow immunoassay, that offers flexibility in sample collection and transportation. The kit can be purchased in various formats depending on sampling preferences.

The unique patented DEVEL-A-TAB can be used to collect 2 faecal samples by the patient. This dried faecal sample has up to 30 day’s stability prior to testing.

For those samples that are sent to the lab in faecal pots, there is a faecal collection stick inside the buffer tube which can also be used to sample the faeces.

Either sampling method can be used and this provides flexibility in the use of the test.

The test is simple to perform and can be done by any healthcare professional.

There is a built in procedural control to confirm validity of testing.

Sensitivity for haemoglobin is 50 ng/ml, with a result in 5 minutes. This provides the ability to do tests in a clinic or other Point of Care (POC) setting.

<table>
<thead>
<tr>
<th>hema-screen™ SPECIFIC</th>
<th>Description</th>
<th>Pack Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>HSSPCAS-10</td>
<td>hema-screen SPECIFIC Tubes &amp; Cassettes</td>
<td>Cassettes will detect 50 ng Hb/ml buffer equivalent to 50µg Hb/g faeces</td>
</tr>
<tr>
<td>HSSPENV-50</td>
<td>hema-screen SPECIFIC Envelope Packs</td>
<td>Each mailing envelope contains: 1 DEVEL-A-TAB slide, 2 collection tissues, 2 applicator sticks, patient instructions</td>
</tr>
</tbody>
</table>

Immunostics
In July 2017 the National Institute for Health and Care Excellence published NICE Guidance DG30: “Quantitative faecal immunochemical tests (FIT) to guide referral for colorectal cancer in primary care”

Based on the peer reviewed data for FIT, the Diagnostics Advisory Committee created an economic model for each of the FIT methods under review.

NICE DG30 recommends FIT for adoption in primary care to guide referral for suspected colorectal cancer in people without rectal bleeding who have unexplained symptoms but do not meet the criteria for a suspected cancer pathway referral outlined in NICE’s guideline on suspected cancer (recommendations 1.3.1 to 1.3.3).

It advises that results should be reported using a threshold of 10 micrograms of haemoglobin per gram of faeces to define the threshold for ruling out colorectal cancer.

The ability to use a simple, easy to use, inexpensive diagnostic test will provide additional assistance in determining the appropriate patient pathway for further investigation, with the potential to reduce the level of requirement for colonoscopies.

The quantitative Faecal Immunochemical Test (FIT) solution from Alpha Laboratories Ltd., is the HM-JACKarc system. It offers fully automated testing on a compact bench top analyser, excellent sensitivity at the low end and simple, hygienic sample collection for patients.

Alpha Laboratories has a long history of supplying the four UK Bowel Screening Programmes with gFOBT and FIT and so is also experienced in supporting logistic solutions for packaging, patient instructions and test returns.

For more information, case studies, and to view videos including discussions with experts in the field, please visit www.alphalabs.co.uk/fit
Faecal Testing

Kyowa Medex Automated Faecal Immunochemical Testing System

The Automated Quantitative Faecal Immunochemical Testing system from Kyowa Medex integrates Analyser technology, with Reagent and Collection device (ARC), to provide a rapid and consistent, high throughput solution for both screening and symptomatic Faecal Occult Blood testing.

Key features:
- Sensitivity: <7 µg Hb/g faeces
- Easy to use sample tube
- Fully automated
- Compact and light
- No prozone effect up to 200,000 µg Hb/g faeces
- High speed performance: 200 samples/hour

HM-JACKarc Analyser

The HM-JACKarc analyser is a compact bench top system that uses Integrated Sphere Latex Turbidimetry to measure faecal haemoglobin concentration.

It has advanced innovative software with touch screen technology, providing a very easy to use interface. There is minimal depth to the programme menus, ensuring quick access to operating screens. The system can be utilised by all grades of staff with minimal training. Different levels of user access authority provide security, so that only advanced users can amend settings etc.

HM-JACKarc has been designed to provide rapid results with maximum convenience for the operator.

The ability to load up to 80 samples at any one time provides walk away capability and enhanced productivity. Additional consumables and samples (up to a total maximum of 80) can be added at any time during the testing process.

HM-JACKarc has a time to first result of just 5.6 minutes with additional results every 18 seconds, generating up to 200 results per hour.

The technology and software ensures that the system can be used in either screening or symptomatic assessment applications, since cut-off concentrations can be selected depending upon requirements.
The latex reagent is composed of consistently sized latex particles. The polyclonal antibodies bound to the surface of the latex in high concentrations ensure a very high antigen capture ratio.

This achieves two key benefits:

- **A wide linear dynamic assay range**
  0-400 µg Hb/g faeces

- **A very high hook capacity (200,000 µg Hb/g faeces)** so that it still generates a result for samples higher than the top standard, ensuring no patient is given an artificially low result.

As with any method, the pre-analytical component is key to result accuracy.

Sample size and consistency have always been an issue with faecal testing, but with the new collection picker for the HM-JACKarc, this is made easier for those taking the sample, irrespective of whether this is done by a laboratory professional or by the patient.

- Screw in picking stick, 95kPa compliant vial
- Hexagonal hole and rubber septum enables accurate collection of the faeces
- Seal and collection indicator window confirms usage
- Collection picker is loaded directly onto the HM-JACKarc
Alpha Laboratories has extensive experience in diagnostics for digestive health.

We have been involved with the National Bowel Cancer Screening programme since 1998 and have been its sole supplier of hema-screen™ (faecal occult blood tests).

Alpha Laboratories also helped pioneer the routine use of calprotectin assays for differentiating between IBD and IBS. This novel biomarker provides a reliable, non-invasive test with significant cost and patient benefits. NICE guidelines (DG11-2013), now advocate the use of faecal calprotectin as a first line test in patients presenting with gastrointestinal symptoms indicative of IBD or IBS. It is also a valuable marker for monitoring and managing IBD positive patients.

Find out more at our dedicated website: www.calprotectin.co.uk

Continuing to bring leading edge solutions to clinical scientists and gastroenterologists alike, our latest additions to the range include innovative products for scalable calprotectin testing and rapid TNF-α drug monitoring.

The introduction of the IBDoc® calprotectin home test offers a new approach to help support patient care and customised therapy.

Advancing bowel cancer screening and symptomatic assessments, the HM-JACKarc Quantitative Faecal Immunochemical Test (FIT) system brings higher specificity and sensitivity within a convenient automated platform.

Passionate about finding new ways to help science improve people’s lives through its evolving range of specialist diagnostic and laboratory products.

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