

HbA1c is an indispensable marker in the diagnosis and treatment of diabetes, and its change over time is important for diabetic patients. When patients are transferred or moved from different medical facilities, there is a special attention on the difference of the HbA1c value between facilities and analyzers.

The Yumizen M100 Banalyst can measure HbA1c using a dedicated chip that uses μ TAS technology. Reagents based on immunoturbidimetry are enclosed in the dedicated chip, sample weighing, reagent reactions, and measurement are performed inside the chip. In cooperation with Kyoto Prefectural University of Medicine (KPUM), the performance of the Banalyst HbA1c chip was evaluated (accuracy, repeatability, and correlation with HPLC).

1. Accuracy

JCCRM423-10b (Inspection Medical Standard Material Organization) was measured 10 times at each concentration and compared with the reference value. The mean value of each concentration was within the range of the uncertainty of the reference value, and high accuracy was confirmed.

	(NGSP%)		
	M	H	HH
Reference value	5.59	7.70	10.57
Uncertainty	0.14	0.19	0.25
Mean Banalyst value	5.63	7.67	10.53
Reference - Mean Banalyst value	0.04	-0.03	-0.04

2. Within run precision (repeatability)

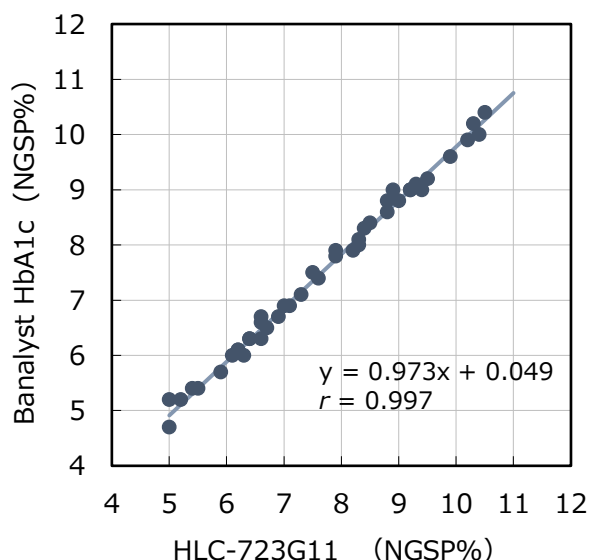
Each concentration of JCCRM423-10b was measured 10 times to determine the standard deviation (SD) and coefficient of variation (CV%). SD was 0.05, 0.05, 0.14, and CV was 0.86%, 0.63%, 1.35%.

		M	H	HH
Reference value	[NGSP%]	5.59	7.70	10.57
Mean Banalyst	[NGSP%]	5.63	7.67	10.53
SD	[NGSP%]	0.05	0.05	0.14
CV	[%]	0.86	0.63	1.35

N=10

3. Correlation with HPLC method

43 EDTA whole blood samples were measured with the Yumizen M100 Banalyst and Tosoh automatic glycohemoglobin analyzer HLC-723G11, and the correlation was confirmed. The linear regression equation was $y = 0.973x + 0.049$ and the correlation coefficient was 0.997.



HPLC = High-Performance Liquid Chromatography

Comment from Dr. Toru Inaba (Clinical Laboratory Specialist) KPUM

Clinics that provide daily medical care for diabetics have been using small HbA1c devices and are increasing the number of in-house measurements. When selecting medical equipment, particularly for patients going back and forth between multiple medical institutions, it is important to confirm the basic performance to obtain reliable data

Check this video to see what happens inside the Banalyst chip!

