

HAEMOGLOBIN A_{1c} CALIBRATOR (HbA_{1c} CAL)

CAT. NO. HA 3444

GTIN: 05055273203530

INTENDED USE

This product is intended for *in vitro* diagnostic use in the calibration of HbA_{1c} on clinical chemistry systems.

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

The calibrator must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions. Avoid contact with eyes, skin & clothing. Wash thoroughly after handling. Avoid ingestion.

Calibrator Level 1: Alkaline Solution containing 0.4% NaOH.

Health and Safety Data Sheets are available on request.

STORAGE AND STABILITY

Opened: Store refrigerated (+2°C to +8°C). Stable to expiration date, if kept capped in original containers and free of contamination.

Unopened: Store refrigerated (+2°C to +8°C). Stable to expiration date printed on the individual vials.

PREPARATION FOR USE

1. Mix by inversion at least 5 times to ensure homogeneity prior to use.
2. Refer to the Calibration section of the individual analyser application.
3. Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

N.B. Calibrators Do Not Require Pretreatment.

MATERIALS PROVIDED

Haemoglobin A_{1c} Calibrator Level 1 (1 x 8 ml)
 Haemoglobin A_{1c} Calibrator Level 2 (1 x 2 ml)
 Haemoglobin A_{1c} Calibrator Level 3 (1 x 2 ml)
 Haemoglobin A_{1c} Calibrator Level 4 (1 x 2 ml)
 Haemoglobin A_{1c} Calibrator Level 5 (1 x 2 ml)
 Haemoglobin A_{1c} Calibrator Level 6 (1 x 2 ml)

MATERIALS REQUIRED BUT NOT PROVIDED

None.

ASSIGNED VALUES

A value (mean) has been assigned to this lot of calibrator at Randox Laboratories Ltd.

LEVEL	SIZE	PROD. NO.	LOT NO.	EXPIRY	HbA _{1c} g/dl	TOTAL HAEMOGLOBIN g/dl
1	8 ml	HA022	2174HA	2021-02	0.00	18.98
2	2 ml	HA023	2175HA	2021-02	0.46	N/A
3	2 ml	HA024	2176HA	2021-02	0.62	N/A
4	2 ml	HA025	2177HA	2021-02	0.81	N/A
5	2 ml	HA026	2178HA	2021-02	1.28	N/A
6	2 ml	HA027	2179HA	2021-02	1.95	N/A

ASSIGNED VALUES

LEVEL	SIZE	PROD. NO.	LOT NO.	EXPIRY	HbA _{1c} μmol/l	TOTAL HAEMOGLOBIN mmol/l
1	8 ml	HA022	2174HA	2021-02	0.00	2.94
2	2 ml	HA023	2175HA	2021-02	1.74	N/A
3	2 ml	HA024	2176HA	2021-02	2.35	N/A
4	2 ml	HA025	2177HA	2021-02	3.07	N/A
5	2 ml	HA026	2178HA	2021-02	4.84	N/A
6	2 ml	HA027	2179HA	2021-02	7.38	N/A

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