Quantum Blue®

Success Stories
Therapeutic Drug Monitoring

Quantum Blue® TDM assays in routine practice

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Can you introduce yourself and your organization?

We are specialized in the treatment of patients with intestinal bowel disease (IBD). Our Convent hospital has a very big outpatient clinic where we see about 700 IBD patients over the year. A high percentage of our patients are on biologic therapies.

When did you introduce rapid TDM testing with Quantum Blue®?

We introduced the Quantum Blue® Infliximab test in our lab in 2016, and the Quantum Blue® Adalimumab in 2018.

"The Quantum Blue® rapid TDM is easy and fast."

How do you use the Quantum Blue® TDM for IBD patient management?

We need rapid feedback from the laboratory about current trough levels in patients who are on biologics, mainly infliximab, for their perfect management. The Quantum Blue® TDM is important in the management of the later therapy of IBD and this was the main reason we introduced it. Before we started using the Quantum Blue® TDM, we performed the trough level measurement with an ELISA test where we normally had to wait two to three weeks until we received the results. This was far too long for our patients.

Do you measure drug levels during induction?

We use the Quantum Blue® TDM in different situations. One very important situation is when we start induction therapy or when we get patients on a new biologic, mainly infliximab or adalimumab. In the induction phase we want to get more informations about how the treatment responses.
We are happy when we see that the fecal calprotectin level decreases, the faster the better, while having high trough levels.
When we get the results about the trough levels early, we can say if the patients get the correct treatment or if we have to shorten the intervals or to increase the dose. Then we can adjust the medication for the later maintenance phase.
We normally make the first measurement at the end of the induction period. For patients treated with infliximab we like to have levels above 20 µg/mL on week six. It is important to bring the drug level in correlation with the fecal calprotectin value, the patients quality of life and their symptoms.

"Within 30 to 60 minutes we get the trough levels and can adjust the drug therapy in the same patient visit."

How do you use biologics trough levels during maintainance phase?

I think there are different situations for the use of trough level measurement during the maintenance phase. When we have patients who are stable on the maintenance dose, we routinely check the trough level once or twice a year. We try to keep levels between 4 and 7 µg/mL. But when we have levels above 15 µg/mL, with low calprotectin values, we could try to extend the interval or reduce the dose. On the other side, when we have patients who get symptomatic, with an increased fecal calprotectin or with problems like perianal disease or fistulas, but with drug levels around 10 µg/mL, we would try to shorten the interval or to increase the dose. For both biologics, infliximab and adalimumab, it is the same.

„It is very important to combine drug level and calprotectin measurement for ideal treatment decisions."

So, do you combine drug levels with calprotectin and how do you interpret the results for therapy decisions?

Yes, that is very important. I think most of the time we have to combine it because we can not get treatment desicions when we have only one of these two values. We always need the calprotectin to have information about the inflammation burden, and information about how the biologic is tolerated, at the same time. We need to know the reason of a treatment failure: low trough level resulting in increase of medication, or patient not responding to the drug anymore (with high drug levels). In this case, it might be the decision point to switch the therapy either to a different drug class or to a different TNF alpha blocker.

Are you satisfied with Quantum Blue® TDM in IBD patient management?

I am very happy with this easy to use and fast result tool! The Quantum Blue® is implemented in our laboratory and tests are performed by our laboratory staff. Normally, most of our patients we see in our outpatient clinic bring us a stool sample. In addition, a nurse will draw blood from the patients and we bring it to the laboratory for analysis. Within 30 to 60 minutes, we get the results from the trough level measurement as well as calprotectin and other measurements we want. When I have all results I can talk with the patients about the next steps in their therapy, which is very import. This is very important since I can say to the patients "your calprotectin is going up the last three times and your trough level is not that high I want, so we have to change the therapy". Or, I can say "everything is fine, you have normal calprotectin values and the trough level is in a good range, we stay on the therapy like it is right now".

To wrap it up: what are the main advantages of Quantum Blue® rapid TDM for you?

The tests are easy to use. We only have to wait 30 to 60 minutes to get the values and then we can react in the same visit and change the treatment of the patients. This is the big advantage for this point of care test.

Dr. ssa Giuliana Cangemi

Central Laboratory of Analyses, Gaslini Intitute Pediatric Hospital, Genova, Italy

Can you introduce your organization?

In the Central Laboratory of Analyses in the Gaslini Institute Pediatric Hospital in Genova, one of the main tasks is to perform therapeutic drug monitoring (TDM). The laboratory was specialized in the TDM of small molecules and for four years now, we are also performing TDM for biologics. Most of the requests are coming from pediatricians in the Central Laboratory of Analyses, however requests from external laboratories are also accepted and tests are performed. It happens also that outsourced patients come to the Gaslini Institute with a prescription for the TDM tests.
I would say that we had more requests from gastroenterologists when we started, but today rheumatologists are also keen in requesting TDM for both infliximab and adalimumab.

Which technique do you use for TDM measurement and why did you choose this one?

The first technique used for the TDM of the anti-TNFα such as infliximab and adalimumab was ELISA. This method was time consuming and also not economically viable when we had to perform a test including calibration and controls just for one patient. To avoid increasing the price of the assay, we had to wait to have enough samples to perform a batch. The price per patient was different depending on the number of patients tested per batch. This was also quite complicated to handle from an economical point of view.

„The previously used ELISA method was time consuming but also not economically viable."

