

Intended Use

This product is for the purpose of monitoring accuracy and precision in the quantitative determination of human hemoglobin A1c (HbA_{1c}) in blood by FORA Hemoglobin A1c Analyzer systems. For *in vitro* diagnostic use only.

Summary

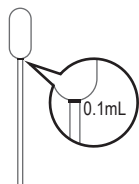
Quality control testing using the FORA Hemoglobin A1c Control Solution should be done to confirm that your FORA Hemoglobin A1c Analyzer System is working properly and provides reliable results. Only when controls are used routinely and the values obtained are within an expected range printed on the label can get accurate results for patient samples be assured.

Reagents

The lyophilized Hemoglobin A1c controls are hemolysates prepared from packed human erythrocytes. The controls provide two levels of Hemoglobin A1c, level 1 in the normal range and level 2 in the elevated range.

Reagent Preparation

1. Remove the protective seal on the vial.
2. Use dropper to reconstitute vials with 0.1 mL deionized water. Make sure the quantity of deionized water is just equal to 0.1 mL. Mix for 10 minutes and observe for undissolved material.



Note!

1. After mixing with deionized water, flick the vial for dissolving easily.
2. The droppers of L1 and L2 using for quality control test shall not be reused.
3. The air is not allowed to be in while sucking controls by the dropper.

Reagent Storage

1. Store controls at 2-8°C. Stable until expiration date if sealed tightly. PROTECT FROM LIGHT AND HEAT.
2. Reconstituted controls retain their assigned values for at least 3 weeks if stored at 2-8°C and sealed tightly.
3. In avoidance of a qualitative change from light and heat, it is recommended that the control solution test shall be done at room temperature no more than 30°C. Close the control tightly and put it into foil pouch within 1 minute after each use to protect from light. Store in the refrigerator as well. Do not take it out from the refrigerator for more than 30 minutes.

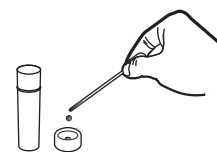
Precautions

1. This product is for *in vitro* diagnostic use only.
2. Although this product has been tested and found non-reactive for Hepatitis B Surface Antigen (HbsAG) and HIV, no known test can offer assurance that products derived from human blood will not transmit disease. Therefore all human serum products and patient specimens should be handled in the same manner as an infectious agent.
3. Do not pipette by mouth. Avoid contact with skin and mucous membranes.

Procedure

1. Import the lot information of cartridge by calibration card.
2. Remove one foil package (containing a reagent cartridge) and control solution from refrigerated storage.
3. Upon removal from refrigerated storage, allow the reagent cartridge and control solution to warm up at room temperature for 10 minutes (in the unopened foil pouch).
4. Open the foil package.
5. Remove the reagent cartridge from the foil pouch.

6. Squeeze out one drop of control solution and place it on the top of the vial pack.



7. Touch only the tip of capillary to the control solution. Control solution will automatically flow into the capillary.



8. Inserting the capillary holder into cartridge.
9. Insert the cartridge into the system.
10. Start the analysis.

Note!

1. Shake the vial thoroughly before use to ensure the control solution mixed well.
2. Avoid affecting the measuring results, do not suck up bubbles on the liquid while sucking the samples.

Materials Provided

1. Hemoglobin A1c control solution level 1
2. Hemoglobin A1c control solution level 2

Materials Required but not Provided

1. FORA Hemoglobin A1c Systems (FORA A1C100 Hemoglobin A1c Analyzer and FORA A1C101 Hemoglobin A1c Test Cartridge)
2. Deionized water

Limitations

Things to look for that might cause inaccurate results are improper pipetting and inadequate mixing.

Expected Values

See values listed on label. The assayed limits are to be used as a guide in determining the accuracy of the assay procedure. The assay results for the controls should fall within the stated expected range. If they do not, the assay should be repeated, checking closely for the factors mentioned in "Limitations".

Symbol	Referent
	<i>In vitro</i> diagnostic medical device
	Consult instructions for use
	Temperature limitation
	Use by
	CE mark
	Authorised representative in the European Union

Symbol	Referent
	Batch code
	Manufacturer
	Model number
	Caution, consult accompanying documents
	RoHS Compliance

ForaCare Suisse AG
Neugasse 55, CH9000, St. Gallen,
Switzerland
www.foracare.ch

MedNet EC-REP GmbH
Borkstraße 10, 48163 Münster, Germany

ACS025 (L1), ACS026 (L2)

20°C ± 0.5°C



**For use with the FORA A1C100 Hemoglobin A1c Analyzer
and FORA A1C101 Hemoglobin A1c Test Cartridge**