Glycosylated haemoglobin with the D-100™ from Bio-Rad: network innovation!
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The Sud-Ouest BIOmedica laboratory group is focussed on using the best in current innovations to equip its testing network at their new technical facility in Lannemezan. Dr Pierre Recurt-Carrère and Alain Pinet tell us how they have proceeded and why, in regard to glycosylated hemoglobin, they decided to renew their trust in the company Bio-Rad by selecting their new system: the D-100.

Spectra Biologie: As a technical facility that uses the latest technology, your group has the reputation of being state-of-the-art concerning innovation. What reflections have brought you to make these recent changes?

Dr Pierre RECURT-CARRERE: Since as early as 1993, BIOmedica Laboratories has been the leading company for the practice of medical biology in south-west France. Today the company includes 7 laboratories in addition to 2 associated laboratories which are in the process of being integrated, with 14 biologists in total. Each site has maintained its own specificity for a long time but the group’s total activity was too spread out across the country. We felt it was necessary to bring our activities together into just one site. Because none of our previous sites had the required space, we had a de novo technical facility built to house the activity of all our laboratories, except our testing related to hospital or emergency activity. To date, we take on an average of 1500 records/day and the continued presence of 3 biologists is assured. The previous sites have essentially become analytical laboratories apart from emergencies dealing with certain pre-defined parameters which are dealt with there.

Spectra Biologie: This new technical facility has given you the possibility of reconsidering your general organisation. Have things changed?

Dr Pierre RECURT-CARRERE: Indeed, equipping this site was the opportunity to take advantage of the latest innovations! In particular, we had to install an integrated analytical network compatible with virtually all our future systems. The other innovation was inserting systems from various suppliers which had never been «transplanted» onto this network. Even if we had encountered certain difficulties inherent to these technical challenges, our laboratory has always endeavoured to use state-of-the-art equipment in order to best serve its patients. We are also one of the few laboratories to have connected immunology, biochemistry, haemostasis and haematology. That is 8 different systems from various suppliers in the same network. Furthermore, negotiating the network directly with the suppliers has enabled us to uphold freedom of choice for our partners. Maintaining this flexibility and independence is essential to us: we can continue to select systems where each one has proven their analytical reliability and performance in their field. The network does not stop there because we have also planned to add Bio-Rad’s D-100 system for HbA1c testing from now until the end of the year. EDTA tubes serve multiple examinations: counts, groups, glycosylated hemoglobin, BNP or certain hormonology tests. For the comfort of our patients, it appears more appropriate to perform a maximum number of analyses from the same tube rather than continue to sample several EDTA tubes for the same assessment!

Spectra Biologie: In regard to the HbA1c analyses, you have opted for Bio-Rad’s D-100 System. How was this decision made?

Dr Alain PINET: We have opted to continue our innovative relationship with Bio-Rad! We have been carrying out HPLC since 1993 and we have been collaborating in this field with Bio-Rad since 2000 onwards: we have worked with the Variant™ II and then the Variant II Turbo. We were already satisfied with their very reliable systems and the expertise of this company in regard to the HPLC technique. Moreover, we had to continue with the reference technique. The Variant II Turbo could not absorb the flow from our new technical facility for much longer. Bio-Rad has therefore enabled us to add the D-100 system which had already won us over on paper for its innovation. After trialling it’s software we were able to observe the excellent resolution of chromatograms with detection of variants. We have therefore opted to be the first laboratory to equip itself with this new equipment. After two months we have not regretted this decision! Performing 80 tests/hour, our throughput has doubled which was our principal goal. In addition, it is very simple to use: the activity is very smooth especially when integrating into the network. The software is also very user-friendly because it has been simplified at the request of biologists. The management of movements is to a large extent facilitated. In addition to these benefits, we have observed better resolution and a better framework.
of the most well-known haemoglobin variants. We therefore obtained very reliable results together with enhanced subsequent procedures to perform in regard to the rate of variant and percentage with respect to total haemoglobin. As for analytical quality, even though I was already very satisfied with the Variant II Turbo, the D-100 system has enabled us to split our CV in 2 with CV values currently between 0.5 and 0.6%! Finally this system can be integrated into an analytical network which was obviously important for our facility. We are therefore very satisfied with this selection.

