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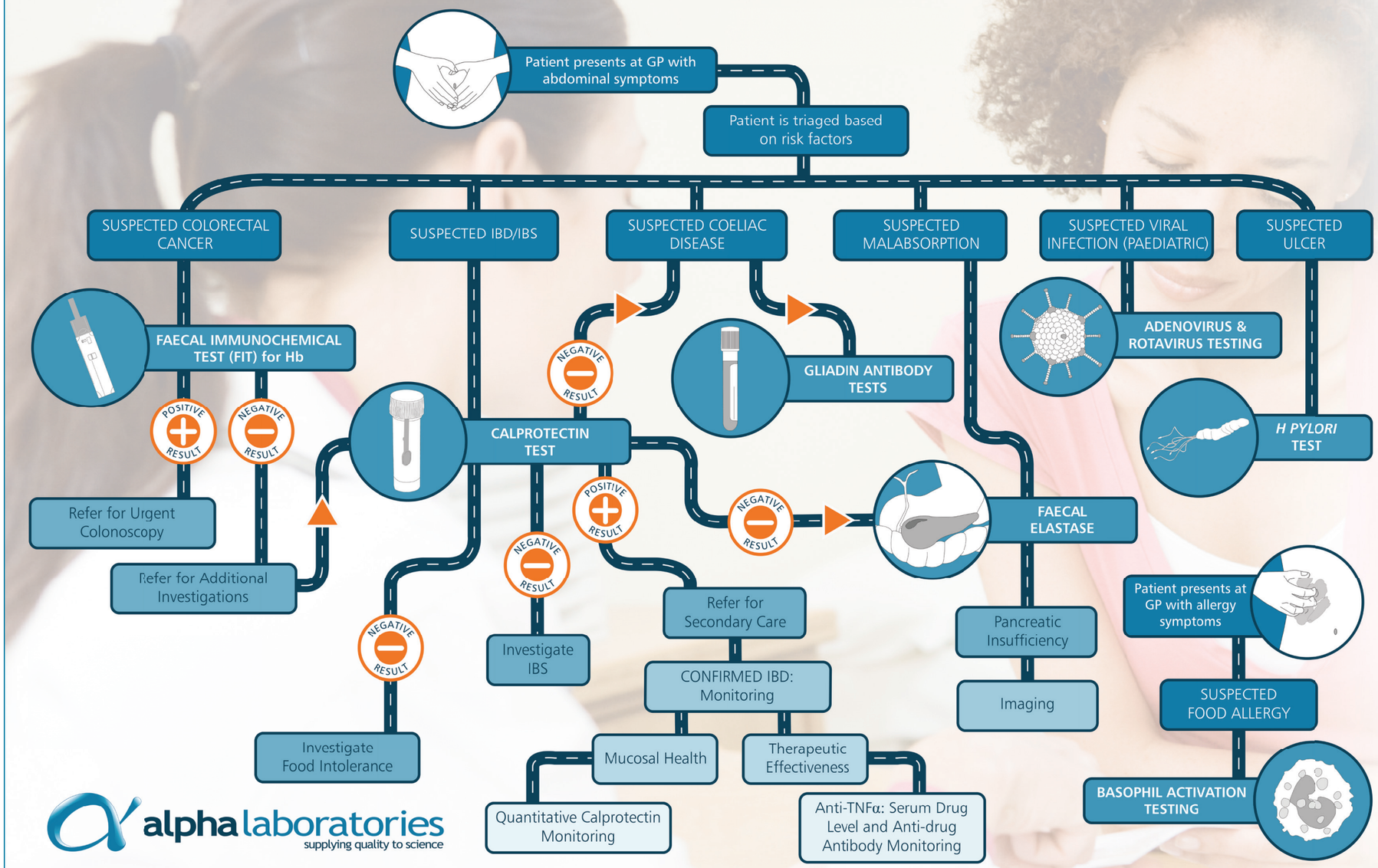
supplying quality to science

Diagnostics for Digestive Health Management

- Faecal Sample Collection and Extraction
- Calprotectin Testing
- Anti-TNFα Therapy Monitoring
- Pancreatic Elastase Tests
- Bowel Cancer Screening and Symptomatic Testing
- Infectious Disease Assays
- Food Allergy Testing

Digestive Disease Patient Pathway



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It's all about the Patient...

Alpha Laboratories has been at the forefront of faecal testing in the UK for over 20 years.

This was initially as the market leader for guaiac-based faecal occult blood testing. We won tenders for bowel screening in all four UK countries, as each launched its own screening programme.

Continuing to provide leading edge products, Alpha Laboratories introduced the first faecal immunochemical testing (FIT) method for screening, initially being awarded the contract for quantitative FIT as the front line test in the Scottish Bowel Screening Programme. Tender wins for FIT screening in Wales and Northern Ireland followed.

In addition, we have actively worked with NICE to incorporate FIT into the pathway for patients with suspected lower GI cancer. Combining a highly sensitive and specific test with logistics support, we are helping to roll out FIT for symptomatic testing right across the UK.

This is leading 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 BÜHLMANN 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.

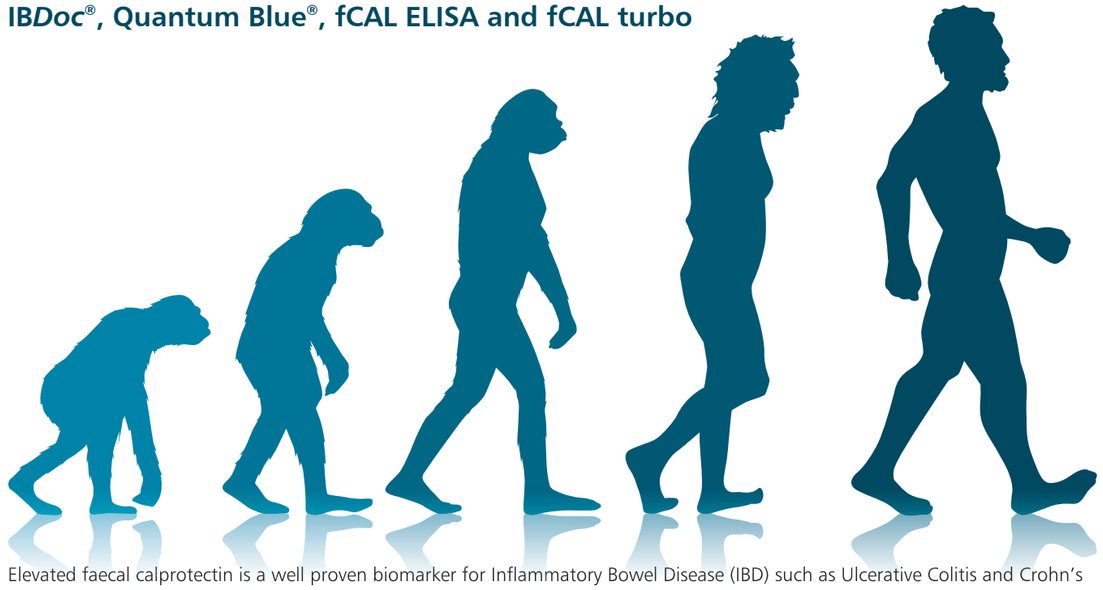
In addition to this expertise in FIT and Calprotectin testing, Alpha Laboratories offers a range of other tests to assist clinicians in the assessment of digestive disorders.

