

CALEX Instead of Stool Pots



The Patients’ Opinion

Ailsa Ralph, NHS Trainee Clinical Scientist
Author - Amanda Appleton, Senior Product Manager, Alpha Laboratories Ltd.



With the onset of COVID one of the big challenges faced by many hospitals was having sufficient access to bio-safety cabinets for sample handling, due to the unknown infection risk from viral RNA which could be detected in the samples. Many hospitals had to prioritise which samples/tests would be performed. In the absence of spare capacity in the safety cabinets, the only way Lanarkshire could maintain their calprotectin service was to give the CALEX sample extraction device to the patients to prepare directly, rather than sending in a portion of the stool in a pot (universal tubes) for processing by the laboratory staff.

Giving CALEX to patients was implemented in 2020, and seemed to work well so Lanarkshire has continued with providing CALEX for submission of samples for faecal calprotectin testing.

95% Compliance

The compliance rate for the CALEX has been high at 95%, and this was reported in an article in the 2022 Leading Edge (http://files.alphalabs.co.uk/e-mags/Leading_Edge_2022_Issue_1/6/index.html). Dr Ailsa Ralph has subsequently distributed two surveys amongst patients and front-line clinical staff to gain an insight into the user experience and see if there was anything that could be improved upon, and she talks here about their findings.

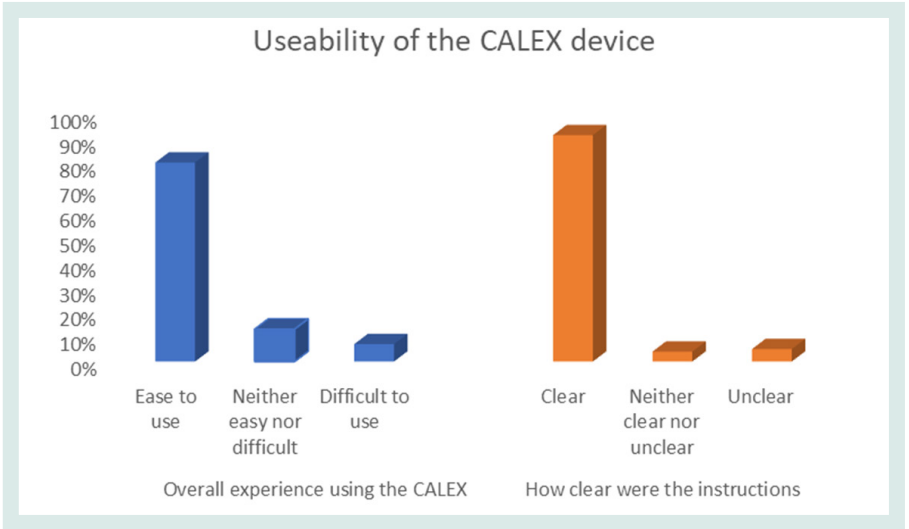
Patient Surveys

“For the survey we developed a series of closed questions with a scoring system from 1 – 5 with 1 being the best and 5 being the worst. There was also a comments section for free text at the end of the survey.

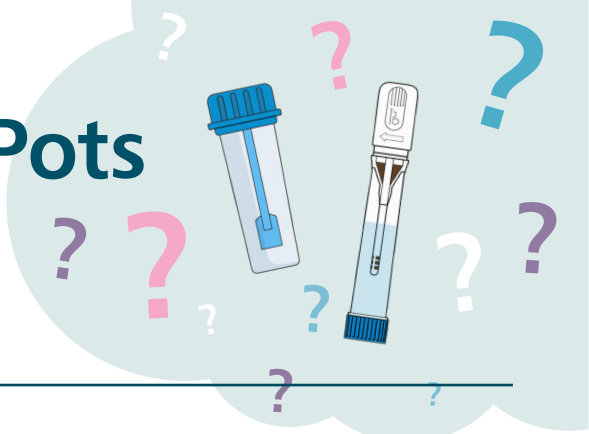
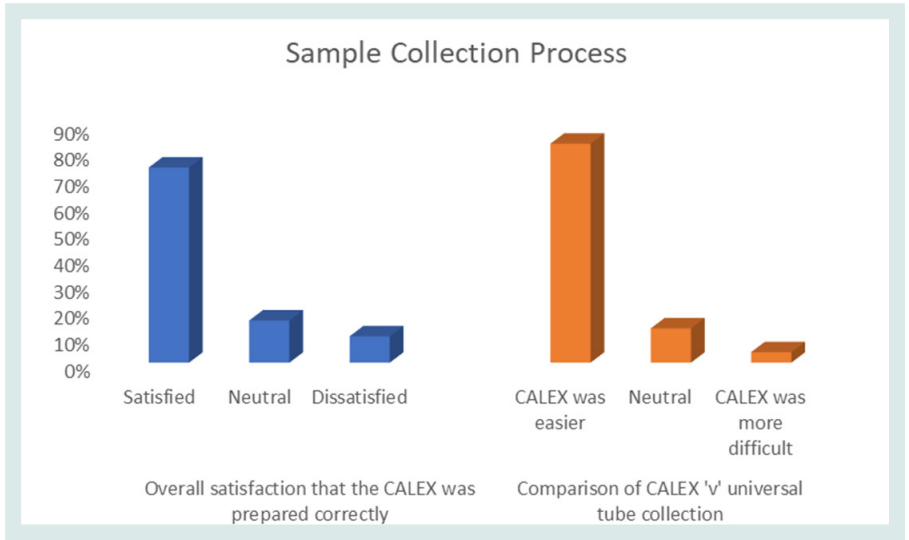
The surveys were designed to try and assess how easy the CALEX was to use, how clear the instructions were, how confident patients felt collecting their samples using the CALEX and if patients had past experience collecting faecal samples with the standard stool pots, then how did that compare with their experience using the CALEX.

