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News and Information from Tosoh Bioscience, Inc.

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Tosoh Bioscience, Inc. Introduces the ST AIA-PACK HbA1c Assay on the AIA-360 and AIA-600 II Analyzers

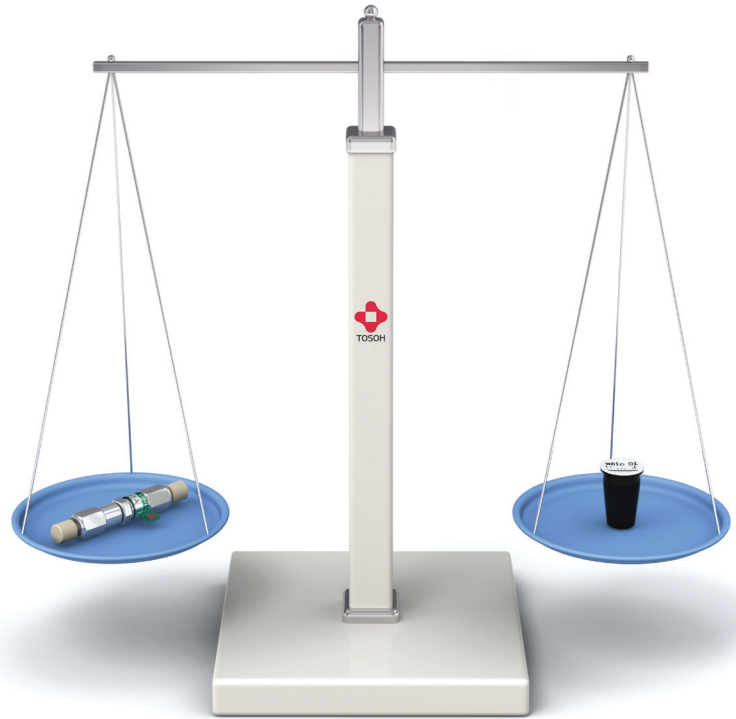
A Complete Solution for HbA1c Testing

Tosoh Bioscience, Inc., a pioneer in HPLC HbA1c testing has developed an HbA1c test that uses Tosoh's well known "Unit Dose Test Cup" technology for the AIA-360 and AIA-600II analyzers.

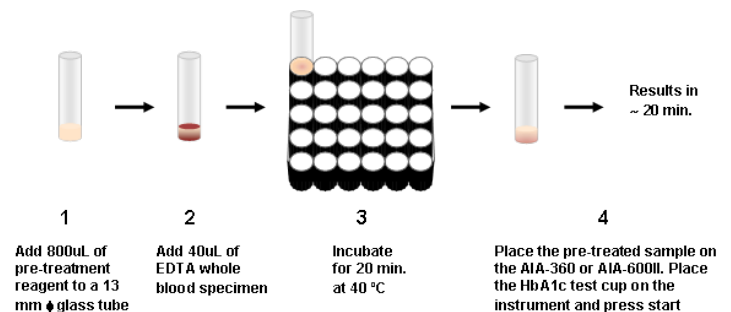
The ST AIA-PACK HbA1c assay uses EDTA whole blood specimens and is available in the 10 minute incubation format. The final result is in HbA1c % and does not require separate measurements of total hemoglobin and HbA1c. The ST AIA-PACK HbA1c is directly traceable to the International Federation of Clinical Chemistry (IFCC) reference calibration. Calibrator values are provided in both IFCC and NGSP units. The ST AIA-PACK HbA1c is NGSP certified on the AIA-360 and AIA-600II analyzers.

The ST AIA-PACK HbA1c has been shown to be substantially equivalent to the HPLC method - Tosoh Automated Glycohemoglobin Analyzer HLC-723G7. The ST AIA-PACK HbA1c assay has no interference from variants HbC, HbD and minimal interference with HbS and HbE. HbF does not interfere with the assay result up to HbF concentrations of 10%. The ST AIA-PACK HbA1c has a within run precision of <2% and a total precision of <4%. The unit dose test cup and 90 day calibration stability help low volume HbA1c users to minimize costs and prevent reagent wastage.

Tosoh believes that HPLC is the gold standard for HbA1c testing and offers the ST AIA-PACK HbA1c as a cost effective solution for low volume laboratories to expand their immunoassay test menu without compromising quality.



