

New HbA1c diabetes diagnostic technology from Sebia will help laboratories facing the fast changing environment of diabetes assessment

Paris, November 7th, 2011, Sebia, a leading provider of protein electrophoresis for diagnosis of a wide range of diseases, announces today the launch of its next generation separation method for HbA1c testing. The new test used with Sebia's automated capillary electrophoresis product, Capillarys TM 2 Flex Piercing brings the accuracy, high throughput, and robustness required for laboratory use worldwide.

The arrival of the new method is very timely as some very significant changes have taken place. HbA1c is an important test recommended by the American Diabetic Association (ADA). Originally used for monitoring, it has now been recommended also for diagnosis of patient glycemic status. HbA1c refers to glucose modified hemoglobin A (HbA) specifically at N-terminal valine residues of hemoglobin beta chains.

The HbA1c playing field, for both laboratories and their referral clinicians, is also changing with increased incidences of diabetes both in emerging countries, where hemoglobin disorders are prevalent, and in countries facing population migrations. HbA1c tests therefore have to detect these variants to give an accurate result.

Moreover, the International Federation of Clinical Chemistry HbA1c Working Group has introduced new analytical requirements and new regulations. This group has established rules for the production of calibrators and the annual assessment of industry assays and has selected a straight and simple calculation formula.

This change of paradigm and the increased incidence of interferences caused by a patient's clinical status, have led Sebia to develop a next generation separation method for HbA1c measurement.

Drawing on ten years' experience in capillary electrophoresis, Sebia has adapted HbA1c technology into an assay that can be used routinely by labs around the world and also overcomes the difficulties due to the presence of blood conditions that interfere with analyses.

The high resolution capacity of capillary electrophoresis holds significant advantages over other methods. It enables pathologists to separate the HbA1c fraction from other fractions, or interfering substances, better than any other separation already existing on the market, such as HPLC, says the company.

Furthermore, unlike most competing products, Sebia's assay uses the straight and simple calculation formula selected by the IFCC Working Group ($HbA1c = HbA1c / [HbA1c + HbA0]$). The simplicity of this calculation formula leads to fewer risks from interferences and greater accuracy in the results.

The system offers a high throughput of around 40 tests per hour, without compromising the quality of separation. The product is fully compliant with international regulations and has NGSP and IFCC certification.

"Thanks to our powerful separation technology, we can now offer worldwide a product that complies with the new HbA1c requirements and responds to the unmet needs of the growing diabetes market especially for patients with a complex physiological status," says Benoit Adelus, Sebia's chief executive officer.

Expert users' experience is already confirming the high quality results produced by the new system. A team at the University Hospital of Reims, France, recently demonstrated that the Sebia HbA1c assay showed no interferences or no altered results in the presence of a number of problem areas. These include carbamylated, labile, acetylated and fetal hemoglobins, bilirubin, lipids and hemoglobin variants such as HbS, HbC, HbE and HbD. The assays showed overall excellent linearity and good reproducibility. Further investigations are under way with key opinion leaders in different countries to explore further the unique advantages of this new test, how it contributes to the detection and monitoring of diabetes and its reliability even in physiologically complex situations.

The Sebia HbA1c assay and analyzer were also tested at a large laboratory MEDIBIO (Melun-France) under stringent conditions of use. They showed capabilities for streamlining laboratory workflow and reducing hands-on time. "All the tests performed demonstrated the exemplary sturdiness of the equipment, which never failed despite the abusive use to which it was put," says Dr Frank Mentz, head of the global analytical platform.

About Capillarys TM 2 Flex Piercing

The HbA1c assay is the latest addition to the Capillarys TM 2 Flex Piercing menu, including proteins electrophoresis, immunotyping, hemoglobin variants and CDT (alcohol abuse marker). The system processes the HbA1c assay directly from whole blood capped tubes and is used either dedicated for HbA1c or for polyvalent use.

The fast HbA1c validation interface using the "Mosaic Screen" display mode, allows the validation of up to 48 patients' results at a time, with a visual colour code for each category of results.

The Capillarys TM 2 Flex Piercing uses the phoresis software SQL/Client Server with two major capabilities: unlimited data storage with patient history recap and intranet connection to other Sebia systems with remote, multiple validation platforms.

In 2012, Sebia will introduce the HbA1c on its smaller throughput automation, Minicap TM Flex Piercing, offering the full list of features available on its Capillarys TM 2 Flex Piercing.

Capillarys TM 2 Flex Piercing key next generation HbA1c features include:

- High resolution capillary electrophoresis
- Strong discrimination capacity
- Separation clear, cut and precise
- Calculation formula, simple, direct – IFCC formula
- No interferences or altered results
- Instruments dedicated or polyvalent
- Fast validation via Mosaic Screen
- Central validation from several instruments via the SQL Client/Server
- Certified NGSP-IFCC

About Sebia

Sebia develops, manufactures and markets protein electrophoresis tests and analyzers, dedicated to the in vitro diagnosis of cancer, inflammatory, metabolism and hemoglobin disorders. Sebia's focus on electrophoresis techniques allows it to maintain a sustained R&D program, providing access to genuine solutions for any type of lab. Both agarose gel and capillary assays and their dedicated automation are designed to be integrated into the same routine workflow, for gel (ASSIST, HYDRASYS™ 2) and for capillary electrophoresis (CAPILLARYS™ 2, MINICAP™). Sebia has recently diversified its activity by introducing CAPILLARYS™ 2 Flex Piercing, the most advanced capillary technology, providing a high level of performance, and bringing walk-away automation. Tests available are serum proteins, urine proteins, immunotyping, high resolution electrophoresis, CDT measurement and hemoglobinopathy screening for whole blood in primary capped tubes. Recently, Sebia adapted this innovative technology to the field of diabetes, to fulfill the growing worldwide demand for more accurate and reproducible methods for HbA1c measurement. For further information: <http://www.sebia.com>

**Press and Analysts Contact
Andrew Lloyd & Associates**

Vicky Leek / Andrew Lloyd
vicky@ala.com / allo@ala.com
Tel +44 1273 675100
