



Outsourcing Calprotectin Stool Pre-analytics to the Patient's Home

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NHS Lanarkshire, to the east of Glasgow, is the third largest NHS Health Board in Scotland. It serves 655,000 people at the Hairmyres, Wishaw and Monklands Hospitals.

Faecal calprotectin testing for the diagnosis and monitoring of inflammatory bowel diseases is conducted at the Monklands Hospital. Jacqui McGuire and Neil Syme, Consultant Clinical Biochemists from the Biochemistry Department at Monklands explain how their testing has evolved over recent years.

"We perform around 400 faecal calprotectin tests a month across NHS Lanarkshire. Initially, when we first introduced the assay we used the BÜHLMANN fCAL® ELISA and CALEX extraction device, running the assays on a Dynex DS2 ELISA processor. As the volume of tests increased we switched to the BÜHLMANN fCAL® turbo assay on our Roche platform, in the spring of 2021. Since we were already using the CALEX® extraction method, this transferred to the turbo assays, retaining consistency and benefiting from the much easier work flow with the turbo method.

Challenges of the Pandemic

With the onset of COVID we were faced with a number of challenges to our testing processes. With concern regarding the risk of infection from stool samples, we didn't have adequate access to bio-safety cabinets to handle our patient samples for the extraction process.

The only way we could continue the service was if the patients could take their own samples directly in the CALEX devices. So, we implemented a process to outsource the calprotectin pre-analytical sample collection and preparation to the patients at home.

We don't offer faecal calprotectin in a primary care setting, so samples tend to just be from secondary care for monitoring purposes.

We had discussions with the clinical team and recognised that the CALEX direct sample collection process is really very similar to that for the faecal immunochemical test (FIT) sample pickers used for bowel cancer screening and symptomatic testing. Since patients currently do this themselves very successfully, there was no resistance to rolling out a similar format for calprotectin testing.

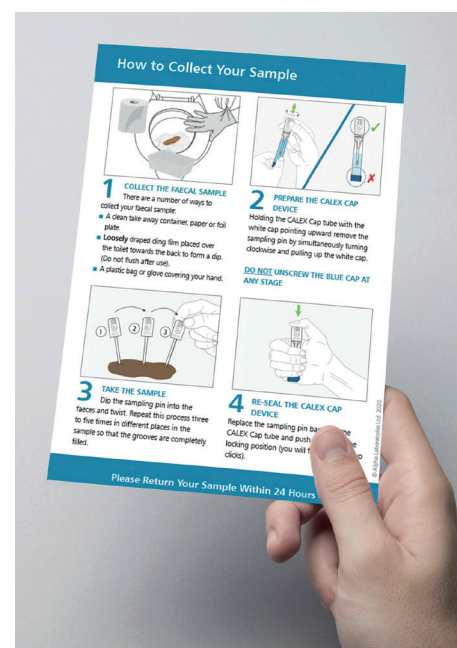
CALEX Stability

The only real issue we had was the stability of the CALEX tubes when stored at ambient temperature, because the clinic doesn't have enough capacity to store them in the fridge. When the process was initially established, the information we had was that the CALEX was stable at ambient for 3 months. So, we add an expiry date label to the tubes when they are issued to the clinic, so that this can be monitored on their return.

The clinic are dispensing the CALEX devices and a specific instructions for use (IFU) document is supplied to the patients when a test is required. In the main this is by post but if the patient is coming into clinic for a face to face appointment, then they are being issued with the CALEX then.

We ask for the patient demographic label to be applied to the tube when it is sent out and we re-label with a barcode when they are returned. Going forward this will be replaced by an ordercoms label when that is implemented.

Once the sample has been collected the patients drop the CALEX back at their GP and it is brought to Wishaw Hospital to be sorted and separated from all the other samples, before being sent across to the Monklands Hospital. The CALEX tubes are checked for the ambient expiry date, and the level of buffer in the tubes, stored in the fridge and batches of tests are then run two to three times a week.



Testing Compliance

In terms of patient compliance in using the CALEX to directly collect their faecal sample for calprotectin testing, it has been very good at around 90%. This is actually significantly better than we get for the FIT. The calprotectin test requests we get are from secondary care and so a lot of it is repeat testing for monitoring. So, the patients are more engaged than with the FIT which is usually a one off.

