CH50 Calibrator

Intended use
The CH50 Calibrator is designed to be used with Autokit CH50 for the determination of total complement activity (CH50) in serum.

Reagents and ingredients
Calibrator 1 1 bottle x 0.5 mL
Calibrator 2 1 bottle x 0.5 mL
Calibrator 3 1 bottle x 0.5 mL
Calibrator 4 1 bottle x 0.5 mL
Calibrator 5 1 bottle x 0.5 mL
Contains human serum.

Reagent preparation
Remove vials from freezer. Remove the cap and stopper and gently tap down all lyophilized material to the bottom of the vial. Accurately add 0.5 mL of distilled or deionized water to dissolve the contents of each of the Calibrators. Replace the stopper securely. Make sure that all the lyophilized material is covered with fluid and allow the vials to stand at room temperature for 5 minutes with occasional, gentle shaking. When all the material has been reconstituted at the bottom of the vial, turn the vial on its side and allow the reconstituted material to “roll around” the walls of the vial by rotating the vial slowly. Invert the vial and allow the fluid to cover the stopper for 20-30 seconds with gentle shaking. Return the vial to the upright position and remove the stopper. Allow any fluid which may have been trapped in the stopper to drain down.

Once the Calibrator is reconstituted, keep the solution on ice for at least 30 minutes. Store at 2-8°C thereafter and use it within 8 hours.

Assigned values and their determination
Assigned values: See bottle labels.
Determination: Based on Mayer’s method1.

Storage condition
Store at –10°C or lower.

Warnings and precautions
For in vitro diagnostic use.
Not to be used internally in humans or animals.
Do not use this calibrator for any other purpose than described herein.
Human serum material was used in the manufacture of this calibrator. The raw human serum used was tested and found negative for HBsAg, anti-HIV antibody and anti-HCV antibody. Because no test can offer complete assurance that products derived from human blood will not transmit infectious agents, it is recommended that the calibrator should be handled with the same biohazard precautions used for patient specimens.
UDI (Unique Device Identification) is on the box. Keep box until reagent is finished.
Reference

Ordering information

<table>
<thead>
<tr>
<th>Code No.</th>
<th>Product</th>
<th>Package</th>
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<tbody>
<tr>
<td>997-43801</td>
<td>CH50 Calibrator</td>
<td>5 conc. x for 0.5 mL</td>
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Revision date: Apr. 1, 2018