Pricing and Online Ordering at www.alphalabs.co.uk

Complete Range of Solutions for Calprotectin Testing

Future-proof your Calprotectin Testing with BÜHLMANN:

IB*Doc*®, Quantum Blue®, fCAL ELISA and fCAL turbo



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:

- To monitor IBD positive patients to assist in better patient management
  - Predicting flares
  - Predicting post-operative relapse
  - Predicting response to therapy
  - Helping to keep patients in remission out of hospital

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**

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.

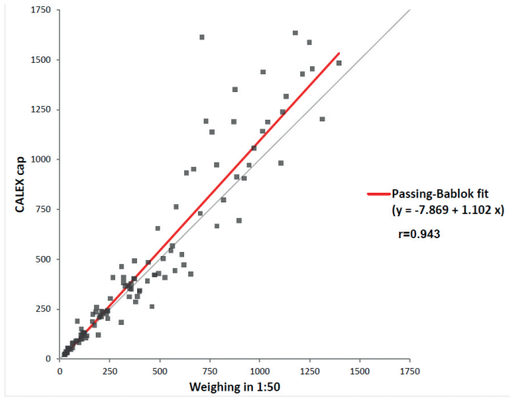
- Ease of use for laboratory personnel and patients
- Delivers a precise amount of faecal sample
- Optimised sample dilution for maximum efficiency in stool extraction
- Application as a primary tube for many ELISA robots and routine biochemistry analysers
- 95kPa postal compliant
- UN3373 and IATA 650 compliant for transport by air
- Modifications to the blue & white caps at either end enable them to be used on laboratory track systems for a truly automated workflow
- NEW - CE marked patient collection kits are available containing an IFU, CALEX Cap, two stool collection sheets, a label and a plastic bag

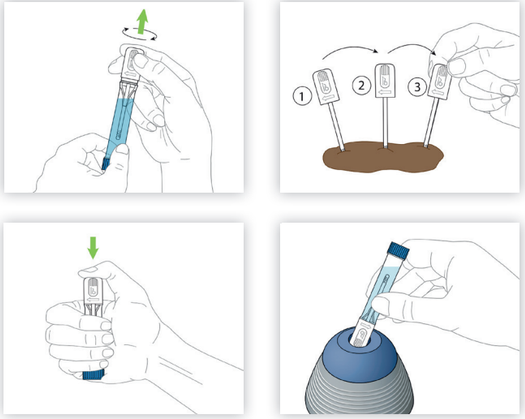
"The Calex Cap improves the pre-analytical sample handling, with reduced hands on time and simplified procedure as there is no need to weigh out samples or dilute before use."

Vacu-Re-Caps can be used to quickly and cleanly reseal the CALEX after analysis.

CALEX® Cap compared to manual extraction

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





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

CALEX Cap Calprotectin Stool Extraction Device		
Product code	**Description**	**Pack Size**
B-CALEX-C50	CALEX Cap Device	50 tubes
B-CALEX-C200	CALEX Cap Device	200 tubes
B-CALEX-C500	CALEX Cap Device	500 tubes
B-CALEX-CCSET25	CALEX Cap Collection Set	25 sets
AP0021	15.2mm Vacu-Re-Caps	1000

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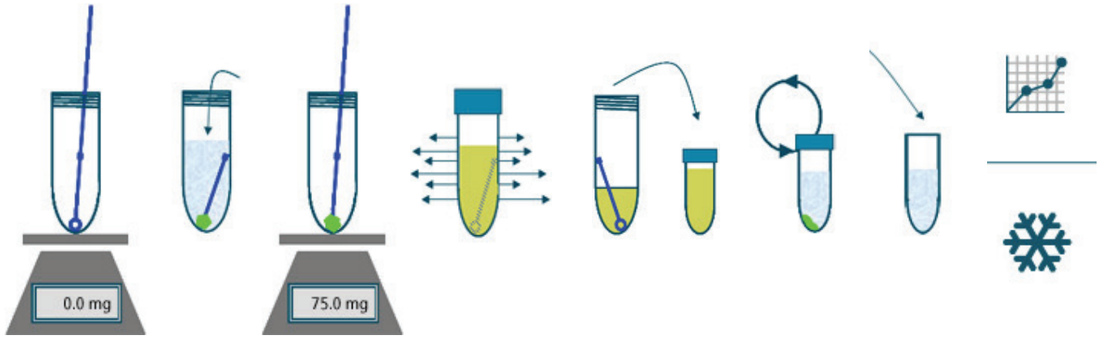
Manual Weighing

Weighing the sample is still considered the Gold-Standard sample extraction method.



Step 1:
Pre-weigh empty tube and inoculation loop and tare to zero
Step 2:
Add 50 – 100mg faeces
Step 3:
Add 49 volumes of 1 x B-CAL-EX
Step 4:
Close tube and vortex vigorously for 30 min (highest speed)
Step 5:
Transfer 1.5ml into a fresh tube
Step 6:
Centrifuge for 5 min at 3,000 x g
Step 7:
Transfer supernatant into a fresh tube
Step 8:
Continue immediately to ELISA procedure, or store at >-20°C

Extraction Buffer

Product code	Description	Pack Size
B-CAL-EX3	Extraction buffer	3 x 125ml
B-CAL-EX12	Extraction buffer	12 x 125ml

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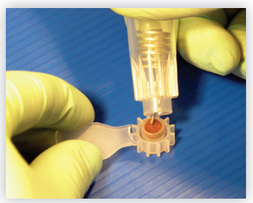
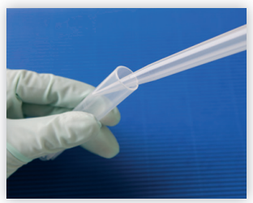
Smart-Prep

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



Smart-Prep Faecal Extraction Device

Product code	Description	Pack Size
B-CAL-RD	Smart-Prep Faecal Sample Preparation Kit	50 tubes

BÜHLMANN Laboratories

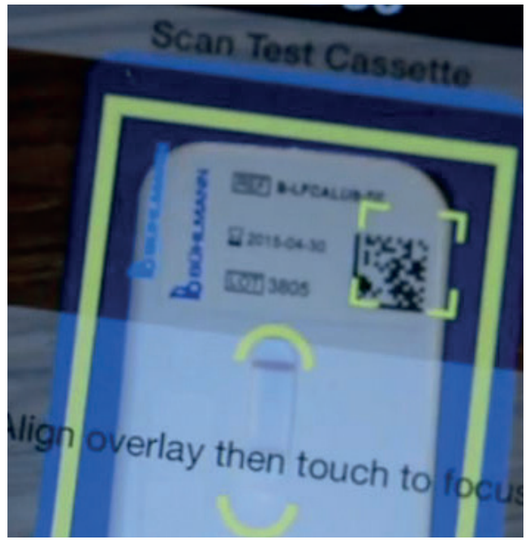
Calprotectin Monitoring with IB*Doc*® Home Test

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. The BÜHLMANN IB*Doc*® enables patients to perform quantitative calprotectin tests themselves and then use their smartphones to read the results.

