



## Successful Routine Use of Quantum Blue® Therapeutic Drug Monitoring (TDM) Assays in an Italian Children Hospital

### An interview with Dr. ssa Giuliana Cangemi\*

*\*Head of the Chromatography and Mass Spectrometry Unit of the Central Laboratory of Analyses in Gaslini Institute Pediatric Hospital in Genova, Italy*

#### **Dr. ssa Giuliana Cangemi, 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 in the Central Laboratory of Analyses are coming from pediatricians. However, requests from external laboratories are also accepted and tests are performed. It also happens 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 to get TDM results 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-TNF $\alpha$  such as infliximab and adalimumab was ELISA. This ELISA method was time consuming and also not economically viable when we had to perform a test including

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

calibration and controls just for one or few patients. 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.

#### **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. At this time, only the rapid assays for trough levels were available and we decided to keep the ELISA method for the antibody measurement. This was not convenient, and we were ready to use the Quantum Blue® Anti-Infliximab and Anti-Adalimumab as soon as they were available.

As antibodies assays from the manufacturers are not standardized against each other, we did not perform a technical method comparison but went straight for a clinical evaluation of the BÜHLMANN assays. The clinicians only require a qualitative measure of the antibodies as their need is to know whether immunization is

present or absent. Once they reviewed the good results of the evaluation, we directly switched from the ELISA to the Quantum Blue® assays and now we are using the full TDM portfolio from BÜHLMANN in our daily routine.



Dr.ssa Giuliana Cangemi at the 19<sup>th</sup> International Congress of Therapeutic Drug Monitoring & Clinical Toxicology 2021, September 19-22, 2021, Rome, Italy

#### **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 children. In addition, having the result within one hour from blood taking is an improvement

in the rapid result reporting. At the beginning of the TDM measurement some time ago, we occasionally had primary non responders or secondary non responders due to treatment failure. In these cases, we had to

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

try to quickly run a test, that was performed reactively.

Today, we have screened all 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.

However, in our daily organization of normal routine, we have set-up a specific day once a week for TDM measurements. This is really appreciated by the clinicians. They exactly know when they will get their results. Despite this test agenda, we

sometimes get additional samples to be tested within another day of the week. Today, with Quantum Blue® flexibility, we have the possibility to do so, knowing exactly the costs of running only one sample per day.

**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 the complete picture of the patient situation. If the serum levels are within the therapeutic window, the results are optimal and there is no need to additionally test for antibodies. Conversely, when drug is undetectable, the fact that we can measure the antibodies at the same time helps physicians 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 developments on the Quantum Blue® Reader?**

Today we are performing the four

*"Because of the quick turnaround time of the Quantum Blue® TDM assays, we have also started to test patients just before they are discharged from the hospital."*

BÜHLMANN assays in our daily routine: Quantum Blue® Infliximab, Quantum Blue® Adalimumab, Quantum Blue® Anti-Infliximab and Quantum Blue® Anti-Adalimumab. I would say that TDM with Quantum Blue® is part of our routine use now and a very valuable tool for the clinicians to decide on dose increase or decrease, but also to support the strategy of within or in between class switch of drugs.

If I would have a wish for the future, I would think that a rapid assay for the measurement of tocilizumab might be interesting for juvenile arthritis patients. We have tested an ELISA technique already but would be more interested in a rapid test. In addition, vedolizumab serum levels would be interesting and an anti-TNFα method from capillary blood. For children, this would be very attractive.

Dr. ssa Cangemi, thank you very much for this interview.



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