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Fecal pancreatic elastase

BÜHLMANN fPELA® turbo on cobas® c501

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The Medical Laboratory Center Dr. Risch is a privately owned group of routine medical laboratories with 14 competence centres across Switzerland and Liechtenstein. It was founded in 1970 by Dr. Gert Risch and is managed today by his sons, Lorenz and Martin Risch. Their core laboratories have held accreditation under ISO/IEC 17025:2017, since 1997.

We successfully introduced the automated, turbidimetric assay for fecal calprotectin, the BÜHLMANN fCAL® turbo, on our Roche cobas® c501 in Autumn 2019. The BÜHLMANN fCAL® turbo replaced a classical ELISA assay. The main motivation for this change was to increase flexibility in planning lab work and to avoid having to run samples batchwise on plates. Additionally, the introduction of the ready to use CALEX® Cap device resulted in more stable stool extracts.

After the successful establishment of the calprotectin assay and the

release of the new turbidimetric pancreatic elastase assay from BÜHLMANN Laboratories AG, it was an obvious step to consolidate those two turbidimetric assays on the cobas® system.

Since most of our pancreatic elastase requests from hospitals and general practitioners also include the request for fecal calprotectin quantitation, it was inefficient to follow two different extraction protocols. We could significantly reduce our workload for fecal extraction because with CALEX® Cap the same extract can be used for both analyses. In addition, because the samples could both be run on an automated cobas® system, the turnaround time (TAT) was optimized. We can also run the assays from different locations within our laboratory group.

BÜHLMANN fPELA® turbo on Roche cobas® c501

Before implementing the BÜHLMANN fPELA® turbo assay on the cobas® c501, we used a plate-based ELISA solution running on the DSX ELISA robot from Dynex.

No major hurdles appeared during the transition process to the new pancreatic elastase assay provider. We started at an early phase when the new assay was not yet IVD certified. Therefore, only a limited amount



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of performance data was available. With the IVD CE registration of the product by BÜHLMANN in June 2020 this changed, and a comprehensive set of performance data is now available.

The BÜHLMANN fPELA® turbo offers a broader measuring range than the ELISA at the higher, normal pancreatic elastase levels, therefore many tested samples with non-pathological levels exceeded the ELISA measuring range and consequently could not be used for the quantitative method comparison.

The advantage of the BÜHLMANN fPELA® turbo assay is that less samples require a dilution compared to the ELISA method. The limited measuring range of the ELISA increases the variance of the two assays but also

„With the BÜHLMANN fPELA® turbo we see an optimized turnaround time and less preparation efforts are needed.“

shows the improved performance of the BÜHLMANN fPELA® turbo assay. We highly appreciated that the same medical cut-offs can be applied to both assays.

In summary we were satisfied with the support by BÜHLMANN.

„The analysis with the cobas® is more flexible, more cost efficient and faster than classical microplate based ELISA assays.“

higher range”. We can recommend the BÜHLMANN fPELA® turbo due to the easy sample preparation leading to more stable extracts. The analysis with the cobas or a similar system is more flexible, more cost efficient and faster than classical microplate-based ELISA assays.

**This interview was shortened and edited for a better overview*

CALEX® Cap for fecal extraction

For the sample preparation we use the CALEX® Cap extraction device from BÜHLMANN which already has been introduced with the turbidimetric fCAL turbo assay. Pancreatic elastase and fecal calprotectin can be measured from the same extraction, leading to less preanalytical variation. For fecal sample extraction the CALEX® Cap provides acceptable reproducibility, which is limited due to the heterogenous nature of the sample material itself.

The handling of the device is simple, and the extract stability is improved. Also, for the lab technicians it is more convenient to run the extractions with the CALEX® Cap, compared to the former methods used.

„The introduction of the CALEX® Cap device resulted in more stable extracts.“

Expectations of the BÜHLMANN fPELA® turbo

In summary, our expectations for the BÜHLMANN fPELA® turbo are fulfilled. We see a shorter turnaround time and less preparation efforts. No interferences to any other assay running on the system or any implausible results have been observed so far. Significantly fewer dilutions are needed and less samples must be reported as “measured



BÜHLMANN fPELA® turbo and CALEX® Cap