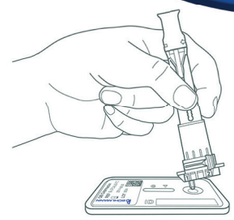
The CALEX® Valve allows patients to process their own samples without the need for vortex mixing, centrifuging or pipetting. The valve at the base of the device dispenses a precise amount of liquid onto the lateral flow test device. After 12 minutes the calprotectin assay result is read using the smartphone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

- First CE marked Calprotectin Home Test
- Quantitative Rapid Test with results between 30 - 1000µg/g
- Consistent results with other BÜHLMANN Calprotectin assays: - **Quantum Blue®**
  - **fCAL ELISA**
  - **fCAL Turbo**
- Consistent results with endoscopic and histologic results. (See Figure 1)
- Calibrated for use with numerous smartphones including: Apple, Samsung, LG, Sony and HTC; please see our website for an up-to-date list

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

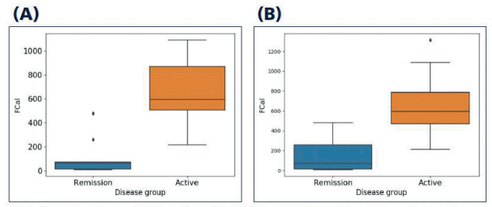


"IB*Doc* has far exceeded our expectations. We have been overwhelmed at its popularity with patients and it has hugely enhanced the delivery of quality of care."
K. Sugrue, IBD nurse, Mercy



"IB*Doc* is amazing and allows me to feel more in control of my Crohn`s disease. I can use it anytime to check if I`m having a flare up. It is very reassuring..."

Figure 1: Distribution of FCal for remission and active disease



(A) Remission defined as UCEIS = 0 AND Nancy = 0. Active disease defined as UCEIS ≥4 AND Nancy ≥3.
(B) Remission defined as UCEIS = 0 -1 AND Nancy <=1. Active disease defined as UCEIS ≥4 AND Nancy ≥2.
p-values <0.000001 for both (A) and (B)

Walsh A. et al. ECCO 2018 P262

IB*Doc*® Home Test

Product code	Description	Pack Size
LF-IBDOC8	IB*Doc* Home Test Kits	8
BI-IBDOC	IB*Doc* Starter Pack	Each

BÜHLMANN Laboratories

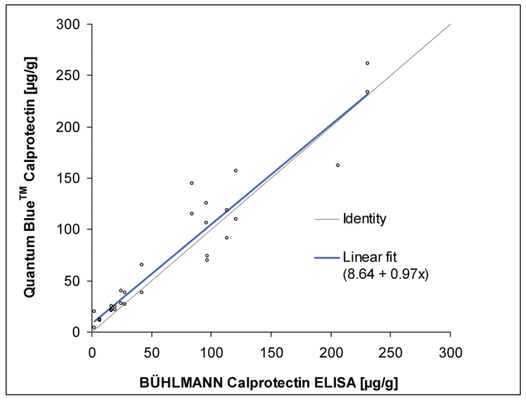
Quantum Blue®: Quantitative Rapid Calprotectin Test

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 bench top reading device.

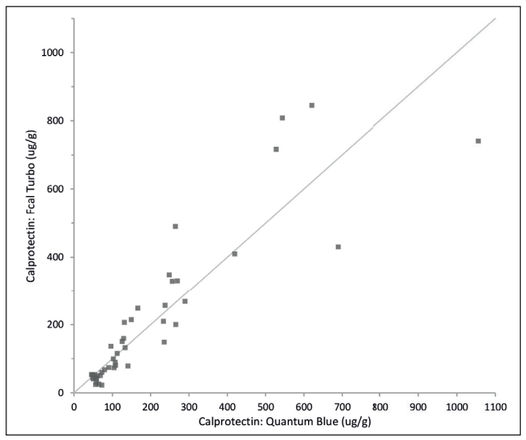
The Quantum Blue® reader analyses the signal intensity from the test and control line to give a quantitative value and is standardised with the BÜHLMANN fCAL™ ELISA.

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.

Correlation Across the Healthcare Network:



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



Correlation of the Quantum Blue Calprotectin Test and the BÜHLMANN fCAL turbo

Why Use Quantum Blue Calprotectin?

- Quantitative measurement of calprotectin in faecal samples
- Results in 12 minutes
- Excellent correlation with laboratory assays and endoscopic findings
- Simple, rapid extraction and test process
- Unilateral connectivity to LIMs via dedicated middleware
- Compact benchtop reader with touch screen
- 2 analytical ranges available for screening or monitoring applications
- High and low control included in the kits
- Barcode scanner for patient/sample data entry
- Results directly printable or downloadable to USB
- Other assays are also available including: Serum calprotectin and Serum trough levels for Biologics and Antibody levels

Quantum Blue® fCAL Assays

Product code	Description	Pack Size
LF-CHR25	Quantum Blue® fCAL high range 100-1800 µg/g	25 tests
LF-CALE25	Quantum Blue® fCAL extended range 30-1000 µg/g	25 tests
BI-POCTR-ABS3	Quantum Blue Reader 3rd Generation	1 unit

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"This rapid bedside test can facilitate clinical decisions on hospital admission, such as deciding whether the IBD treatment should be intensified. Similarly, in the ambulatory setting, it is crucial when determining whether a patient should undergo endoscopy or not."
Moniuszko. A et al. Polish Archives of Internal Medicine. 2017

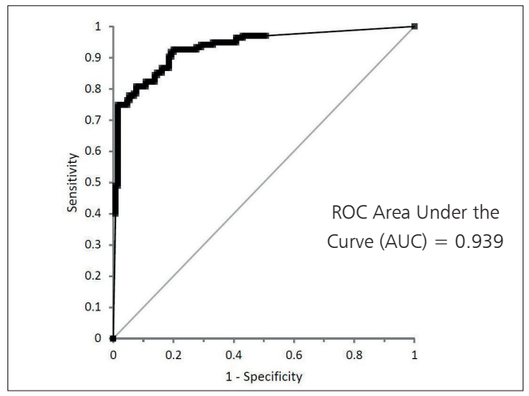
Calprotectin ELISA: Quantitative High Throughput Test

The BÜHLMANN fCAL ELISA method is the most popular method for ELISA calprotectin testing in the UK, with flexibility to choose the extraction method and kit size options with flexi-strip format for large and small volume users.

There is excellent correlation with the BÜHLMANN Quantum Blue and fCAL turbo methods so laboratories who are looking to scale up their testing either to or from fCAL ELISA get a continuity of result which is very important in ensuring a smooth transition.

