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Tosoh G8 Software Version Reference in Third Party Publications and Website References

Tosoh Bioscience, Inc. is committed to providing the highest quality products in the market.

In 2021 Tosoh Bioscience received 510k approval (K200904) for marketing the 5.24 software version (referred to as G8 5.24F) of the HbA1c assay on the G8 HPLC analyzer. Tosoh G8 analyzers on the market have successfully been upgraded to the newest software version. With this software version there is no clinically significant interference with the most commonly occurring hemoglobins such as Hemoglobin S, C, D and E traits. This is a key improvement from the prior version 5.23.

There are some third-party publications and websites that mention Tosoh A1c G8 analyzers but do not specify the software version. There are websites that generally state "Tosoh analyzers" but do not specify the model nor the software version and claim that Tosoh A1c analyzers show interference with variants. Without specific reference to the model and software version, such statements can be misleading.

Always ensure that you are well informed about what software version is being referred to in published materials.

Any published work on the Tosoh G8 prior to 2021 in the US is likely to have used the prior software version (version 5.23). Therefore, any claims made towards performance of G8 in presence of variants using a version prior to 5.24 is not the updated version and not reflective of current performance claims.

Here is an example of a publication where the G8 software version has been referenced correctly:

Evaluation of Interference from Hemoglobin C, D, E and S traits on Measurements of Hemoglobin A1c by Fifteen Methods

Clin Chim Acta. 2021 November ; 522: 31–35. doi:10.1016/j.cca.2021.07.027

Tosoh analyzer G8 with HbA1c assay software version 5.24 and above do not show clinically significant interference in HbA1c results in the presence of common variant hemoglobin traits.

Abstract

BACKGROUND: Hemoglobin C, D Punjab, E or S trait can interfere with hemoglobin A1c (HbA1c) results. We assessed whether they affect results obtained with 15 current assay methods.

METHODS: Hemoglobin AA (HbAA), HbAC, HbAD Punjab, HbAE and HbAS samples were analyzed on 2 enzymatic, 4 ion-exchange HPLC and 9 immunoassay methods. Trinity Premier Hb9210 boronate affinity HPLC was the comparative method. An overall test of coincidence of least-squared linear regression lines was performed to determine if HbA1c results were statistically significantly different from those of HbAA samples. Clinically significant interference was defined as >6% difference from HbAA at 6 or 9% HbA1c compared to Premier Hb9210 using Deming regression.

RESULTS: All methods showed statistically significant effects for one or more variants. Clinically significant effects were observed for the Tosoh G11 variant mode (HbAD), Roche b 101 (HbAC and HbAE) and Siemens DCA Vantage (HbAE and HbAS). All other methods (Beckman Coulter B93009 and B00389 on DxC700AU, and Unicel DxC, Ortho Clinical Vitros 5.1, Roche cobas c 513, Siemens Dimension RxL and Vista, and Enzymatic on Advia and Atellica, Tosoh G8 5.24 and 5.28, and GX) showed no clinically significant differences.

We thank you for your continued and dedicated support to Tosoh products.

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