

News Release

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Study Presented at Diabetes Technology Society Meeting Finds In-Office A1CNow+® Monitor Demonstrates Precision & Accuracy in A1C Testing

Leverkusen, Germany (December 15, 2008) – A new study presented recently at the Annual Meeting of the Diabetes Technology Society found that A1CNow+®, an easy-to-use, A1C (HbA1c) monitor demonstrated precision and comparable accuracy to the high-performance liquid chromatography (HPLC) laboratory method. This was the conclusion of researchers from the Diabetes Center of the Christliches Krankenhaus in Quakenbruck, Germany. A1CNow+ is the only portable, hand-held, point-of-care, A1C monitor on the market.

A1CNow+ allows for fingerstick or venous blood draw testing and immediate, in-office A1C results as compared to more time-consuming lab analysis methods. A1CNow+ is NGSP-certified for the measurement of A1C levels. In the U.S., is Clinical Laboratory Improvement Amendments (CLIA) - waived for home use.

“Accurate and reliable in-office A1C testing with the A1CNow+ monitor provides immediate results for patients and physicians. This more convenient approach to blood monitoring and patient/doctor consulting can help improve diabetes management by creating the most effective treatment plan at the time of consultation, without delay.” said Thorsten Petruschke, MD, Director of Medical, Clinical & Scientific Affairs Bayer Diabetes Care Europe. “Bayer is proud to be able to offer patients a proven A1C monitor that can help simplify the lives of people with diabetes.”

Study Design and Results

Lithium-heparin full blood samples from 120 people with diabetes (A1C range 5–11%) were divided into aliquots for immediate precision and accuracy testing. Precision was assessed by calculating the coefficient of variation (CV) of repeat measurements (n=20) of four blood samples; two at normal (5.5% and 5.1%) and two at high (11.0% and 9.6%) A1C levels. Accuracy was assessed using correlation analysis to compare the A1C results of multiple blood samples over a wide A1C range obtained with the three assays systems.

CVs for the normal A1C level were 3.6% and 2.75% for the 5.5% and 5.1% A1C samples, respectively. A slightly high CV result (7.2%) at the A1C 11% level may be an artifact as the CV result for the A1C 9.6% sample was 3.07%, similar to those at normal A1C levels. The DCA 2000 and HPLC reference system were not significantly more precise than the A1CNow+ system at normal A1C levels or at A1C at 9.6%. In accuracy testing, regression coefficients of 0.96 and 0.98 were obtained for comparison of the A1CNow+ with the HPLC and DCA 2000 systems, respectively.

About A1C (HbA1c)

A1C is formed when glucose in the blood binds irreversibly to hemoglobin to form a stable glycated hemoglobin A1C complex. Since the normal life span of red blood cells averages about 120 days, the A1C level will change as new red blood cells are made.

A1C values are directly proportional to the average concentration of glucose in the blood over the past two to three months. A1C values are not subject to the daily fluctuations that are seen with blood sugar monitoring.

The ADA recommends that the test be performed every three months for patients who have A1C values at or above 7% and every six months for patients with A1C values below 7% as well as during treatment changes or after periods of elevated blood glucose levels. The ADA also added a recommendation for point-of-care A1C monitoring to their 2006 professional practice guidelines emphasizing the importance of routine real-time A1C monitoring of persons with diabetes.

The Diabetes Control and Complications Trial (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS) studies showed that lower A1C values are associated with prevention of, or significant decreases in, the development of serious eye, kidney and nerve disease. For every 1 percent reduction in A1C, the risk of developing eye, kidney and nerve disease associated with diabetes is reduced by 40 percent. (CDC National Diabetes Fact Sheet, United States, 2005).

The ADA clinical practice guidelines indicate diabetes is under control when the A1C result is less than 7% percent. The Links and Resources page of the ADA website (www.diabetes.org) contains several resources to assist patients and health care professionals in diabetes management.

Bayer HealthCare, Diabetes Care

Bayer HealthCare, Diabetes Care supports customers in 100 countries and stands in a long tradition of leading the way in diabetes care product innovation since the introduction of CLINITEST reagent tablets in 1941. The face of diabetes care was changed in 1969 when the first portable blood glucose meter and test strips were introduced. Bayer HealthCare further innovated diabetes management by being the first company to introduce a suite of blood glucose monitors with No Coding™ technology. The BREEZE®2 and CONTOUR® blood glucose monitoring systems offer people with diabetes an unparalleled choice in diabetes management systems. In July 2006, Bayer HealthCare Diabetes Care acquired Metrika Inc., maker and manufacturer of A1CNow+, a meter-based diabetes monitoring system for measurement of A1C (glycated hemoglobin) an important indicator of long term blood sugar control. Bayer HealthCare Diabetes Care global headquarters is located in Tarrytown, New York, in the United States and operates as part of Bayer HealthCare LLC, a member of the worldwide Bayer HealthCare group. The Headquarters for the region Europe-MERA is located in Basel as part of Bayer Consumer Care AG, in Basel.

Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subsidiary of Bayer AG, is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Diabetes Care and Pharmaceuticals divisions. The pharmaceuticals business operates under the name Bayer Schering Pharma. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. Find more information at www.bayerhealthcare.com.

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