Assay Details:

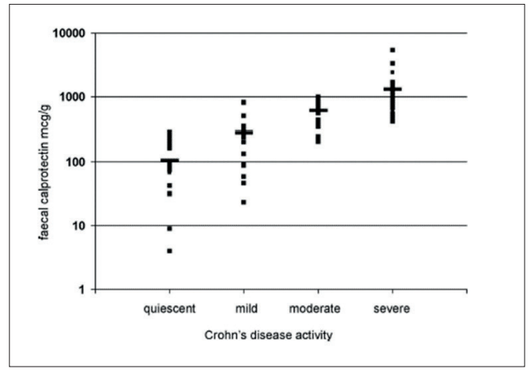
- Measurable range is 10-600 µg/g or 30-1800 µg/g: same test kit, two different protocols
- Easily automated on ELISA processors with CE protocol available for the DS2® and DSX®
- The kit includes all calibrators and quality controls ready to use
- Excellent correlation with endoscopic findings and clinical outcome
- Linear beyond the stated range



ROC analysis for IBD/IBS differentiation

"The BUHLMANN fCAL ELISA utilizes the optimal combination of high sensitivity and NPV at discriminating IBD and IBS as well as other non-IBD disorders both in adults and paediatric patients at a cut off of 80ug/g."
Berinstein et al 2019 Crohns & Colitis Journal

Using the calprotectin to monitor patients can also determine the level of severity of the disease activity:



"In conclusion, faecal calprotectin is a highly sensitive real-time biomarker of Crohn's disease mucosal activity. It provides an insight into disease ahead of symptoms, so predicting for disease outcomes without recourse to expensive and invasive testing."
Tuvill BMJ Mapping of CD Outcomes

Calprotectin ELISA

Product code	Description	Pack Size
EK-CAL	fCAL ELISA single plate	96 wells
EK-CAL2	fCAL ELISA two plates	192 wells
EK-CAL2-WEX	fCAL ELISA two plates without buffer	192 wells

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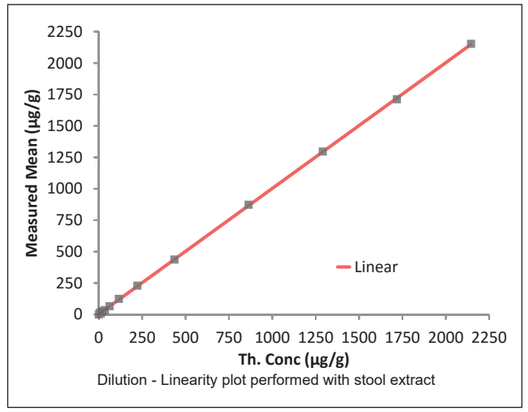
BÜHLMANN fCAL® turbo

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.

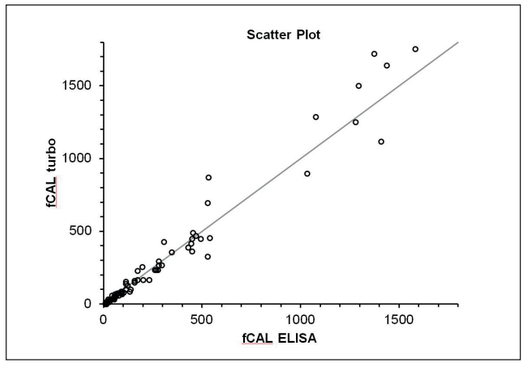
With the ability to run on many standard clinical chemistry analysers (see www.alphalabs.co.uk/kk-cal for the most up to date list of analyser protocols available), there is no requirement for additional equipment saving expense on capital purchase, service contracts and valuable laboratory space.

Why Use BÜHLMANN fCAL® turbo?

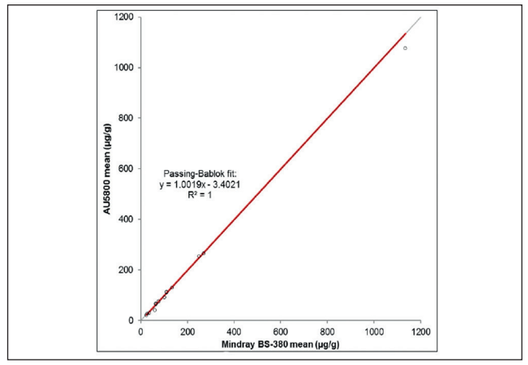
- Fastest calprotectin test with results in 10 minutes
- Wide initial test range (20 - 2000 µg/g) keeps dilutions to a minimum
- Optional automatic on-board dilution for samples >2000 µg/g to give reportable results up to 8000 µg/g
- CALEX extraction device simplifies sample preparation and is loaded directly onto the analyser streamlining the workflow
- Can be used with track systems in full random access mode
- 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



Dilution - Linearity plot performed with stool extract



fCAL turbo on the Siemens Advia 2400



Mindray BS-380 vs. AU5800 n=14

fCAL® turbo		
Product code	**Description**	**Pack Size***
KK-CAL	fCAL turbo kit (reagents, controls and calibrators)	~200
B-KCAL-RSET	fCAL turbo reagents	~200
B-KCAL-CASET	fCAL turbo calibrators	6 levels, 1ml each
B-KCAL-CONSET	fCAL turbo controls	3 x 2 levels, 1ml each
B-CAL-EX3	Extraction buffer	3 x 125ml
B-CAL-EX12	Extraction buffer	12 x 125ml

BÜHLMANN Laboratories *Will vary depending on analyser

Anti-TNFα Therapy Monitoring

Anti-TNFα drugs provided a major biotherapeutic breakthrough in the treatment of chronic inflammatory conditions and are also used for the treatment of Inflammatory Bowel Diseases when patients do not respond to steroids. These drugs 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 and Antibody 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
- Good correlation with ELISA methods
- Good linearity across the range
- Individually sealed cassette ensures quality
- High and low control included in the kit

Quantum Blue® Anti-TNFα Monitoring		
Product code	**Description**	**Pack Size**
LF-TLIF10	Trough level Infliximab 0.4-20 µg/ml	10 tests
LF-TLIF25	Trough level Infliximab 0.4-20 µg/ml	25 tests
LF-TLAD10	Trough level Adalimumab 1-35 µg/ml	10 tests
LF-TLAD25	Trough level Adalimumab 1-35 µg/ml	25 tests
LF-ADIF10	Trough level anti-infliximab antibody	10 tests
LF-ADIF25	Trough level anti-infliximab antibody	25 tests
LF-ADAD10	Trough level anti-adalimumab antibody	10 tests
LF-ADAD25	Trough level anti-adalimumab antibody	25 tests

BÜHLMANN Laboratories

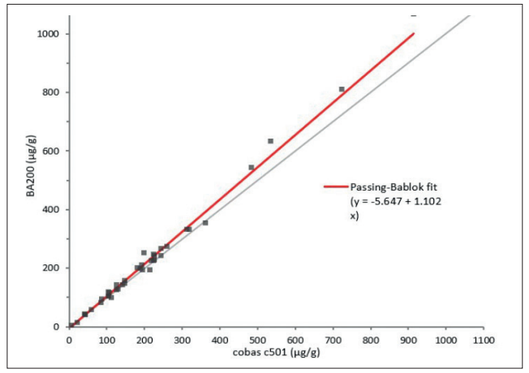
Pricing and Online Ordering at www.alphalabs.co.uk

BioSystems BA200 Analyser

The BioSystems BA200 analyser is also available either for capital purchase or on a reagent rental basis to run the BÜHLMANN fCAL turbo and fPELA asssays. This bench top instrument offers an excellent alternative to the main stream analysers for faecal testing with comparable performance and efficiency:

