

Sebia Focus - N°13

October 2014



capillary
sebia flex piercing



Sebia HbA1c assay set up on two CAPILLARYS 2 Flex Piercing in the Arnaud-Biolys-Origet laboratory

HbA1c Interview with Dr ESTEPA and Dr LEMAITRE,
associated Biologists at the ABO+ Arnaud-Biolys-Origet laboratory, (Tours - France)

Can you describe the Arnaud-Biolys-Origet laboratory to us and its activities?

The SELAS* ABO+ was created in March 2013 following the merger of the Arnaud-Origet SELAS* and Biolys, hence its name. The laboratory was opened in December 2013, on the site of the Leonard de Vinci Health Center in Chambray-les-Tours (France), at the intersection of the A10 and A85 highways, and the ring road. Therefore, the laboratory is easily accessible for all sites. It receives work from 16 sites, spread out among the Indre-et-Loire and the Loir-et-Cher departments and has an average daily activity of 2600 patients.

In February 2013, you choose SEBIA capillary technology for HbA1c measurement. Can you describe your current organisation for this measurement?

We currently perform 75 000 HbA1c tests per year, as only the 10 laboratories from the former Arnaud-Origet SELAS send them to the laboratory for analysis. Due to outstanding contracts and the uniformity of our computer system, the former Biolys laboratories will only send their HbA1c analyses at the end of 2014. This will represent an added activity of 30 000 HbA1c tests each year. HbA1c are currently analysed 6 days a week, from 10:00 am to 6:00 pm, on two CAPILLARYS 2 Flex Piercing systems.

According to your experience, what differentiates capillary electrophoresis from other conventional methods? What are the key advantages of this method?

We have a good knowledge and extensive experience of capillary technology as we have used it for many years to perform serum protein electrophoresis (12 000 tests a year). Indeed, we have had no fears concerning the quality and the reliability of the technique. For HbA1c measurement, we previously used a conventional HPLC technique but we often noted the presence of hemoglobin variants. In these cases, it was not possible to give a reliable HbA1c result and we had to substitute the analysis with a fructosamine measurement. Owing to the high resolution capillary technology, we obtain a more clear-cut and precise separation of the different hemoglobin fractions, thereby increasing peak resolution. The curve mosaic screen with its color coding is a useful validation system. It saves time and easily draws our attention to the presence of hemoglobin variants. Finally, patients' follow-up is facilitated through rapid visualisation of the patient history.



"We currently perform
75 000 HbA1c tests per year" ...
"HbA1c are currently
analysed 6 days a week, from
10:00 am to 6:00 pm, on two
CAPILLARYS 2 Flex Piercing."

*SELAS, Société d'Exercice Liberal par Action Simplifiée

sebia

Did you inform your clinicians about this change of method? If yes, how did you do this? Did you have any feedback from your clinicians following this change?

Yes, we wrote an information article in our quarterly publication dedicated to the clinicians. We explained our choice for changing the method and the advantages linked to this new methodology for patient follow-up. This message was received by the clinicians and the information accomplished its aim. We have received no special feedback from our clinicians.

Since changing, have you more the opportunity to alert your clinicians to the presence of a variant or of a disrupted HbA2? If yes, do your clinicians appreciate this service?

Yes, when a hemoglobin variant is present, we inform the clinician through a relevant comment. If it is a new finding and the patient is not known, we suggest performing an electrophoresis of the hemoglobin in order to characterise this variant. We also mention the suspicion of beta-thalassemia, indeed the hemoglobin A2 quantification is an added value of the capillary technique.

HbA1c measurement is part of the accredited analysis of your laboratory. Could you describe the different steps you took for the accreditation of this bench for Capillarys 2 Flex Piercing?

Following the installation of the Capillarys 2 Flex Piercing instruments in February 2013, we decided to include HbA1c among our accredited analyses. We submitted a file in June 2013 for an audit in September 2013. Today, four of our technicians are certified for this measurement. The certification of the technical staff includes a technical training validated by a competency test. The 3 level competency test comprises a practical test on the instrument and a multiple-choice test. The competency testing of the biologists was carried out via a training meeting made by the referring biologist of its activity (Dr LEMAITRE). In addition, the biologists had to review the HbA1c consultancy document, which we had drawn up. The validation of the method was undertaken using our established protocol. During the installation of the Capillarys 2 Flex Piercing, we assessed the repeatability, the intermediary reliability, the correlation with our previous method, as well as contamination. To a lesser extent, we validated the repeatability and the contamination following the move of the Capillarys 2 Flex Piercing to the new site. We monitor daily the results of the internal quality controls, and then we print a monthly statistical report for controls. The CVs in percentage have to be less than 2%. If they are between 2 and 3 %, monitoring of the instrument is set in place. A corrective action is carried out if they are superior to 3%. The Phoresis Core software allows monitoring of all the information with regard to the patients' results, which is necessary for the accreditation requirements.

Did you use the accreditation support tools proposed by SEBIA? How did these tools help you in your approach?

SEBIA provided valuable help during the validation process. The application engineer showed us the validation protocols, as well as the excel tools proposed by your company, and helped us during the installation of the Capillarys 2 Flex Piercing. We have followed your recommendations and are very satisfied that we are accredited for the HbA1c analysis. We have also contacted your quality manager and your diagnostic department for questions regarding the validation of the methods or for results interpretation.

Your activity will increase soon. How will you organize the HbA1c analysis in your laboratory?

As we have previously discussed, we will be increasing the number of HbA1c analyses by 50% by the end of this year. This increase of activity could be easily absorbed by the two existing Capillarys 2 Flex Piercing by increasing the operational ranges. However for convenience, in order not to interfere with the current bench organisation, our preferred solution is to add a third instrument. This will enable us to keep the same number of technicians and the same running time. We think also to add the CDT measurement by capillary electrophoresis on one of our Capillarys systems. Indeed, we work in collaboration with two hospitals specialised in addiction which order this test, in addition to requests from driving licence authorities.