We don't seem to see much spoilage of samples with the CALEX (overloaded, no buffer, not labelled) probably <5%.

We see a lot more spoilage with the FIT pickers but again that is probably for the same reasons of repeat users verses naïve users.

Our compliance level is really good – a retrospective audit from the last six months showed that we did 500 samples per month with a return rate of 95%. Of the samples that were returned only 6% were unable to be tested.

The implementation of the patient preparing the CALEX has certainly streamlined the laboratory workflow. It has freed up the space we used to do the extractions in and staff resource.

There are discussions around opening the service to primary care and if this does go ahead then having the CALEX sent in ready prepared certainly lessens the impact on the laboratory from the increased workload.

Having the samples arrive at the laboratory already in the CALEX has also helped in sample reception. Previously samples arrived in a universal tube and then the reception team needed to determine if it was for microbiology or biochemistry. Having the sample in the CALEX makes it immediately clear that the test is for calprotectin.

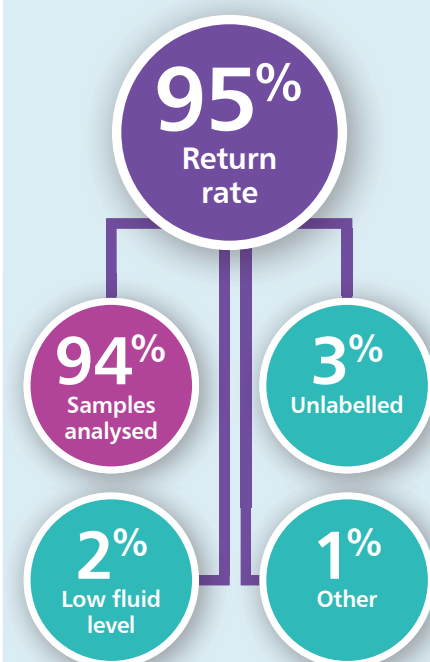
Enabling the patients to prepare the CALEX themselves has saved us plenty of time in the laboratory and we would certainly recommend that other hospitals investigate how to make this work for them.

It is worth noting that the ambient stability of CALEX is due to be extended later this year to at least 12 months, which will help with logistics."

For more information, visit our calprotectin website calprotectin.co.uk/calex



Analysis of CALEX Tubes Returned July-Dec 2021



Ready To Use Samples

UN3373 Compliant CALEX® Cap Collection Set for Faecal Extraction

The BÜHLMANN CALEX® Cap is the first and only stool extraction device certified for safe air and land transportation according to IATA 650 (UN3373) regulations. This allows the option to outsource pre-analytics to the patients' homes, keeping stool samples away from the laboratory. Their small amount of sample is sealed in the CALEX and can be mailed directly to the laboratory or clinic.

By getting the patient to use the CALEX to collect their sample at home, it is fully extracted and ready for calprotectin testing on arrival, using the BÜHLMANN Quantum Blue POCT assay or the ELISA or fCAL turbo laboratory assays. The same sample can also be tested for pancreatic elastase testing using the BÜHLMANN fPELA® turbo assay.

CALEX is the same extraction device used in the laboratory setting. The optimised dilution of stool sample yields maximum extraction efficiency while offering stability of the calprotectin (7 days at room temperature) and p-elastase (7 days at room temperature) extracts.

This convenient solution increases safety for laboratories and revolutionizes speed, efficiency and cost savings in the stool testing workflow.



The kit contains:

- ✓ Instructions for use
- ✓ 1 X CALEX Cap
- ✓ 2 x Sample collection sheets
- ✓ 1 x Label for the CALEX
- ✓ 1 x Plastic bag



To help facilitate the logistics the BÜHLMANN CALEX® Cap Collection Set is specifically designed to simplify sample handling by patients.

It provides convenient, hygienic and safe sample collection for the patient and provides a quality, ready extracted sample for analysis in the clinic.

For more information on CALEX and to purchase please visit our website alphalabs.co.uk/calex