Key Features

- CE marked applications for BÜHLMANN fCAL turbo and fPELA assays
- CALEX Cap can be loaded directly onto the analyser
- Software is LIM enabled with built in barcode reader for samples and reagents
- 200 tests per hour
- 88 position free configuration
- LED technology
- Quick pause (6-24 seconds) to enable loading and unloading of samples and reagents
- Chilled rota for reagents and samples
- Other assays are available to be used on the instrument



Method comparison with the Roche c501

BioSystems BA200 Analyser		
Product code	**Description**	**Pack Size**
83200	Bench top analyser	Each

BioSystems

Products for Pancreatic Insufficiency

Pancreatic insufficiency is the reduction of production or transportation of the digestive enzymes which results in the inability to properly digest a meal (fats, proteins and carbohydrates). The insufficiency is not usually absolute, it is variable, which then has a graded impact on digestion and hence symptoms. Patients can suffer from a variety of gastric symptoms which can range in severity but include abdominal pain, weight loss, diarrhoea, smelly loose stools, flatulence, loss of appetite and fatigue – all of which can be confused with a variety of other gastric complaints; so performing a simple stool test to determine the level of elastase (a pancreatic enzyme) helps with the diagnosis of this condition – then clinicians just need to determine the cause...

BÜHLMANN fPELA® Assay

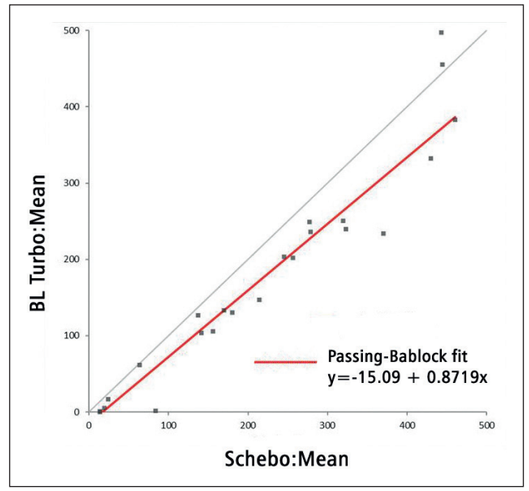
The new BÜHLMANN fPELA® assay for faecal pancreatic elastase utilises the same CALEX extraction device as the fCAL turbo assay, so it is possible to run both tests from a single extract.

The fPELA assay is random access and runs on standard clinical chemistry analysers (Roche, Abbott, Beckman, Siemens etc) although there is also the BioSystems BA 200, a stand-alone solution as well. The assay is turbidimetric, with a dynamic range of 10 - 5000μg/g. Time to first result is 10 minutes with further results following every few seconds thereafter, making it one of the fastest faecal elastase assays available.

Why use the BÜHLMANN fPELA Assay?

- Utlilises the same CALEX extraction device as the fCAL turbo assay
- Random access testing on standard clinical chemistry analysers
- Comparable results to the current ELISA based methods

Data from historic NEQAS samples shows the new BÜHLMANN fPELA gives comparable results to the current ELISA based methods:



fPELA® Assay		
Product code	**Description**	**Pack Size**
KK-PELA	fPELA turbo kit	~100 tests*
B-KPELA-RSET	fPELA turbo reagents	~100 tests*
B-KPELA-CONSET	fPELA turbo controls	3 x 1ml High and Low control
B-KPELA-CASET	fPELA turbo calibrators	6 x 1ml calibrators
B-CALEX-C50	CALEX sample extraction device	50 tubes
B-CALEX-C200	CALEX sample extraction device	200 tubes
B-CALEX-C500	CALEX sample extraction device	500 tubes

BÜHLMANN Laboratories *Will vary depending on analyser

Pricing and Online Ordering at www.alphalabs.co.uk

Quantitative Faecal Immunochemical Test (FIT)

The faecal immunochemical test (FIT) is an established test for the quantification of haemoglobin in faeces. Faecal haemoglobin has been used as a biomarker for gastrointestinal disease for decades, primarily in colorectal cancer screening programmes, using qualitative, guaiac-based, faecal occult blood tests (gFOBT).

In July 2017, the National Institute of Health and Care Excellence (NICE), published the Diagnostic Guidance DG30 "Quantitative faecal immunochemical tests to guide referral for colorectal cancer in primary care". This recommends the use of FIT in primary care to guide referral for suspected colorectal cancer in patients who present with unexplained gastrointestinal symptoms, but do not meet the criteria for referral in the *suspected cancer referral pathway*.

Furthermore, in July 2022, the Association of Coloproctology of Great Britain and Ireland and the British Society of Gastroenterology (BSG) published guidelines for identifying patients requiring further bowel disease investigation. The recommendations emphasized FIT testing in primary care, the diagnostic accuracy of FIT for colorectal cancer with suspected cancer signs or symptoms, acceptability of FIT testing for symptomatic CRC in most circumstances, anti-discrimination at any stage of the diagnostic pathway and finally, the development of a programme to facilitate FIT implementation.

Colonoscopy resource is overburdened, and many colonoscopies yield no pathology. Implementing FIT can triage patients into secondary care, reserving resource for high risk patients or those presenting with red flag symptoms.

FIT has proven not only to be an invaluable resource in the identification of colorectal cancer, but also for detection of pre-cancerous growths. Colorectal cancer is the fourth most common cancer in the UK and is highly treatable if identified early.

FIT is now used in all UK nation's Bowel Cancer Screening Programmes, and it is the test of choice in primary care referral pathways for colorectal cancer. Using a cut-off of 10 μg Hb / g faeces, FIT can be used by clinicians to determine the ideal pathway for patients, quickly and reliably. It presents a cost-effective, easy to use, non-invasive test, which has helped improve the uptake of testing in screening and symptomatic cohorts, helping increase the value of the test in the pathway.

The complete FIT solution provided by Alpha Laboratories Ltd, includes the HM-JACKarc platform which is recommended for use in the NICE DG30 guideline. A compact, bench-top system for rapid, automated testing of FIT samples, the HM-JACKarc is straightforward to use, low-maintenance, and features excellent low-end sensitivity (limit of detection: 1.25 μg Hb / g faeces) with a linear assay range of 7 – 400 μg Hb / g faeces. In conjunction with the user-friendly sampling device and bespoke Patient Packs, the FIT solution offered by Alpha Laboratories provides a tailor-made package to support primary care, patients, laboratories, and clinicians throughout the entire pathway.

For more information, case studies, and to view videos including discussions with experts in the field, please visit: **www.faecal-immunochemical-test.co.uk**

HM-JACKarc Automated Faecal Immunochemical Testing System

The automated quantitative Faecal Immunochemical Testing system from Minaris Medical integrates **A**nalyser technology, with **R**eagent and **C**ollection device (ARC), to provide a rapid and consistent, high throughput solution for both screening and symptomatic faecal immunochemical testing. The system comprises of three key components: the analyser, the reagents, and the sample collection device.

- HM-JACKarc state-of-the-art automated analyser
- Dedicated, sensitive, latex agglutination reagents
- Bespoke faecal sample tube

HM-JACKarc Analyser

The HM-JACKarc is a dedicated bench-top analyser which uses integrated spherical turbidimetry for the quantification of haemoglobin in faeces.

