Switching from Phadia to BÜHLMANN for a More Efficient Calprotectin Service



Dr Elodie Hanon, Principal Clinical Scientist at the Freeman Hospital, Newcastle.

The Newcastle upon Tyne Hospitals Foundation Trust is one of the largest NHS trusts in the UK, covering six hospitals.

Elodie and her team in the department of blood sciences perform over 10 million tests each year, providing a service over two sites: the Freeman Hospital and the Royal Victoria Infirmary.

Previously they were using Phadia EliA I, but the launch of the Phadia EliA II led to a review of their calprotectin method. They decided to evaluate both the Phadia EliA II and the BÜHLMANN fCAL® turbo calprotectin assays.

Elodie explains the evaluation and the reasons behind the change to the BÜHLMANN fCAL turbo method.

"Calprotectin testing is recommended by NICE to check which patients require referral to gastroenterology. We currently test about 100 samples per week, although the numbers are increasing all the time. Our samples come in from both primary and secondary care. Although the samples are batched for testing, they are extracted each day upon receipt by the reception staff, and then frozen until analysis.

BÜHLMANN CALEX® Sample Extraction

It was very straight forward to train the reception team to use the BÜHLMANN CALEX extraction device.

The process is now much quicker than previously, as there are fewer steps involved than there were with the Phadia extraction device.

Liquid Samples

The other really big advantage of the CALEX extraction is that it can be used with liquid samples, by just pipetting 10µl of the sample into the buffer. Previously this was an issue as the Phadia assay is not CE marked for liquid stool samples. For these samples we would have to use a weighing method, which was a more complex procedure.

The gastroenterologists were particularly pleased that we changed to a reliable method for these samples as it is really patients that produce liquid samples that need the calprotectin result more than most.

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Roche Cobas c702

One of the main reasons we decided to try the BÜHLMANN fCAL turbo was that it could be run on our main line analyser (the Roche Cobas c702). This would make life much easier for us, and immunology were also pleased to have the capacity back on their immuno CAP.

The protocol was very straight forward and we loaded it onto the analyser ourselves.

There was some concern in the beginning that faecal material would go through the line and affect the probes, but we spoke to another lab running the assay on a c702 who said they had no issues.

It was agreed that the calprotectin samples would be run on a Sunday, just before the planned shutdown procedure. This is an acceptable compromise for us to be able to run on the main analyser.

Two method comparisons were performed:

- Phadia EliA I versus Phadia EliA II
- Phadia EliA I versus BÜHLMANN fCAL turbo

As expected from EQA data, the results between the various assays do not correlate well [Figures 1 and 2].

However, we found good precision and repeatability [Table 1] with the fCAL turbo and good linearity across the range. [Figure 3]

Due to the poor correlation between results for the different assays, we reviewed the results' categorisation to see if it would change the clinical decision, and generally this agreed.



Preparing faecal samples for calprotectin extraction.



Vortexing the CALEX device for loading on the Roche Cobas c702



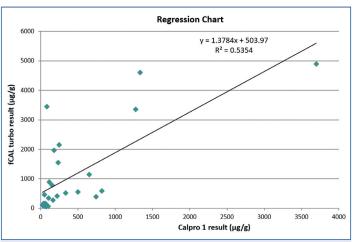


Figure 1. Phadia EliA I versus BÜHLMANN fCAL turbo

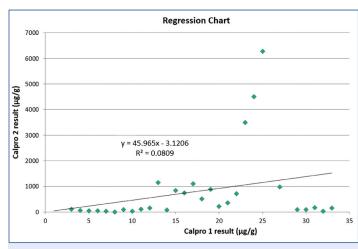


Figure 2. Phadia EliA I versus Phadia EliA II

Test	BÜHLMANN fCAL turbo		Phadia 250 EliA II	
	Mean µg/g	%CV	Mean μg/g	%CV
Between run precision (11 days)	67.73	2.8	23.27	23.4
	228.63	1.7	213.91	5.8
Within run precision (on 5 days)	317.69	1.1	157.76	9.5
	843.24	2.8	852.16	2.7

Table 1. BÜHLMANN fCAL turbo shows good precision and repeatability

Phadia EliA I is a trademark of Thermo Fisher Scientific Inc.

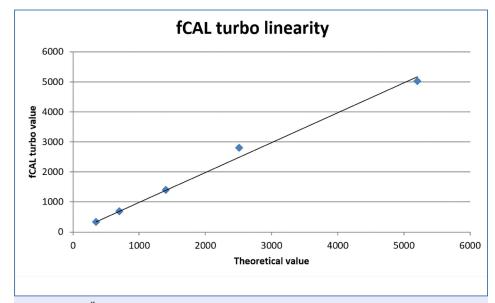


Figure 3. BÜHLMANN fCAL turbo shows good linearity across the range

CAL LIPO FOR LI

Reporting Results up to 8000µg/ml

We spoke with the gastroenterologists and explained that we were looking to change assays and that the results might not be comparable.

However, they were very positive about the switch, especially when they realised we could test the liquid samples and report results up to 8000µg/g to help with monitoring and flare prediction.

We went live with the fCAL turbo in March 2018, and there really have been no issues. The turn-around time is still the same as we are only running assays once a week, but the workflow is so much easier and we have certainly noticed an improvement on the EQA, with better agreement within our group.

Overall, I think everyone is very pleased with the switch, and I would certainly recommend fCAL turbo to other labs who may be considering a change." BÜHLMANN fCAL® turbo is a very rapid and flexible turbidimetric assay for faecal calprotectin. CE marked protocols are now available on many major clinical chemistry platforms. To find out more and read other user case studies please visit:

www.calprotectin.co.uk/fcalturbo

If you are interested in evaluation of fCAL turbo in your laboratory please contact us at digestivedx@alphalabs.co.uk