

HbA1c calibrator

Hemoglobin A1c Calibrator Set

revised 2018.12.

Intended Use

This product is for purpose of calibrating results in the quantitative determination of human hemoglobin A1c(HbA1c) in blood automated immunoassay. For in vitro diagnostic use only.

HBV Ag. Ab :	Negative	(-)	Negative	(-)
HCV Ag. Ab :	Negative	(-)	Negative	(-)
HIV Ag. Ab :	Negative	(-)	Negative	(-)
TP :			Negative	(-)
ATLV Ab. :			Negative	(-)

Preparation and storage

Reconstitute each calibrator vial using 1.0ml of deionized water. Mix gently and stand 1 hour before use. Store in 2~8 °C and use within 10 days after reconstituted calibrators.

Lot No. : 138ACJ

Manufacture Date : 2023.10.02.

Exp. Date : 2025.04.

【Calibrator value】

For the red blood cell method.

Level	color (cap)	HbA1c (3 comp.)		HbA1c II (2 comp.)	
		IFCC (mmol/mol)	NGSP (%)	IFCC (mmol/mol)	NGSP (%)
O	Blue (capsule)	0	0.0	0	0.0
L	Green (capsule)	38	5.6	39	5.7
M1	Yellow (Capsule)	61	7.7	61	7.7
M2	Orange (capsule)	110	12.2	111	12.3
H	Pink (capsule)	163	17.1	163	17.1

For the whole blood method.

Level	color (cap)	HbA1c (3 comp.)		HbA1c II (2 comp.)	
		IFCC (mmol/mol)	NGSP (%)	IFCC (mmol/mol)	NGSP (%)
O	Blue (capsule)	There are no target assigned for 3comp reagent		0	0.0
L	Green (capsule)			44	6.2
M1	Yellow (Capsule)			68	8.4
M2	Orange (capsule)			122	13.3
H	Pink (capsule)			189	19.4

Calibration process may be affected by external conditions, contact your distributor for more details

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試験者	品質管理課長	製造管理者
		