The analyser is easy to use; a touchscreen, minimal menu depth, and password protection allows safe customisation of the system according to your pathway regardless of your cut-off.

Up to 80 samples can be loaded at any one time, with a time to first result of 5.6 minutes, and subsequent results every 18-seconds, giving a throughput of 200 samples per hour. Being quick to set up and maintain, the analyser can be used in high-throughput screening settings or lower-throughput symptomatic testing.

The assay has a linear range of 7 – 400 μg Hb / g faeces, a limit of detection of 1.25 μg Hb / g faeces, and no prozone effect to 200,000 μg Hb / g faeces. This provides assurance that the result is accurate: no patient is given an artificially low result while samples with a very low haemoglobin concentration will not be missed.

1. Load samples and reagents
2. Press START
3. First result in 5.6 minutes

Key features:

- Limit of Detection: 1.25 μg Hb / g faeces
- Limit of Quantitation: 7.00 μg Hb / g faeces
- Linear assay range: 7 – 400 μg Hb / g faeces
- No prozone effect up to 200,000 μg Hb / g faeces
- High-speed performance: 200 samples / hour
- Time to first result: 5.6 minutes

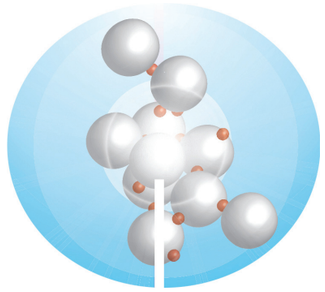
HM-JACKarc Analyser + Barcode reader

Product code	Description	Pack Size
057562	HM-JACKarc Analyser	1 unit
065553	EXTEL HEMO AUTO HS Latex	4 x 18ml
065556	EXTEL HEMO AUTO HS Calibrator	8 x 1ml
065557	EXTEL HEMO AUTO HS Control	8 x 1ml
065555	EXTEL HEMO AUTO Buffer	1 x 250ml
063631	EXTEL HEMO-AUTO MC Collection Picker	200 pieces
063632	EXTEL HEMO-AUTO MC Collection Picker	400 pieces
053150	HM-JACK Reaction Cell	1000 pieces
053151	HM-JACK Sample Cup	500 pieces
057848	HM-JACK Print Paper A	2 rolls
052404	Wash Liquid (Auto Detergent H)	1 x 200ml

Minaris Medical Co., Ltd.

Reagents

The main two reagents are the latex reagent, and buffer solution. The latex reagent comprises of latex particles, coated in polyclonal antibodies specific to human haemoglobin. The high concentration of latex particle and antibody ensures a high antigen capture ratio.



This provides four key benefits:

- Low limit of detection: 1.25 μg Hb / g faeces
- High hook (prozone) capacity: 200,000 μg Hb / g faeces
- Linear assay range: 7 - 400 μg Hb / g faeces
- Specific to human haemoglobin: no interference from dietary meat / iron

Sample Collection Device

As with all assays, pre-analytical variation must be kept to a minimum, and that's particularly challenging when patients are completing the sampling at home, and when the sample is from stool. Stool is rarely homogenous in nature, and the variability in composition can make sample collection challenging.

The HM-JACKarc collection device is designed with ease-of-use in mind, while ensuring good quality laboratory samples. The collection device is designed with two small dimples in the end of the sampling stick to allow the patient to accurately sample 2 mg of faeces with no laboratory experience or measuring equipment.

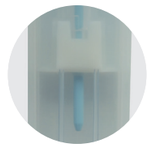
The septum in the sample collection device scrapes off excess faecal matter, ensuring the 2 ml of buffer solution is accurately dosed with 2 mg of stool. This offers a hygienic sampling method, which only involves collecting one stool sample, and sampling the stool once. The device contains a biocide to minimise the risk of haemoglobin degradation by the microbiome in the stool, and the device is tested to a 95 kPa pressure differential: making the tube strong and leak-proof.

Once the sample is collected, the collection device is stable for 14-days at room temperature, and 120-days at 2 - 8 C. The sample is pre-diluted (in a 1:1 ratio) and is ready to be loaded directly onto the analyser.

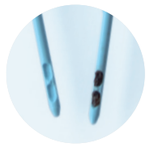
The sample does not require any pre-analytical processing (dilution / filtration etc.) prior to loading. The analyser reports results in ng Hb per ml of buffer; since the HM-JACKarc uses a 1:1 dilution ratio, this can be directly converted (1:1) to μg Hb per gram for result reporting.

The hygienic sampling device has helped increase the uptake of participation in bowel screening programmes; offering participants a straightforward test, which only involves one sampling process and includes a robust sampling stick, has increased the number of those returning the test, and so helped identify more early-stage cancers.

Tamper evident seal and sample viewing window



Rubber septum to remove excess sample



Oval sample collection dimples

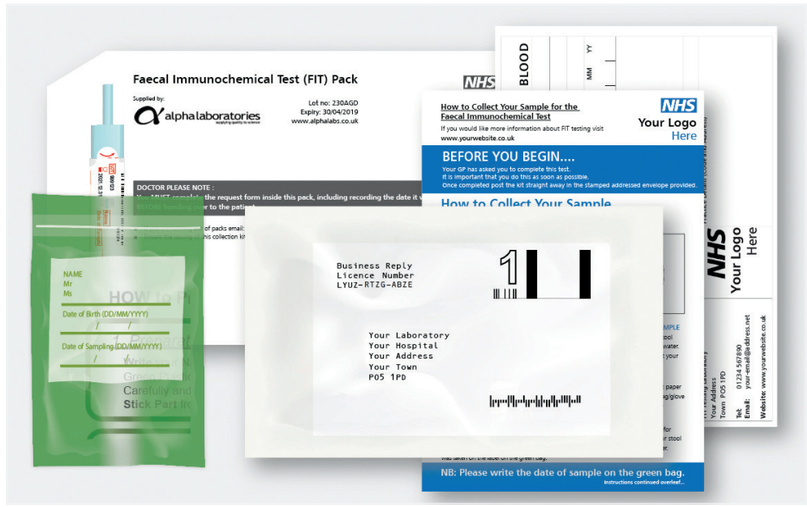
Overlabel prevents contamination of the piercing area

Complete FIT Patient Packs

The convenience of patient sampling at home is one of the advantages of FIT. However, when setting up a FIT service we are often asked how best to facilitate getting the test to the patient, and how the patient returns the test to the laboratory. Alpha Laboratories has extensive experience in the area and we can help with bespoke Patient Packs. We can create a custom solution for your pathway which supports the GP, patient, and sample reception teams.

Each service may be managed slightly differently; varying in the information provided to patients, the onward pathways, and the method of returning the sample. A bespoke instruction leaflet not only provides the patient with a clear, easy-to-follow guide to help them collect a good quality sample, but it can provide additional supporting information; such as links to "How-To" videos, QR-codes for additional information, or contact numbers for enquiries.

The instruction leaflets have proved extremely beneficial for users. In a recent case study with the South West Cancer Alliance, their patient questionnaires highlighted that 95% of respondents found the instruction leaflet easy to understand, and 96% of respondents knew what to do with their test once complete.