Spectra Biologie: How was the D-100 System set up?
Dr Alain PINET: The system was one of the first to arrive on our new premises. Everybody was curious about discovering it! To tell you the truth, the on-site Bio-Rad team did not have much to do! Once unwrapped, installation was very fast and it has worked very well since the end of March. It was as simple as that!

Our individual feature was having previously obtained certification for glycosylated hemoglobin. It was necessary to ensure continuity of this when changing equipment and location. Because I am used to HPLC and this company’s products, I took responsibility for this and everything went very smoothly.

Before opening the technical facility, the previous system located at Saint-Gaudens continued to work. One and a half months before the opening, we began to classify the system by performing repeatability and reproducibility tests which were very satisfactory. In parallel, we undertook a one-week transition from the former Variant II Turbo system to establish the correlation. All this was in response to obligations related to the new technical facility’s other activities and those related to the network! We were ready 15 days before launch with the authorisation for set up.

Operating for the moment in isolation, it was not restricting because it was sufficient to bring the network directly onto the system. We are therefore very satisfied with it. Our partnership with the company Bio-Rad is now long-term but they still offer clients a real added value.

Spectra Biologie: After two months of use, what is your assessment of this new system?
Dr Alain PINET: Above all, I appreciate its analytical performance. In terms of reproducibility, I have moved to 0.6%! This leaves me a good margin to determine total error and wins over our trust in regard to renewing our certification.

Next the management of CQI (Continuous Quality Improvement) is much easier, which is highly relevant. Routine and software management is very user-friendly. Moreover, I arrived at the technical facility before being trained on how to use the system. Assisted by a technician, we passed the CQI and were verifying the methods necessary to start the D-100 system very easily! The equipment is very intuitive, which is a marker of quality and user-friendliness.

Start-up was also very simple from the point of view of computer connections. Here again we find continuity in innovation: the connection of the D-100 system was very fast. On the advice of the company Bio-Rad, we maintained the same connection on our central SIL, which is a very robust system. The connection is therefore not with the network’s middleware but directly with the laboratory system. This has relieved us greatly because we found the same referential as before but in an improved context.

As for the system software, this is simplified on a large scale. In accordance with our needs, Bio-Rad has provided a modified version with a connection that places parameters in an alarm status. So there is no need to edit all the chromatogram graphs. Tickets are only printed out in the case of detection of anomalies in regard to the baseline, the area under the curve, of variants. The D-100 system will block the results. With an automatic connection that sends proven results to the SIL and this auto-validation system, we can devote ourselves to the graphs that require special expertise. The company has therefore adapted its product to our needs.

Finally, in regard to the post-sales service, we have only had to contact them once after a leak which was resolved by the technician. They visited the next day to verify the installation. We already knew about their responsiveness due to our previous systems and we were not disappointed. This remains an important criteria; even if the HbA1c is not an emergency and the sample is stable for 6 days, we remain attached to the concept of reporting results at D0 and we were reassured by being able to lay down our trust in the quality follow-up of the company Bio-Rad.

Bio-Rad – Diabetology-Hemoglobinopathies

D-100™ Hemoglobin Testing System
The fastest HbA1c result with hemoglobin variant detection

Speed
• 80 tests per hour
• On-the-fly buffer replacement
• Streamlined result review with on-board Advisor software

Quality
• Accurate HPLC results
• No interference from common variants
• Presumptive identification of hemoglobins E, D, S, and C

Simplicity
• One touch operation
• Smart consumables with RFID tags for automated traceability
• No calibration for up to 10,000 tests

*Not available in the US