

# Sebia Focus - N°6

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capillarys  
sebia flex piercing

## Interview - Feedback on HbA1c testing with the Capillarys 2 Flex Piercing instrument from BIOTOP DEVELOPPEMENT Laboratory (13) CERBA EUROPEAN LAB Group

**Dr. Joseph Carvajal is an associate biologist at BIOTOP DEVELOPPEMENT. He is a former “Intern of Hospitals” (resident) in Marseille, a practitioner of Immunology at the University Hospital de la Conception and is head of the Technical Support Centre in Marseille.**

Good day to you Dr. CARVAJAL. Can you describe the BIOTOP DEVELOPPEMENT laboratory to us along with its activities?

BIOTOP DEVELOPPEMENT is a multi-site medical biology laboratory in Marseille and Pays d'Aix. It is comprised of 32 sampling sites and a technical support centre that centralises the entire analytical and administrative work of the group.

The technical support centre routinely processes around 2,500 urgent cases per day. We carry out 97% of our analyses on-site. Aside from this, our association with the CERBA laboratory in 2011 has enabled us to benefit from its expertise in innovative and highly specialised analyses.

In addition to our activities in the city, we provide biology services for over fifty institutions (hospitals, clinics, nursing homes and so on). This has forced us to take a hard look at our turnaround times and deliver results with a certain degree of urgency.

The logistics system we use for transporting samples ensures a continuous flow to our centre. We have just submitted the COFRAC accreditation file and the initial audits should take place in the coming months.

For this reason, the choice of all materials is subject to very strict specifications.

What were your needs and motivations for changing the HbA1c test method, what were you looking to achieve...?

Quite simply, we needed to update our equipment, which had come to the end of its useful life and no longer met the necessary productivity criteria. It had become obsolete in terms of speed, mechanical reliability and even

quality, due to the lack of IT traceability. We wanted a solution capable of handling a constant flow of more than 200 HbA1c tests per day. Something reliable and equipped with the latest IT tools in order to achieve accreditation. Initially, our primary aim was not to change the HbA1c method.

Why did you choose the SEBIA HbA1c assay with the CAPILLARYS 2 Flex Piercing instrument?

This analyser meets all the requirements of the specifications that we drew up. We were able to test it in a trial that lasted three weeks and

this allowed us not only to compare it with our former HPLC instrument, but also one of its competitors (also an HPLC).

At the ergonomic level: our technical team were impressed by its ease of use and maintenance. At the productivity level: a rate of 40 samples per hour was achieved and the continuous loading feature allows good flexibility in terms of assuring results are produced right through the day. We can meet our daily requirements easily with two instruments and a part time technician loading and unloading the samples.



*“...the continuous loading feature (of CAPILLARYS 2 Flex Piercing) allows good flexibility in terms of assuring results are produced right through the day”*

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At an IT level: all data is easily accessible and archived. Traceability is easy to manage. The Phoresis software is also familiar to the whole team, as it is already used in the CAPILLARYS 2 device that we use for serums.

At the biological level: the results are well correlated with those of the competing HPLC device and those of our previous HPLC analyser. The most common haemoglobin variants are managed perfectly by the software, which offers a very reliable autonomous assessment in HbA1c testing. Moreover, we were impressed by the excellent clarity of the results which distinguish the various fractions very well. This is one of the advantages of capillary electrophoresis, as the separation time is longer than HPLC. The slower speed is compensated for by the presence of eight capillaries that can process 8 samples simultaneously.

This choice gives us a back-up for our CAPILLARYS 2, in terms of versatility: this is one of the decisive arguments. If necessary, it can be switched to serum mode very quickly.

Capillary electrophoresis is a technique that has proven itself very effective but its use in the field of HbA1c testing is entirely new. What evidence has been provided by SEBIA?

The technique is new and any innovations in our area must demonstrate their relevance in relation to the existing technique.

This means that it must at least demonstrate equivalence to the existing techniques. To do this, SEBIA provided us with a very well-researched and substantial bibliography. The references in French, the work of Professor Gillery CHU Reims, published in many journals, offer a solid guarantee.

And, as I have already said, we carried out our own tests that corroborate the results achieved elsewhere.

After 10 months of use, has the SEBIA HbA1c assay with the CAPILLARYS 2 Flex Piercing instrument met your expectations?

We have two CAPILLARYS 2 Flex Piercing instruments that fit perfectly into our work-flow and ensure that we produce reliable results quickly. The audit file for accreditation of the methods does not indicate any particular problems. In this sense, this solution meets our needs perfectly.

Has the choice of the SEBIA HbA1c assay with the CAPILLARYS 2 Flex Piercing instrument simplified your organization? Does this method/tool allow you to save time?

There is a big difference compared to our previous solution. If we were to compare competing solutions on the market today, I could not be as categorical. But my brief comparison trial makes me think that we would have similar results in terms of productivity, with the added advantage of a back-up for the CAPILLARYS 2 device we use for serums.

How have prescribers reacted to this new method? How have you convinced them? Do they appreciate the added medical value of this new technology?

As part of our efforts to launch this new method, we have, of course, changed our information for prescribers through various means (mail, an article on our website, comments on the report and telephone calls if needed). We have especially focused on the correlation established with the HPLC and the reliability of the results in the presence of common variants of haemoglobin. To date, we have had no unfavourable feedback.

What is the key point that would push you to recommend the SEBIA CAPILLARYS 2 Flex Piercing instrument to other laboratories?

This instrument can accommodate the continuous flow of samples that a modern technical support centre experiences on a daily basis. It combines good ergonomics with a production output rate that meets current standards and permits accurate interpretation of well-presented results. It is also possible to market it as a back-up for a CAPILLARYS 2 used for serums.

Do you process haemoglobins on CAPILLARYS 2 Flex Piercing and if so, what do you think?

Yes, we conduct a series of analyses for twenty patients a week. This technique, combined with the interpretation of the FBC (Full blood count) and iron levels, ensures a diagnosis of exclusion for haemoglobinopathy. It is also a good screening technique that provides a rough diagnosis which can be confirmed by other methods.

It is interesting to note that we do a lot of screening for haemoglobinopathies based on anomalies detected during an HbA1c measurement.