Getting a FIT Sample from Patient to Laboratory

Customising your FIT service need not stop at a bespoke instruction leaflet. If your FIT service directly involves Primary Care (the patients are handed the sampling collection device while attending a GP consultation), your service will benefit from Alpha Laboratories' Complete Patient Packs.

The complete patient packs are bespoke to your service, and may contain: instruction leaflet, sample return envelope, test/laboratory request form, sample collection device, stool collection aid (Fe-Col®), patient information sheets, and/or questionnaire cards – all packaged into a discrete envelope for the Primary Care provider to hand to patient for at-home sample collection.

For further information, or to enquire about creating your own FIT packs, please visit:
www.faecal-immunochemical-test.co.uk/patient-packs

Patient Pack Components

Instruction Leaflet:

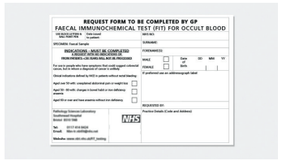
A "how-to" guide on the collection of the stool, sampling process, and return of the sample. May contain additional supporting information such as links to helpful websites, contact numbers, and a "what next" section as to the onward pathway.

Return Envelope:

The collection device may be posted back to the laboratory or taken back the GP's surgery for collection by routine laboratory transport.

Test/Laboratory Request Form:

A test request form may be required by the laboratory to process the sample and track result reporting. The GP is sometimes asked a series of questions as to the reason behind the FIT referral, this form can be used to collate the patient information along with the quantitative FIT result.



Sample Collection Aid:

The Fe-Col® collection paper is an innovative sample collection paper, designed to fit around the toilet seat, and allow you to catch the stool sample before it touches the toilet bowl or water. It is a hygienic sample collection method which allows the patient to use the toilet as they would normally. The paper contains no additives, or adhesives, and the edges can simply be torn, allowing the paper and the stool to fall into the toilet for hygienic disposal. The paper is biodegradable and is safe for the sewage system.

Patient Information Sheets:

Depending on the pathway (Rapid Diagnostic Centres, routine GP visit, clinics, etc) you may wish to include a patient information sheet. It may outline in more detail what the test is for, why they have been asked to complete it, and what happens next.

Questionnaire Cards:

Newly started services, or services undergoing changes may wish to receive feedback on their FIT service, not just regarding the test but the pathway. We can help you design a questionnaire card to include with the test return to help gather data on patient feedback.

We can also provide:

- Small, grip seal bags to mail the sample
- Padded envelopes for general mailing
- Freepost, pre-addressed envelopes for ease of use

FIT Kit Ordering Portal

The FIT Kit ordering portal is a solutions-based interface that enables hospitals, trusts, and service co-ordinators to log in and order FIT Kits for direct delivery to GP surgeries.

The ordering portal combats the currently demanding administrative processes required of laboratory staff for distributing FIT kits and other common issues in hospital sites such as dealing with bulk deliveries, HGV traffic on-site, storage limitations, packaging waste and numerous logistic challenges.

The user-friendly interface allows flexible purchasing for both ad-hoc (48hr) delivery and forward ordering for the coming months, similar to scheduled orders. Additionally, the ordering portal offers a significant time and cost saving approach, and a postal tracking service benefit. The Royal Mail T48 service offers clear advantages – above the simple workflow improvements.

Key Benefits

- Reduced administration time
- Improved stock management
- Reduced storage requirements
- Less packaging waste
- Improved efficiency with an end-to-end ordering process

How does the FIT ordering portal work?

Each user is required to place an open purchase order with Alpha Laboratories Ltd, for example, 500 boxes of 50 kits. Log in credentials for each site will allow access to site specific products.

Users will select the quantity of FIT Kits, delivery date and shipping address for the specific order. Upon submission, the order will be processed and delivered as per order requirements.

To sign up, or for more information please contact **fit-kits@alphalabs.co.uk**

PillowPac² Mailing Solution

The PillowPac² compliant sample return envelope is specifically designed for Faecal Immunochemical Test (FIT) sample collection devices.

The slim, light-weight envelope offers a robust and easy-to-use logistics solution for use with National Bowel Screening and home FIT testing kits.

It is designed to lay flat in the outbound pack to the patient, then when the sample is ready to return, the pack is squeezed and pops up allowing the tube to be easily placed into the pack. The pack is then sealed shut using a self-seal system and is then used as a return envelope to the lab for testing.

- Cost effective
- Improved efficiency for laboratory processing
- Includes self-seal system
- Fixed absorbent material for any contamination or leakage
- Ease of opening manually or using automated opening solutions.
- Size: 102mm Wide x 173mm Long (142mm when closed)
- Thickness: 1.35mm when flat – 16mm when popped
- Absorbent Capacity: 2.5ml
- Weight: 13g (empty)

PillowPac² Mailing Solution		
Product code	**Description**	**Pack Size**
SHU-04-2-2	PillowPac² - sample return envelope	1000

Shuttlepac®

Fe-Col® Faeces Sample Collection Device

- 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

Fe-Col® Faecal Collection Papers		
Product code	**Description**	**Pack Size**
FC2010	Fe-Col® Faecal Collection Paper with Instructions for Use (IFU)	1000
FC2030	Fe-Col® Faecal Collection Paper in Dispenser Box of 50	5 x 50

Alpha Laboratories Ltd. *See Website for more information and details*

Qualitative Faecal Immunochemical Test (FIT)

The DIAQUICK FOB Cassette can be used to screen for lower gastrointestinal pathologies such as colorectal cancers and adenomas which may bleed resulting in occult blood in the stools. This is a qualitative immunochromatographic lateral flow assay which specifically detects human haemoglobin. Unlike guaiac tests there is no need to follow a restricted diet prior to testing to avoid false positive results.

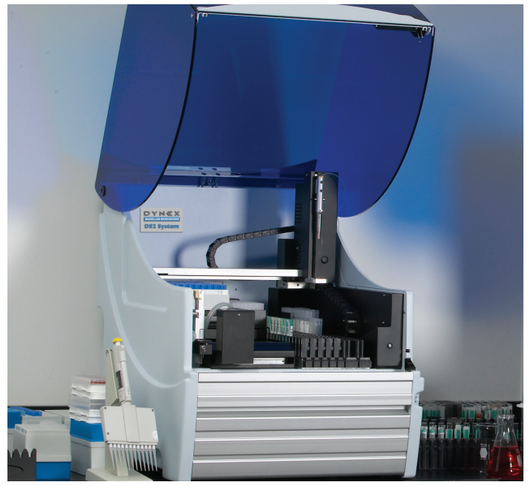
- Result in 5 minutes
- Immunochromatographic assay
- Sensitivity 6µg Hb/g faeces (50ng/ml Hb)
- Sample stable in collection tube for up to 3 days at ambient
- No dietary restrictions

DIAQUICK FOB		
Product code	**Description**	**Pack Size**
Z01101CE	FOB DIAQUICK Test Cassette	25 tests

Dialab

Dynex DS2® ELISA Processor

The DS2® ELISA Processor from Dynex Technologies is a 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.

CE marked applications are available for the BÜHLMANN fCAL ELISA assays on the DS2.