Patient Responses

The surveys were sent with the CALEX to patients who were being asked to do a faecal calprotectin test between May 2022 to January 2023. During this time there were 6312 requests for faecal calprotectin laboratory testing.



There were 59 surveys returned (although not all questions were answered in some cases – the data shown is from the responses received in each case). The results indicated that the majority of the patients found the instructions accessible and the CALEX easy to use:



The next questions were aimed at trying to understand how satisfied the patients were with using the CALEX to collect the samples and what the comparison was to collecting the sample in universal tubes instead.

There were 13 ‘no responses’ received for the last question regarding the comparison between the historic universal tube and current CALEX collection method which was significantly higher than the other questions. The assumption here is that the historic universal tube had not previously been used.

It can be seen from the responses that the vast majority of patients found the CALEX easier, or certainly no more difficult to use to collect their stool samples into, than the traditional universal tubes and they were confident that they had completed the process correctly.

25% of the patients who responded to the survey also filled in comments. Detailed feedback is invaluable as it lets us know what went well and what needs improving. In broad terms, these can be categorised as follows:

- Missing instructions:
 - Patients reported using Google or YouTube to find out how to use the devices, and I think this suggests that we need to look at our processes for how we get the CALEX and the instructions to the patients.
 - Not clear on where to return the CALEX to, and again I think this may need to be clearer on our instructions - what the patient does with the sample once it is collected.
- Sample collection concerns:
 - Difficulty getting the white cap off – this could be an issue for older patients or those who may have dexterity issues. However, in the main calprotectin is more often a test used for younger patients. The older age group are more likely to receive faecal immunological testing (FIT) instead.
 - Difficulty getting sample into the grooves with different sample consistencies.

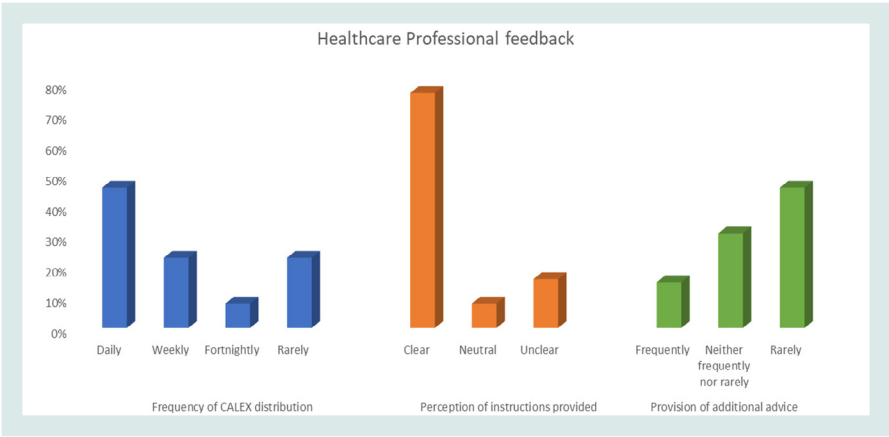
“This was easier than the universal tube – it was straight forward and the instructions were clear as they also came with images to refer to.”

“More confident that the device was used correctly.”

Although there were some issues highlighted, there was also quite a lot of positive feedback which was nice to see.

Healthcare Professionals

A second survey was sent to front line healthcare professionals who are issuing the CALEX devices to the patients and providing advice on their use. In the main this would have been secondary care professionals, but there would have been an element of primary care too. We received 13 responses back indicating that generally the



CALEX were given out frequently and that they thought the instructions were clear. Some of the additional feedback that came from the healthcare professionals was that advice was often sought from patients regarding whether the buffer needed to remain in the CALEX tube and there was confusion regarding the storage requirements for the CALEX.

CALEX Preferred to Sample Collection via Universal Tube

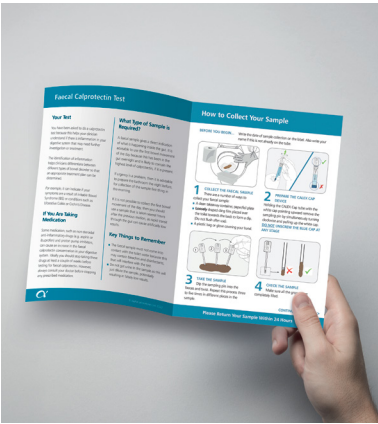
The majority of patients found the CALEX devices easy to use, with accessible instructions and overall the CALEX were rated in preference to the standard universal tubes. The feedback shows that there could be improvements in some areas on the instructions regarding sample consistency challenges and the presence of the extraction buffer. Also, in the implementation to ensure instructions accompany each CALEX device, as they are currently provided to the front line staff separately.

Changes have already been made to the IFU, to address the storage condition confusion that came up during the survey, as the CALEX can now be stored at ambient, so that eliminates the concern and makes it much easier to implement going forward.

We actually used the generic IFU from the www.calprotectin.co.uk website so there is no specific information regarding the return of samples and in the main this has been fine for us, but it might be worth considering a customised version with detailed return requirements if it proves to be a problem moving forward.

In the main this has been a very reassuring exercise, confirming that what we are doing is very well accepted and seems to be working for the majority of patients. This was also demonstrated in the fact that the previous audit showed a 95% compliance rate and only 6% of returned samples couldn't be analysed (incorrect liquid level, spoiled, not labelled) showing that patients were able to follow the instructions.

It has certainly made our lives a lot easier in the labs and the patients are finding it easy to use, so giving the CALEX to the patients is certainly something that we plan to continue to do.”



For more information please visit: www.calprotectin.co.uk/calex