

HbA1c Control Set

■ Intended Use

Hemoglobin A1c (HbA1c) Control Set are intended for the use as an assayed quality control of quantitative HbA1c immunoturbidimetric assay. For *in vitro* diagnostic use only.

■ Preparation Procedure

1. Remove the seal and stopper from the vial.
2. Add 500µL of distilled water to the vial.
3. Allow the vials to stand for 30 minutes, then rotate gently until completely dissolved.

■ Handling Precaution

1. Do not interchange reagents between different lot numbers.
2. Repeated freeze-thaw cycles must be avoided
3. Although blood materials used for HbA1c controls have been tested and found negative for HBs antigen, antibody to HIV and antibody to HCV, it should be considered potentially infectious and handled in accordance with good laboratory practice using appropriate precautions.
4. In case reagents accidentally contacted either with eyes, mouth or skin, clean up the contacted parts with plenty of water as a first-aid treatment, consult a doctor, if such is required.
5. Reagent vials should be incinerated or disposed of in line with regulations on medical or industrial waste law.
6. Do not use the reagents in this kit for purposes other than HbA1c measurement.

■ Storage and Stability

Lyophilized vials of HbA1c Control stored at 2-8°C are stable until the expiration date on the label. Once reconstituted, HbA1c Control is stable at 2-8°C for a week.

■ Components

2 vials lyophilized

0.5 mL /vial

■ Assigned Value

Control	Label	Lot.	Expiry Date	Control Value(%)
CTL-L	White	W16D112W	2017.10	4.9-6.7%
CTL-H	Grey	W16D112W	2017.10	12.2-16.6%

The assigned % HbA1c values are lot specific and traceable to a NGSP (National Glycohaemoglobin Standardisation Program).