Automated ELISA Instrumentation		
Product code	**Description**	**Pack Size**
62010	Dynex DS2 Automated 2-plate system	1
Consumables		
62910	Deep well dilution strips	250 x 8 wells
62930	Reagent Bottles - 15ml	10
65950	Reagent Bottles - 25ml	24
65910	Racked Sample Tips	4 x 108
65920	Reagent Tips	4 x 108
65940	Standard/Control Bottles	33

Dynex Technologies

www.faecal-immunochemical-test.co.uk

www.faecal-immunochemical-test.co.uk is a dedicated website providing a central resource for clinicians, laboratories, patients and the public, regarding advances in the detection of colorectal cancer using FIT.

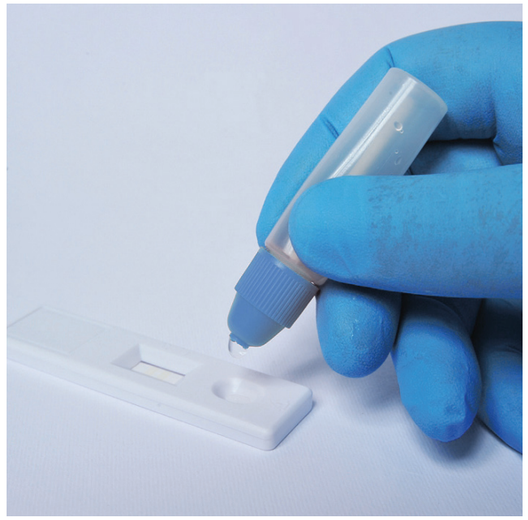
Access to the Experts
Covering both screening and symptomatic testing applications, experiential case studies, plus videos of presentations, and provides access to expertise from key opinion leaders in the field. With an extensive list of literature, publications, resources, related news and events that are regularly updated, this is the **no.1 resource for FIT** in the UK and Eire.

Infectious Diseases

Helicobacter pylori (*H. pylori*)

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		
Product code	**Description**	**Pack Size**
14656	Easy-Card *H. pylori* Ag	20 tests

Sentinel

Food Allergy Testing

The incidence of food allergies is becoming increasingly more prevalent; it is estimated that, in the UK, 1 in 40 infants are developing a peanut allergy, and 1 in 20 infants are developing an egg allergy. With almost a third of allergy sufferers having to change their lifestyle, it is vital to determine who is truly allergic from those who are not; Basophil Activation Testing can be a helpful tool to do this.

Studies have shown that BAT has a higher sensitivity and specificity than standard skin prick tests (SPT) and specific IgE tests (sIgE), making it a useful second line test if SPT and sIgE results are unable to offer a confirmed result.

BAT is a safer alternative to a provocation challenge for your patient. Offering BAT before a challenge test will significantly reduce the number of patients having to undertake a provocation challenge. Eliminating the need for a provocation challenge improves patient safety and comfort.

The true value of BAT lies in its high specificity, (reaching 100% in some studies). A positive BAT result confirms allergy with a high degree of certainty, resulting in fewer of the more dangerous positive provocation challenges being performed.

Basophil Activation Testing

The Flow CAST® system, manufactured by BÜHLMANN Laboratories, represents a significant step forward in *in vitro* allergy testing. Using a unique dual marker combination (CCR3 and CD63) it allows the simple detection of Basophil Activation on whole blood samples via flow cytometry. Flow CAST can be used to identify immediate type allergic reactions and hypersensitivities to suspected allergens.

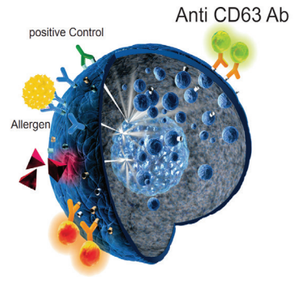
Basophils constitutively express the eotaxin receptor CCR3 allowing for a robust and accurate selection of cells with flow cytometry. CCR3 is detected with a PE-fluorescence labelled monoclonal antibody. This negates the requirement for lengthy and labour intensive leukocyte isolation steps.

Upon response to a purified allergen which is added to the sample, sensitised basophils degranulate and express the cell surface marker CD63. This is detected by a FITC-fluorescence labelled monoclonal antibody. CD63 is currently the best-validated basophil activation marker directly linked to basophil degranulation. The Flow CAST kit can identify both IgE and non-IgE mediated allergies.

The Flow CAST kit is quick and easy to use, with results obtained in ~60 minutes. Samples can be analysed up to 48 hours after collection (up to 24 hours for drug responses). The kit contains all of the reagents and controls needed to run the test.

A New Era for Basophil Activation Testing!

The kit now includes a new version of the wash buffer which contains a stabiliser. Previously, samples needed to be analysed using flow cytometry immediately following completion of the Flow CAST protocol, but the added stabiliser now means the samples can be analysed up to five days after completion of the protocol, if stored at 2-8C and protected from light.
This change will help to improve workflow in laboratories.



An extensive range of over 150 standardised allergens spanning food, drug, insect venoms, inhalants and food additive allergies are available to purchase separately.
Some examples are listed below:

Food Allergens Include:
BAG-F1 EGG WHITE
BAG-F75 EGG YOLK
BAG-F2 COW MILK
BAG-F10 SESAME
BAG-F13 PEANUT

Food Additive Allergens Include:	
BAG2-C103 TARTRAZINE	BAG2-CE123 AMARANTH
BAG2-C111 SODIUM-BENZOATE	BAG2-CE124 NEW COCCINE
BAG2-C112 SODIUM-NITRITE	BAG2-CE127 ERYTHROSINE
BAG2-C113 POTASSIUM-METABISULFITE	BAG2-CE131 PATENT BLUE V
BAG2-C114 SODIUM-SALICYLATE	BAG2-CE132 INDIGO CARMINE
BAG2-CE104 QUINOLINE YELLOW	BAG2-CE151 BRILLIANT BLACK BN
BAG2-CE110 SUNSET YELLOW FCF	BAG2-CE466 CARBOXYMETHYLCELLULOSE
BAG2-CE122 CHROMOTROPE FB	BAG2-CE621 GLUTAMATE

BÜHLMANN Flow CAST®		
Product code	**Description**	**Pack Size**
FK-CCR	Basophil Activation Test Allergy in vitro blood assay	100 tests

BÜHLMANN Laboratories

Visit www.alphalabs.co.uk/allergens for the full range of available allergens.

alpha laboratories
supplying quality to science

Alpha Laboratories has extensive experience in diagnostics for digestive health.

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

We have worked with the programmes to support transition to the more sensitive and specific quantitative faecal immunochemical test (FIT) screening solution on the automated HM-JACKarc platform.

The benefits of FIT are also being applied to symptomatic testing, to triage patients in primary care, providing an improved patient pathway and better management of endoscopy resources.

Find out more at our dedicated website:
www.faecal-immunochemical-test.co.uk

Alpha Laboratories also helped pioneer the routine use of calprotectin assays for differentiating between IBD and IBS. This 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 symptons 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 remote monitoring, scalable calprotectin testing and rapid TNFα drug monitoring.

The IB*Doc*® calprotectin home test offers a new approach to help support patient care and customised therapy.

Alpha Laboratories also offers a range of other tests to assist clinicians in the assessment of digestive disorders, from infectious diseases to allergies.

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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UKAS MANAGEMENT SYSTEMS 0015

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