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New Aid to Diagnose Diabetes and Identify At-risk Patients

Siemens DCA HbA1c Test Kit for DCA Systems

The proven technology you trust. Not just for monitoring.

In 2009, the key diabetes associations recommended expanding the utility of hemoglobin A1c (HbA1c) testing to include not only monitoring glycemic control but also diagnosing diabetes and pre-diabetes. As part of our commitment to fighting chronic disease, the Siemens DCA® HbA1c Test Kit #10698915¹ can be used to identify at-risk patients, and diagnose and monitor diabetes.

HbA1c Level	Guidelines
6.5% 48 mmol/mol	Indicates diabetes
5.7–6.4% (39–46 mmol/mol)	May indicate pre-diabetes

What are the accepted clinical guidelines?²

- Pre-diabetic or at-risk patients should make lifestyle changes to stay in the safe range.
- Diabetic patients should keep HbA1c levels below 7% to minimize the risk of diabetes complications. More—or less—stringent goals may be assigned based on the patient profile.
- HbA1c levels should be measured every 3 months to monitor glycemic control.

The power to practice preventive healthcare

Of the 371 million people living with diabetes in 2012, half were undiagnosed.³ In-office testing with the DCA HbA1c test kit gives primary-care professionals the tools to fight this epidemic on the front lines. Early detection and tight glycemic control help mitigate the serious conditions that accompany diabetes: heart and kidney disease, limb neuropathy, retinopathy, and stroke. More importantly, patients identified as being at risk can stop or reverse disease progression through lifestyle adjustments and/or pharmacological treatment.



Make testing easy and convenient

- Simple, finger-stick test with small 1 uL sample size
- Immediate HbA1c results in just 6 minutes—during the patient visit
- No need for fasting or dietary changes before testing
- More convenient than ingesting glucose beverage and enduring multiple blood draws over a 3-hour period



DCA HbA1c Kit: One kit for diagnosis and management

- Intended use aligns with clinical-practice guidelines
- Identical test procedure—no need for special staff training
- No need to stock extra inventory or order different testing kits
- No software upgrades needed for existing DCA 2000® and DCA Vantage® systems

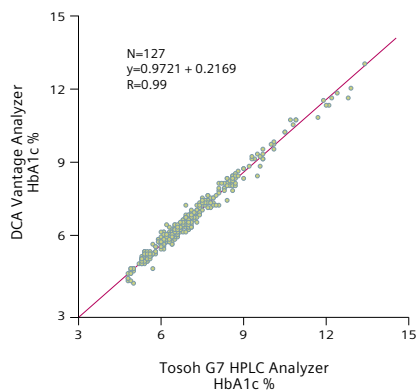
To enhance patient counseling, the DCA Vantage Analyzer provides HbA1c trend graphs to track progress. The analyzer can also convert and report HbA1c results as Estimated Average Glucose⁴ (eAG) values in mg/dL units that are familiar to patients.

Answers for life.

Precise results and good correlation to laboratory methods

Test precision provides confidence that fluctuations in reported results are most likely due to changes in patient status and not test-method variation. The DCA HbA1c test has demonstrated the tight precision necessary when tracking a patient's HbA1c status and making treatment decisions over time.

Comparison of DCA Vantage analyzers versus Tosoh G7 instrument



A total of 127 patient samples were tested, comparing the DCA HbA1c test to the Tosoh NGSP-certified laboratory method. The DCA HbA1c test correlates well, with a correlation coefficient of 0.99.⁵

Proven performance

- An in-house precision study was conducted with a total of 2,160 tests performed. Three different levels of clinical samples were tested in duplicate, twice per day, over 20 days. Three DCA Vantage analyzers and three lots of DCA HbA1c reagent were used. Study results demonstrate very tight precision with coefficient of variation (CV) of 2.0% or less:

HbA1c Level%	CV
5.0%	1.76%
6.5%	1.73%
8.0%	2.02%

- CAP proficiency survey results are published bi-annually at www.ngsp.org. In the December 2012 report, CV ranged from 2.6–2.8% across all target HbA1c levels tested, based on results reported by more than 300 DCA system users.
- Siemens DCA™ systems have consistently achieved annual IFCC and NGSP certifications for more than a decade.

The analyzer that physicians trust

With robust technology highlighted in more than 140 clinical articles, DCA systems are used by three out of four physicians who perform HbA1c testing in the office.⁶ The DCA Vantage Analyzer is one of just two point-of-care HbA1c analyzers that meet tightened NGSP performance criteria.⁷

References:

- Not all product offerings are available in all countries. Not available for sale in the U.S. Kit #10698915.
- Standards of Medical Care in Diabetes - 2012. Diabetes Care, Volume 35; S11-S63, Supplement 1, January 2012.
- International Diabetes Federation. IDF Diabetes Atlas Fifth Edition. Available at: <http://www.idf.org/diabetesatlas/europe>. Accessed 8/2/12.
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- DCA Systems Hemoglobin A1c Addendum to Instructions for Use. 10698776 Rev A, 2012-08.
- GHX Market Intelligence, market data report. Q3 2009 Raw Data File.
- Lenters-Westra E, Slingerland RJ. Clin Chem. 2010;56(1):44.

Siemens Healthcare Diagnostics, a global leader in clinical diagnostics, provides healthcare professionals in hospital, reference, and physician office laboratories and point-of-care settings with the vital information required to accurately diagnose, treat, and monitor patients. Our innovative portfolio of performance-driven solutions and personalized customer care combine to streamline workflow, enhance operational efficiency, and support improved patient outcomes.

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Global Siemens Headquarters

Siemens AG
Wittelsbacherplatz 2
80333 Muenchen
Germany

Global Siemens Healthcare Headquarters

Siemens AG
Healthcare Sector
Henkestrasse 127
91052 Erlangen
Telephone: +49 9131 84-0
Germany
www.siemens.com/healthcare

Global Division

Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591-5005
USA
www.siemens.com/diagnostics

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