



TOSOH BIOSCIENCE, INC.

Tosoh G8: First HPLC Analyzer Cleared by FDA for Diagnosis of Diabetes

South San Francisco, CA -- January 23, 2014 – The Tosoh G8 (Tosoh Automated Glycohemoglobin Analyzer HLC-723G8) has been cleared by the FDA as the first HPLC instrument to be used as an aid in diagnosis of diabetes and identifying patients who may be at risk for developing diabetes.

The Tosoh G8 was initially cleared by the agency in 2008 as a diabetes monitoring device. The intended use has now been expanded so the Tosoh G8 can be used for screening as well. The ADA Clinical Practice Recommendations state that HbA1c can be used to diagnose diabetes using a NGSP-certified method and a cutoff of HbA1c $\geq 6.5\%$.

As compared to other HbA1c testing devices, HPLC methodology is considered the gold standard methodology as it allows for the visual identification of hemoglobinopathies that can interfere with the HbA1c result. Senior HPLC Product Manager Ranka Milojkovic says: "HbA1c is too important of a test for you not to be able to see all that is behind the actual number. You can't just trust that you got the right number; you have to be able to see it with your own eye. Seeing truly is believing."

Also, as the industry leader in precision, the Tosoh G8 has demonstrated high pass rates and CVs of less than 2% in proficiency tests which Milojkovic states, "Having such a high level of precision gives you the confidence that you're getting the right result every time you test."

Finally, Tosoh designed G8 functions from the user perspective, enhancing overall safety and convenience of operation. Ease of use features like flag level sophistication ensure that only the highest quality HbA1c results are being reported. With a compact footprint of 21" w x 19" h x 20" d, the G8 fits easily in most laboratory environments. The G8 provides fast results with an HbA1c analysis time of only 1.6 minutes. Simple touch-screen operation, automatic start-up and daily maintenance make the system extremely user-friendly.

Sample pre-treatment is unnecessary, as the G8 utilizes direct primary tube sampling and cap-piercing. A variety of different sized tubes can be loaded continuously. The operator can also run primary and secondary tubes in the same rack. The G8 easily adapts to changing laboratory workloads by offering a choice of either a 90 sample loader or a 290 sample loader.

Tosoh Bioscience is a world leader in the development of products for HPLC and diabetes monitoring and diagnosis. For more information, contact Tosoh Bioscience at (800) 248-6764 or visit <http://www.diagnostics.us.tosohbioscience.com>.

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