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Evaluation of HbA1c Immunoassay on TOSOH AIA® Immunoassay Analyzer.

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Hemoglobin A1c (HbA1c) is known to be the most important indicator for a long-term assessment of the glycemic state for diabetic patients. According to the International Expert Committee with members appointed by ADA, EASD, and IDF, the A1C assay provides a reliable measure of chronic glycemia and correlates well with the risk of longterm diabetes complications, and the diagnosis of diabetes is made if the A1C level is >/= 6.5 %(1)
TOSOH developed HbA1c immunoassay for TOSOH AIA analyzers for which has provided more than 40 test items including tumor markers, cardiac markers, thyroids, reproductive hormones, etc. We had a chance to achieve performance testing and verify utility of AIA-HbA1c immunoassay using TOSOH AIA-600II.
TOSOH HbA1c immunoassay, ST AIA-PACK HbA1c*, is an enzyme immunoassay which, after pretreatment, is performed entirely in the test cups. The whole blood sample is firstly pretreated with the HbA1c Pretreatment Solution at 40°C for 20 minutes. The pretreated sample is then automatically sampled into an test cup. HbA1c present in the pretreated sample competes with hemoglobin to be captured on the magnetic beads and binds to enzyme-labeled sheep anti-HbA1c polyclonal antibody. After 10 minutes incubation at 37°C, the magnetic beads are washed to remove unbound materials and are then incubated at 37°C with a fluorogenic substrate, 4-methylumbelliferyl phosphate (4MUP). The amount of enzyme-labeled polyclonal antibody that binds to the magnetic beads is directly proportional to the percentage of HbA1c in the sample. A standard curve is constructed using the Calibrator Set aligned to NGSP %, and unknown percentage of HbA1c is automatically calculated using this curve.
The within-run and total precisions (CV%) determined based on guidance from CLSI Protocol EP5-A2 and using 5.4%, 8.3% and 13.2% whole blood control materials were 1.7 - 1.9% and 3.3 - 3.8 %. The linearity range was demonstrated as 2.2 - 15.3 %. No clinically significant interferences were observed in samples containing elevated concentrations of bilirubin, triglycerides, albumin, labile hemoglobin A1c, carbamylated and aldehyde hemoglobins. In the correlation study, the AIA-HbA1c gave a good correlation with commercial kits (TOSOH HLC-723G8 and Siemens DCA-2000) as: AIA-HbA1c = 0.94 x (HLC-723G8) + 0.37, r = 0.96, n = 89. AIA-HbA1c = 0.95 x (DCA-2000) + 0.16, r = 0.977, n = 89. In the case of samples containing hemoglobin variants including HbC, HbS, HbD and HbE, they did not affect the results obtained by AIA-HbA1c. HbF did not interfere with the assay up to 10.0% and specimens from anemic patients did not interfere with the assay for more or equal to 7.0 g/dL total hemoglobin concentration.
In conclusion, we confirmed TOSOH HbA1c immunoassay provided reliable performances for the screening and management of diabetic patients.