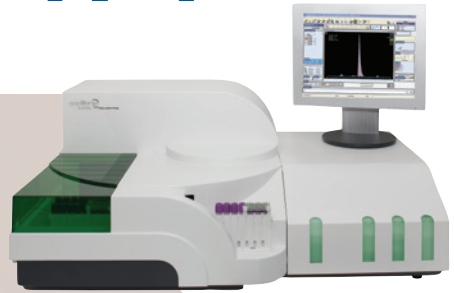


Sebia Focus - N°1

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capillarys
sebia 2 flex piercing

The next generation separation method for HbA1c launched by Sebia has been tested successfully by national network B.P.R

More than 5,000 samples of glycosylated hemoglobin have been tested using Sebia's Capillarys™2 Flex Piercing on MEDIBIO's technical platform in Melun, France. The results obtained demonstrate that the new separation method recently announced by Sebia for the measurement of HbA1c, brings a significant performance improvement. This is due to a simple, direct analysis of HbA1c, the absence of interferences and distortion of results, an excellent reproductibility, a perfect linearity, and traceability from the primary tube to the end result.

Mister Mentz, can you begin by explaining the origins of the Biologie-Pro prospective-Réalité initiative in France?

The BPR initiative resulted from the desire of leading biologists working in the private sector in one region of France to become part of a national network of laboratories, with the aim of pooling their substantial resources to face up to the economic challenges arising from structural changes in the profession while continuing to perform high-quality medical biology at a local level.

Since the initial challenge was to preserve total economic independence while ensuring the interdependence of the network's participants, the BPR network was designed to function with the funds available to the biologists belonging to it, to the exclusion of all other forms of funding.

When it was established on 10 May 2008, the network consisted of six elements. The first step was to create a platform of specialist analyses, all of which had the necessary administrative authorizations for practical application. In three years of activity, the network has spawned various



Interview : Frank Mentz, co-founder of B.P.R the national laboratory network Prospective Biology-Reality

capabilities, including:

- a logistics company that handles the transport of biological samples between the network's participating organizations and within them in compliance with ADR norms;
- a procurement arm that operates through a joint working party, affording better communication with the reagent suppliers, which have become true partners through contracts that are common to all network participants; and
- an operating model for the routine platform and the emergency platform, which is utilized in all the companies

belonging to the network in accordance with a method of common accreditation and a common information technology model (whose ultimate structure will be a single system for the whole network).

Six more entities have since joined the BPR network, which now encompasses 350 laboratories and represents a little over 12% of France's total medical biology effort.

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Why were Sebia and Capillary™ selected for the electrophoresis assays?

Sebia is one of our network's suppliers. The charter governing our operation starts from the principle that the reagent supplier is a partner and not simply a service provider offering the best (which is to say the lowest) cost. The relationship thus has to be conducted on a more scientific level than a purely economic one. Since the network has modern and well-equipped facilities, it was easy to respond positively to Sebia's request that we carry out a test of a new automated instrument to compare it with those currently used for dosing HbA1c assays (the HPLC reference method). Furthermore, we are experienced in this type of exercise, and curiosity about an innovative technique offering the prospect of high quality and greater efficiency did the rest.

Sebia suggested that we test its Capillary™ 2 Flex Piercing automated instrument for dosing our HbA1c assays.

Why did you accept its proposal and what was the objective?

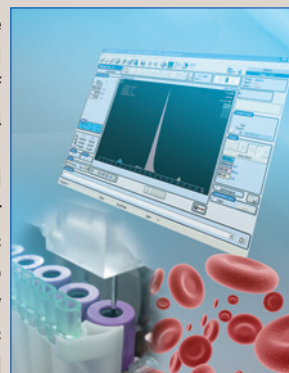
We agreed a protocol with Sebia's scientists that covered the number of tests to be conducted, the length of time to be devoted to the study, the analytical conditions in which the test was to be performed, the mathematical comparison methods to be implemented, the scheduled repeatability tests, and the scheduled material resistance tests. The trial took place over a 28-day period, during which the HbA1c assays dosed at the MEDIBIO technical platform in Melun were systematically tested in parallel on the Capillary™ 2 Flex Piercing automated instrument, applying the same analytical conditions.

The trial involved a little over 5,000 HbA1c assays, so the system handled more than 200 HbA1c a day. Nothing was spared, neither the switch to systematic tests in tandem, nor changes of technique in mid-series (moving to CDT analysis or protein electrophoresis), nor "forgetting" the cleaning procedure at the end of the day. The trial was also designed to demonstrate the reliability and sturdiness of the equipment, and we strove to show that this was the case.

What are your conclusions in terms of analytical potency, ergonomics and rapidity?

All the tests performed demonstrated the exemplary sturdiness of the equipment, which never failed despite the abusive use to which it was put. The quality of the results is in line with the hopes generated by the preliminary tests and there was a very close correlation with the HPLC tests carried out. The speed was comparable with the HPLC method. The

software is easy to use and limited technical training is required. Of course, there is a bidirectional connection and the tube is analyzed without any prior manipulation (automatic piercing). One thus has to conclude that this new method for dosing HbA1c is at least as reliable and efficient as existing ones.



What are the major points of differentiation that you observed between HbA1c Capillary™ 2 Flex Piercing and the systems in use in your laboratory and which could lead you to recommend that Sebia should give them priority over existing ones?

The biggest advantage of Capillary™ 2 Flex Piercing in my opinion is its ability to distinguish between different types of hemoglobin, which is quite excellent given the quality of the separation whatever the rate of total Hb. As a result, it is reasonable to think that one could use this dosing method in diabetics who suffer from hemoglobinopathy, which is not always easy with HPLC (this has led some prescribers to use fructosaminemia for monitoring patients). One might also stress that the absence of a column is a guarantee of peace of mind and of the ease of maintenance procedures. In view of its stability, there will probably not be any problems validating these methods and, at a more general level, winning the trust of the laboratory bench.

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Capillary™ 2 Flex Piercing HbA1c :

High throughput with clear-cut and precise results
The latest innovation from Sebia which completes its range of instruments for capillary electrophoresis.
An innovative, high performance tool that carries out totally reliable measurement of HbA1c (glycosylated hemoglobin).
Simultaneous validation of 48 results from different patients. High throughput. 37 samples per hour (296 samples processed in eight hours).

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