



PRESS RELEASE

Tosoh Announces 510k Clearance for Highly Anticipated Next-Generation GR01 HbA1c Analyzer: A Fast, Accurate and Efficient Solution for A1c Testing

Grove City, OH – [October 3, 2025] – Tosoh Bioscience, Inc., a market leader in clinical diagnostics is proud to announce that it has received US FDA 510(k) clearance for its next-generation system for HbA1c testing - the Tosoh Automated Glycohemoglobin Analyzer HLC®723-GR01 (hereafter “GR01”). The GR01 is intended for monitoring the long-term blood glucose control of individuals with diabetes, as an aid in the diagnosis of diabetes and to help identify those who may be at risk of developing the disease.

With a compact footprint, the GR01 is a fully automated analyzer that harnesses Tosoh’s proprietary non-porous ion exchange HPLC column technology to deliver precise, reproducible A1c results in just 50 seconds — while also detecting the most common hemoglobin variants.

The system delivers excellent precision with CVs \leq 1.1% (NGSP Units). This provides clinicians with higher confidence while diagnosing and managing diabetes.

The GR01 is an ideal solution for both mid and high volume laboratories, offering the speed and efficiency of a high throughput system without the complexity or size typically associated with large analyzers. The analyzer’s automatic buffer change feature keeps the lab running smoothly with no workflow delays.

The analyzer is designed for walkaway operation and user-friendly capabilities to help laboratories save time and labor. The GR01 has an intuitive user interface and seamless integration with a Laboratory Information System (LIS).

“The GR01 is the next step in our legacy of world-renowned analyzers for A1c testing. We are beyond excited to share this system with the community of clinicians working in diabetes management in the United States” said Jim Shaffer, executive vice president at Tosoh Bioscience, Inc.

To receive more information about the GR01 analyzer please visit:

lab.tosoh.com/gr01



TOSOH BIOSCIENCE

For more information about Tosoh Bioscience, Inc. please visit our website:

www.tosohbioscience.us

ABOUT TOSOH BIOSCIENCE, INC:

Tosoh Bioscience, Inc. provides highly sophisticated diagnostic systems for immunoassay and HPLC testing to doctor's offices, hospitals and reference laboratories throughout the Americas. Based in Grove City, OH, Tosoh Bioscience, Inc. is a U.S. subsidiary of Tosoh Corporation which is headquartered in Tokyo, Japan, and is part of Tosoh Corporation's Bioscience Division under the Tosoh Bioscience global brand.

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