



TOSOH BIOSCIENCE, INC.

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Tosoh Bioscience Launches the G8 Software Version 5.24F for Enhanced Reportability of A1c in Presence of Variant Hemoglobins

South San Francisco, CA - August 16, 2021 - Tosoh Bioscience, Inc. has received the 510k clearance for the Software Version 5.24F on the HLC-723G8 HPLC Analyzer for HbA1c testing. The HLC-723G8 HPLC Analyzer (commonly known as the G8) was introduced in the US market in 2008. The G8 was the first HPLC analyzer to get the diagnosis for HbA1c claim in 2014. The release of the 5.24F software further enhances the features of the G8 analyzer. The HbA1c is reportable in the presence of heterozygous HbS, HbC, HbD and HbE. With this software release, a matrix comparison for K2 EDTA and K3 EDTA was also completed that allows the use of both matrices on the G8 analyzer.

About the G8 Analyzer:

The Tosoh Automated Glycohemoglobin Analyzer HLC-723G8 is intended for in vitro diagnostic use for the quantitative measurement of % hemoglobin A1c (HbA1c) (DCCT/NGSP) and mmol/mol hemoglobin A1c (IFCC) in venous whole blood specimens. This test is to be used as an aid in diagnosis of diabetes and as an aid in identifying patients who may be at risk for developing diabetes, and for monitoring of long-term blood glucose control in individuals with diabetes mellitus.

The Tosoh G8 Analyzer is a fully automated A1c analyzer that uses Ion-Exchange High Performance Liquid chromatography. With Tosoh's unique and proprietary resin, the HPLC column delivers high quality separation of Stable A1c from other hemoglobins. Providing an accurate patient A1c result in the presence of most commonly occurring hemoglobins S, C, D and E is important especially considering the racial and ethnic diversity of the population in the US. With the G8 version 5.24F A1c is reportable in the presence of heterozygous HbS, HbC, HbD and HbE.

The G8 is a versatile analyzer that can accommodate low to high testing volumes making it a solution of choice for low to mid to high throughput HbA1c. Tosoh's G8 has consistently shown a CV of less than 2% over the last several years on the CAP Survey making it a reliable and precise analyzer. With a compact footprint of 21" w x 19" h x 20" d, the G8 fits easily in most laboratory environments. The G8 is ideal for hospitals, core labs, and physician office labs. Simple touch-screen operation for automatic start-up and daily maintenance makes the system extremely user-friendly. Sample pre-treatment is eliminated, as the G8 utilizes direct primary tube sampling and cap-piercing. The G8 is also equipped with a sophisticated STAT Port. The G8 easily adapts to changing laboratory workloads by offering a choice of either a 90 sample loader or a 290 sample loader. With the optional LA (Line Automation) model linked via a sample belt line, the G8 can handle a massive workload.

The G8 also comes with an optional 501RP+ software that provides reagent management and automated result review features. Tosoh offers the Reporting Software option for laboratories that would like to have an electronic backup of testing data with the added convenience of track and trend capabilities, an on-board QC program and assist with laboratory validated auto-verification.

ABOUT TOSOH BIOSCIENCE, INC:

Tosoh Bioscience, Inc. (TBI) provides highly sophisticated diagnostic systems for immunoassay and HPLC testing to doctor's offices, hospitals and reference laboratories throughout the Americas. Based in South San Francisco, CA, TBI is a U.S. subsidiary of Tosoh Corporation which is headquartered in Tokyo, Japan. TBI is part of Tosoh Corporation's Bioscience Division.

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