HbA1c Results in 4 Easy Steps:



If you need assistance in setting up the test file, please contact Tosoh Technical Support at 1-800-248-6764

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(continued)

ST AIA-PACK HbA1c Product Information

ASSAY SPECIFICATIONS	
Specimen Type	EDTA Whole Blood
Assay Time	~20 minutes
Calibration Stability	90 days
Assay Range	3.0 to 14.0 HbA1c% (NGSP%)
Reference Range	3.8 to 6.0 HbA1c% (NGSP%)
Within Run Precision	< 2.0 %
Total Precision	< 4.0%

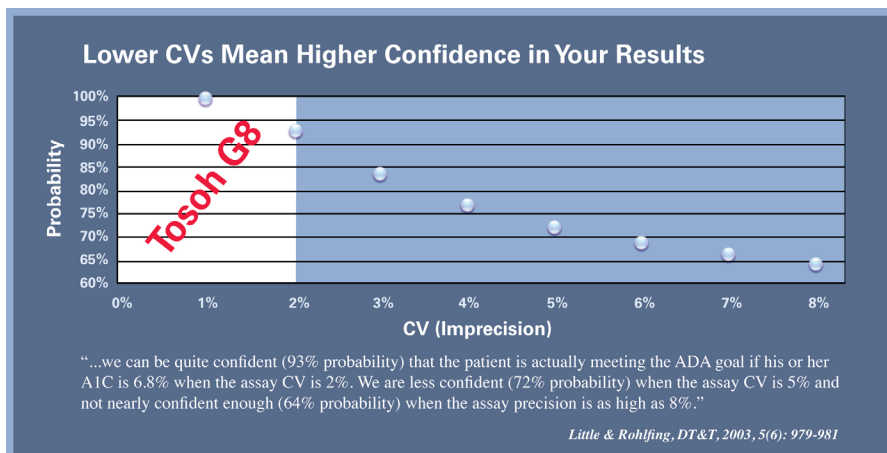


PACKAGING		
Part #	Product name	Description
025218	ST AIA-PACK HbA1c	20 cups x 5 trays (100 tests)
025318	ST AIA-PACK HbA1c Calibrator Set	6 levels, Level 1 - 2 x 5 mL Levels 2 to 6 - 10 x 0.6 mL (Lyophilized)
025418	ST AIA-PACK HbA1c Control Set	2 levels, 4 x 1 mL (Lyophilized)
025718	ST AIA-PACK Pretreatment Solution	4 x 50 mL

The Importance of Accuracy and Precision for HbA1c Results

It is becoming more important for laboratories to measure HbA1c on analyzers which have high levels of both accuracy and precision. In order to achieve these goals, analyzers should have low CVs and little to no bias. The Tosoh G8 analyzer leads the industry in precision with CVs of less than 2% and is utilized by physicians to monitor the long-term efficacy of glycemic control. A high quality HbA1c result is essential because it ultimately decides the course of treatment for a diabetic patient.

To help improve the quality of the HbA1c result, the College of American Pathologists (CAP) has further tightened their proficiency grading criteria to $\pm 7\%$ for 2011 and the National Glycohemoglobin Standardization Program (NGSP) has tightened manufacturer certification criteria to $\pm 8\%$. These efforts are intended to urge manufacturers to improve the quality of the HbA1c and encourage laboratories to use analyzers that provide high quality results.



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Training DVDs Available for the AIA-360 and AIA-600II

The Training DVDs for the AIA-360 and AIA-600II are now being included in the supplemental accessory kit shipped with each analyzer.



This DVD introduces you to the analyzer and takes you through all aspects of operation, including running a calibration, running samples, performing maintenance and making dilutions.

If you have not received this DVD with your analyzer and would like one, please call customer service at 1-866-527-3587 and have your customer number ready.

The part number for the AIA-360 Training DVD is 260004. The part number for the AIA-600II Training DVD is 997022.

New Training Tool Available for the G8 Analyzer

We are proud to announce the availability of a new training tool, the G8 Training DVD which is now being sent with all new G8 analyzer installations.



The G8 Training DVD is intended to be used along with the G8 Training Manual for additional customer training needs. The DVD shows step-by-step instructions for everyday operation and periodic maintenance. It is organized by topic so that you can just go to the exact section you need.

If you are an existing G8 customer please contact Customer Service if you would like to receive a copy of the G8 Training DVD. The part number for the G8 Training DVD is 997032.