How did you introduce the BÜHLMANN Quantum Blue® TDM methods?

Once we have been introduced to the rapid tests from BÜHLMANN Laboratories AG, we decided to perform a method comparison between the ELISA technique and both, Quantum Blue® Infliximab and Adalimumab rapid tests. The results were highly comparable for the trough levels between the Quantum Blue® assays and the ELISA technique, and the switch to the rapid assay was done quickly. We also used the Quantum Blue® Anti-Infliximab and Anti-Adalimumab as soon as they were launched. As antibodies assays from the manufacturers are not standardized against each other's, we didn't perform a technical method comparison but directly a clinical evaluation of the assays from BÜHLMANN. The clinicians only need qualitative measurement of the antibodies as they only need to get the information about the presence or absence of an immunization. Once they reviewed the results of the evaluation, we directly switched from the ELISA to the Quantum Blue® assays and now we are using the four TDM portfolio from BÜHLMANN in our daily use.

"The results of the method comparison between the ELISA technique and Quantum Blue® TDM showed highly comparable trough levels."

Is there any other advantage of using the four BÜHLMANN TDM assays?

Most of our patients are children, therefore the amount of blood needed to perform a test is important. The Quantum Blue® assays only request few microliters of blood, which is perfect for pediatrics. In addition, having the result within one hour from blood taking to the result is an improvement in the results reporting. At the beginning of the TDM measurement some time ago, we sometimes had primary non responders, or secondary non responders due to treatment failure. In these cases, we had to try to quickly run a test, that was performed reactively. Today, we have screened all of our patients from rheumatology and gastroenterology and we are able to perform proactive monitoring thanks to the Quantum Blue® assays. Because of the quick turnaround time, we have also started to sometimes test patients just before they are discharged from the hospital and ready to go back home. We sometimes get samples to run within the day, and we today have the possibility to do it, knowing exactly how much running only one sample per day would cost.

Which measurement algorithm do you follow?

We have decided to run both serum levels and antibodies in parallel as it helps us and the clinicians to get a complete picture of what is happening. If the serum levels are within the therapeutic window, the results are optimal and there is no need of performing the antibodies. When they are in contrary undetectable, the fact we can measure the antibodies at the same time helps the clinicians to take a decision on the action needed.

„TDM with Quantum Blue® is a very valuable tool for the clinicians to decide on dose increase or decrease as well as drug class switches."

Would you be interested in new development on the Quantum Blue® Reader?

Today we are performing the four assays of BÜHLMANN in our daily routine. TDM is really part of our routine use now and helps a lot the clinician decision on the dose increase or decrease, but also to decide on a within or without class switch of drug.
If I would have a wish for the future, I would think that a rapid assay for the measurement of vedolizumab serum levels would be interesting and anti-TNFα method from capillary blood. For children, this would be very attractive.

Dr. Bernard Royer

Clinical Pharmacology and Toxicology Service, Centre Hospitalier Universitaire de Besançon, France

What were the main decision factors that convinced you to work with the BÜHLMANN assays?

The primary motivation for us to install these assays was to reduce turnaround time. At the time, the volume of test requests was too low to justify using an ELISA technique.
We had previously outsourced our testing leading to a long waiting period before we could get the results. Before adopting the Quantum Blue® Reader and BÜHLMANN rapid tests, our average result reporting time was 19 days. This often exceeded the time between two administrations of adalimumab, a crucial drug for patients having inflammatory bowel disease or rheumatoid arthritis.
Since we began using the BÜHLMANN assays, we've significantly improved our ability to meet our clinicians' needs. The assay is now performed as soon as we receive the sample, and the results are sent directly to the services or the prescribing physician, on the same day. Furthermore, economic considerations also played a role in our decision. BÜHLMANN rapid tests, which do not combine drug levels and anti-adalimumab antibodies in a same assay, offer considerable savings in reagents.

"When it comes to antibodies testing, the clinicians are satisfied with a qualitative response."

What is the typical process are you following, from receiving a request to delivering results?

Most requests we handle come from the adult and paediatric gastroenterology departments. There's no standard procedure in place. The requests can come in during consultations, or from the sampling centre. Once we receive the samples, centrifugation is automatically carried out. In our laboratory, the serum assay is perfectly suited to our routine. We perform the tests on a case-by-case basis to ensure swift results delivery to the prescribing physician.

„The primary motivation (...) was to reduce turnaround time."

Which testing algorithm are you following in your routine work?

Our approach is to perform the antibody assay only when the trough level is undetectable.

„(...) we've significantly improved our ability to meet our clinicians needs."

Does the assay design meet your expectations and those of your clinicians?

It is important to have quantitative results for the drug levels, as it can be helpful for clinicians to take some treatment decision. When it comes to antibodies testing, the clinicians are satisfied with a qualitative response. The rapidity of the turnaround time takes precedence over the quantitative aspect of the anti-adalimumab result.

"Economic considerations also played a role in our decision."

Finally, in general, how satisfied are you with the service provided by BÜHLMANN? Do you have any suggestions for improvement?

We are generally satisfied with the service provided by BÜHLMANN. Since August 2023, the shelf-life of the kits has been improved, which is a great news! We were sometimes blocked expiration date which was a bit too short. For centres like ours with low request volume, stability over time is particularly relevant. In addition, the possibility to get packaging of either 10 or 25 tests helps to adapt to the routine work of each laboratory.

Ms Céline Choix, laboratory technician, performing the assay

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