

CERA-STAT™ HbA1c Control Solution



Product description

- Intended use
 - CERA-STAT™ HbA1c Control Solution contains stabilized human glycosylated hemoglobin preparation.
 - Quality control using the CERA-STAT™ HbA1c Control Solution should be performed to confirm that the CERA-STAT™ 4000 Analyzer and CERA-STAT™ HbA1c Test Kit are working properly. Only when the control solutions are used routinely and the values obtained are within the acceptable ranges, the accuracy of test results can be assured.

Acceptable Range

	% HbA1c
Control Solution 1	6.0 ± 1.5 %
Control Solution 2	11.0 ± 2.0 %

- Kit contents
 - Control Solution 1
 - : 1 x 1.5mL – Normal: Stabilized human glycosylated hemoglobin preparation
 - Control Solution 2
 - : 1 x 1.5mL – Abnormal Stabilized human glycosylated hemoglobin preparation
 - Insert paper 1 unit
- Warnings and precautions
 - For *in vitro* diagnostic use only.
 - Use gloves and protective accessories when handling CERA-STAT™ HbA1c control solutions.
 - CERA-STAT™ HbA1c control solutions are derived from blood and should be handled as potentially infectious.
 - Do not use CERA-STAT™ HbA1c control solutions after their expiry date.
 - Discard the vial if there is any evidence of microbial or fungal contamination.
 - Do not use CERA-STAT™ HbA1c control solutions with non-compatible Hemoglobin A1c test device and accessories.

Stability and storage

- Avoid exposure to direct sunlight and temperature above 8°C.
- Do not freeze.
- Unopened control vials
 - The expiry date only applies if the product is stored under the temperature range, 2°C~8°C, in the original container.
- Opened control vials
 - The control solutions will be stable for thirty days after the first opening in condition of stored refrigerated(2°C~8°C) in original containers. Please, write the first opening date on the vial label.
 - Opened control vials should be stored in an upright position.
 - Keep the control solutions in the storage temperature, 2°C~8°C, after use.

Test procedure

- Remove the CERA-STAT™ HbA1c Control Solution vials from refrigerator and equilibrate to room temperature for a minimum 30 minutes.

- Shake the vials for a minimum 10 seconds until a uniform suspension is obtained.
- Remove cap from the vial and fill the capillary tube completely with the control solution.
- Clean the outside of the control solution vial neck and replace the cap.
- CERA-STAT™ HbA1c Control Solution should be assayed in the same manner as ordinary patient samples. Follow the test procedure described in the package insert, enclosed in the CERA-STAT™ HbA1c Test Kit.

Notice

- The acceptable range for analysis using CERA-STAT™ 4000 Analyzer and CERA-STAT™ HbA1c Test Kit has been stated on this insert. The measured value should be within this acceptable range. Retest the control solution if the control solution is outside the range. Retest a sample from a new control vial if the measured value is still outside the acceptable range. The control dose not perform as expected. If the problem persists, contact the customer service center.

Symbol Information

	In vitro diagnostic medical device
	Batch code
	Reference No.
	Temperature limitation
	Use by
	Caution, consult accompanying documents
	Consult instructions for use
	Manufacturer
	Date of manufacture
	European Authorized Representative

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