

HbA1c control

Hemoglobin A1c Control 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. : 110ADE
Exp. Date : 2025. 11.

【Control value】

2022/11/21 reassigned

For the red blood cell method.

| Level | color (cap) | IFCC (mmol/mol) | NGSP (%) |
|-------|--------------------|-----------------|---------------------|
| L | Red (capsule) | 36 (29 - 42) | 5.4 (4.8 - 6.0) |
| H | Colorless(capsule) | 87 (75 - 98) | 10.1 (9.1 - 11.1) |

* 2comp. and 3comp. reagent are same target value.

For the whole blood method.

| Level | color (cap) | IFCC (mmol/mol) | NGSP (%) |
|-------|--------------------|-----------------|---------------------|
| L | Red (capsule) | 41 (34 - 48) | 5.9 (5.2 - 6.6) |
| H | Colorless(capsule) | 97 (84 - 109) | 11.0 (9.9 - 12.1) |

* no target value for 3comp reagent

manufactured by : UMA Co.,Ltd.
2-19-6 Yokosuka Matsudo City Chiba-Ken, 270-0031,
Japan, phone:+81-47-710-4871

| Tester | Quality Control Manager | Manufacturing Control Manager |
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