

CONTROL DILUTION SET 80

ALWAYS KEEP THIS PACKAGE INSERT ON HAND AND CAREFULLY READ IT BEFORE USE. IF YOU HAVE HAD OR COULD HAVE HAD ANY SERIOUS INCIDENT RELATED TO THE DEVICE, PLEASE REPORT IT DIRECTLY TO THE MANUFACTURER OR THROUGH THE AUTHORISED REPRESENTATIVE AND TO YOUR LOCAL REGULATORY AUTHORITY.

INTENDED PURPOSE

CONTROL DILUTION SET 80 is intended for the dissolution and dilution of commercially available freeze-dried control material for use with HA-8180V, HA-8380V or HA-8180T, which are intended for the quantitative measurement of HbA1c and HbA2. CONTROL DILUTION SET 80 is also intended for the dilution of whole blood samples. For *in vitro* diagnostic use and professional use only.

WARNINGS

- If DILUENT 80 or RECONSTITUENT 80 makes contact with eyes or mouth, immediately wash with plenty of water and consult a doctor.
- If it makes contact with skin, wash with plenty of water.
- Discard liquid waste that contains blood sample in accordance with local regulations for biohazardous waste.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- This set is only for HA-8180V, HA-8380V or HA-8180T. DO NOT attempt to use with other instruments. Please refer to the operating manual of the instrument.
- DO NOT use this set beyond its expiration date.
- The expiration date is written on both the box and bottle label.
- After opening, store the bottle at a temperature between 2°C and 8°C to prevent contamination by pathogenic microbes.
- Read the package insert that comes with commercially available controls carefully before use.
- Avoid mixing of reagents after opening the bottle.
- DO NOT use the prepared control if turbidity or foreign matter is present.
- Store the dissolved control at a temperature between 2°C and 8°C.
- Store the diluted whole blood sample and control at a temperature between 2°C and 8°C, and use within 12 hours. Use beyond 12 hours may produce inaccurate measurement results.

PROCEDURE

Whole blood samples (Preparing hemolysis samples)

- Add appropriate volume of DILUENT 80 to whole blood samples.
- The measurable hemoglobin concentration of a diluted hemolysis sample of HA-8180V or HA-8180T is 75 - 225 mg/dL (standard 150 mg/dL), whereas with HA-8380V, it is 45 - 140 mg/dL (standard 94 mg/dL).
- If the concentration does not fall within this range, an error message may be displayed or the reproducibility may become poor.
- If this happens, change the dilution ratio appropriately to adjust the concentration before performing the measurement again. (HA-8180V and HA-8180T use whole blood diluted 101 times, whereas HA-8380V uses whole blood diluted 161 times.)

STORAGE

Unopened: Store this set in a dark place at a temperature between 2°C and 30°C, avoiding direct sunlight.

Opened: Store the bottles tightly capped at a temperature between 2°C and 8°C.

MATERIALS PROVIDED

DILUENT 80: 250 mL X 1 bottle, phosphate buffer containing surfactant.

RECONSTITUENT 80: 15 mL X 1 bottle, phosphate buffer containing surfactant.

Materials of the bottle:

DILUENT 80: Polyethylene (PE) bottle with PE inner cap and polypropylene (PP) outer cap.

RECONSTITUENT 80: PP bottle with PP cap



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