



Sebia HbA1c assay now has CE mark for diagnosis of diabetes

Paris, France, March 1 2016 – Sebia, the world leader in medical diagnostics by capillary electrophoresis, today announces that it has achieved the CE mark for its HbA1c capillary electrophoresis technique to be used for the diagnosis of diabetes. Sebia's capillary electrophoresis, until recently only used for monitoring patients, can now be used in laboratories equipped with Sebia's devices (Capillarys 3 TERA, Capillarys 2 Flex Piercing, Minicap Flex Piercing), in all countries where the CE marking is required, for the diagnosis of diabetes.

Sebia's technique uses quantitative measurement of the hemoglobin A1c. The World Health Organization (WHO)¹ recently recommended the use of HbA1c for diabetes diagnosis². An HbA1c value of 48mmol/mol in IFCC/ SI units³ (6.5% NGSP units⁴) or higher can be used as a cut-off for diagnosis for diabetes. The technique can also help to identify patients who may be at risk of developing diabetes (pre-diabetes patients).

As it does not require fasting, an HbA1c sample can be collected on the patient's first visit to the clinic. When using traditional diabetes testing, such as the fasting plasma glucose method (FPG), patients are expected to fast overnight, usually for 8-12 hours. The accuracy of the FPG testing relies on patient compliance; this presents a major barrier to follow-up and receiving a diagnosis from the clinician.

Furthermore, when the FPG samples are collected, the glucose concentrations decrease over the following two hours, even when a preservative is used. Whereas the HbA1c samples are stable; there is no change in concentration from the time of collection to analysis. Therefore, the HbA1c result will more accurately reflect the situation in the patient at the time of blood collection.

HbA1c testing is already widely used for monitoring patients with diabetes; doctors have a good understanding of the test and its values. The Sebia HbA1c test by capillary electrophoresis has been CE marked for HbA1c monitoring since June 2011.

"We are delighted to have our capillary electrophoresis technique HbA1c CE marked for diagnosis of diabetes," said Benoit Adelus, Sebia's chairman and CEO. "With this certification, we are taking a decisive step in the worldwide commercialization of our technology. We are now targeting major markets where diabetes is growing rapidly, such as the US where 40% people are in a pre-diabetic state and 14% of people have type 2 diabetes⁵. We're also targeting, China, a country where the number of diabetics has increased dramatically in recent years."

"The use of capillary electrophoresis for HbA1c routine screening has greatly improved workflow," said Prof Garry John, consultant clinical biochemist, Norfolk and Norwich University Hospital (UK). "Thanks to the high resolution of different hemoglobin species provided by capillary electrophoresis, it is now

¹ http://www.who.int/diabetes/publications/diagnosis_diabetes2011/en/

² http://www.who.int/diabetes/publications/report-hba1c_2011.pdf

³ International Federation of Clinical Chemistry – Système International

⁴ National Glycohemoglobin Standardization Program

⁵ <http://jama.jamanetwork.com/article.aspx?articleid=2434682>



possible to rely on a fast analysis of the profiles and of the data to reduce the time required for laboratory staff to oversee the review process. Also, HbA1c analysis contributes to the well-being of patients, as they do not need to be fasting at the time of the test."

About diabetes

Diabetes is a chronic disease, officially recognized as a global pandemic. It is among the leading causes of cardiovascular disease, kidney failure and non-traumatic amputations. According to the Atlas of the International Diabetes Federation, nearly 400 million people had diabetes in 2014. This figure is set to reach around 600 millions by 2035.

About type 2 diabetes

Diabetes is defined as a group of chronic metabolic diseases characterized by hyperglycaemia. It is a lifelong condition that causes a person's blood sugar level to become too high. Type 2 diabetes is often associated with obesity and tends to be diagnosed in older people. It is far more common than type 1 diabetes. According to the World Health Organization diabetes will be the seventh leading cause of death by 2030⁶. Diabetes can cause serious long-term health problems. It's the most common cause of vision loss and blindness in people of working age. People with diabetes are up to five times more likely to have cardiovascular disease, such as a stroke, than those without.

About Sebia

Sebia develops, manufactures and commercializes protein electrophoresis tests and analyzers dedicated to the in vitro diagnosis of cancer, inflammatory diseases, diabetes and hemoglobin disorders. Sebia's focus on electrophoresis techniques allows a sustained R&D program, providing access to genuine innovations in any 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 Scan) and for capillary electrophoresis (Capillarys 3, Capillarys 2, Minicap). Tests include serum proteins, urine proteins, immunotyping, CDT measurement and hemoglobinopathy screening for whole blood in primary capped tubes. Recently Sebia has diversified its activity in the field of diabetes to fulfill the growing worldwide demand for more accurate and reproducible methods of HbA1c measurement. Sebia now offers a clear-cut and precise HbA1c test on Capillarys 3 TERA, Capillarys 2 Flex Piercing and Minicap Flex Piercing. In 2015, the company launched the high-speed, high resolution automation electrophoresis program, Capillarys 3.
<http://www.sebia.com/>

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⁶ <http://www.who.int/mediacentre/factsheets/fs312/en/>