Announcement

International clinical harmonization of hemoglobin A1c in Japan: From JDS to NGSP values

The report from “The Committee on the Standardization of Diabetes Mellitus-Related Laboratory Testing” of Japan Diabetes Society (JDS)

In 2009, the International Expert Committee manifested the recommendation regarding the use of HbA1c in diagnosing diabetes mellitus as an alternative to glucose measurements \(^1\text{–}^3\). JDS extensively evaluated the usefulness and feasibility of the use of HbA1c in diagnosis of diabetes based on the Japanese epidemiological data and then the “Report of the Committee on the Classification and Diagnostic Criteria of Diabetes Mellitus” was published in Journal of Diabetes Investigation\(^4\) and Diabetetology International\(^5\). The new diagnostic criterion in Japan came into effect on July 1, 2010. According to the new version of the criteria, HbA1c (JDS) ≥ 6.1% is now considered to indicate a diabetic type, but it is also needed to confirm the previous diagnosis criteria of high plasma glucose (PG) levels to diagnose diabetes mellitus. If both any PG criteria and HbA1c in subjects have met the diabetic type, those patients are immediately diagnosed to be diabetes mellitus\(^4,^5\).

The HbA1c values are well measured by a high resolution type ion-exchange HPLC (KO 500) method. Furthermore, standardization of HbA1c in Japan has been initiated from 1993 and the serial reference materials from JDS Lot 1 to JDS Lot 4 are well certified using the DCM until now. In the new diagnosis criteria\(^4,^5\), the new cut point of HbA1c (JDS) 6.1% for diagnosis of diabetes mellitus, which is equivalent to the internationally used HbA1c (NGSP) 6.5%, since HbA1c (NGSP)(%) is reported to be equivalent to 1.019 x HbA1c (JDS)% + 0.3%, which is reasonably estimated by the equation of HbA1c (JDS)% + 0.4%, since the difference between the 2 equations is within error of HbA1c measurements (2 ~ 3%).

However, on October 1, 2011, Reference Material Institute for Clinical Chemistry Standards (ReCCS, Kanagawa, Japan) has been certified as Asian Secondary Reference Laboratory (ASRL) using KO 500 method and the reference materials JCCRM411-2 (JDS Lot 4) after successful completion of NGSP network laboratory certification. Therefore, the HbA1c value is now traceable to Diabetes
Control and Complications Trial (DCCT) reference method. The comparison has been performed with Central Primary Reference Laboratory (CPRL) in University of Missouri School of Medicine. Conversion equation from HbA1c (JDS) to HbA1c (NGSP) values is officially certified as follows; NGSP (%) = 1.02 x JDS (%) + 0.25%, conversely, JDS (%) = 0.980 x NGSP (%) – 0.245%. Based on this equation, in the range of JDS values ≤4.9%, NGSP (%) = JDS (%) + 0.3%, in the range of JDS 5.0~9.9%, NGSP (%) = JDS (%) + 0.4%, and in the range of JDS 10 ~ 14.9%, NGSP (%) = JDS (%) + 0.5%. These results indicate that the previous equation of NGSP (%) = JDS (%) + 0.4% is also confirmed in the present equation considering a 2~3% error of HbA1c measurements.

Thus, council meeting of JDS have finally decided to use HbA1c (NGSP) values in clinical practice from April 1, 2012, although HbA1c (JDS) values will be put down until people become familiar with the new expression. Finally, it is also important to have an emphasis that the new HbA1c (NGSP) values can be directly measured and printed out from April 1, 2012. However, both new diagnostic reference values and target values of glycemic control are all shifted to those equivalent values of HbA1c (JDS).

References