

997-43801
112207

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

CAL 1	1 vial x for 0.5 mL
CAL 2	1 vial x for 0.5 mL
CAL 3	1 vial x for 0.5 mL
CAL 4	1 vial x for 0.5 mL
CAL 5	1 vial x for 0.5 mL

Contain human serum.

Calibrator preparation

For reconstitution of contents, add precisely 0.5 mL distilled or deionized water to each Calibrator vial. The reconstituted solution must be kept on ice for at least 30 minutes. Store at 2–10 °C thereafter and use it within 8 hours.

When you get ready to reconstitute, please follow this procedure:

1. Remove vials from freezer.
2. Remove the cap and stopper and gently tap down all lyophilised material to the bottom of the vial.
3. Immediately add the appropriate amount of cold (2–8 °C) distilled water directly to the lyophilised material.
4. Replace the stopper securely.
5. Making sure that all the lyophilised material is covered with fluid, allow the vials to stand at room temperature for 5 minutes with occasional, gentle shaking.
6. 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.
7. Invert the vial and allow the fluid to cover the stopper for 20–30 seconds with gentle shaking.
8. Return the vial to the upright position and remove the stopper.
9. Allow any fluid which may have been trapped in the stopper to drain down.
10. Use the material as directed. **DO NOT REFREEZE THESE MATERIALS!**

Assigned values and their determination

Value assigned: see bottle label
Determination: based on Mayer's method¹

Storage

Store at -10 °C or below.

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 use than described herein.
- The application of this test is reserved for professional use only. Please refer to applicable national and regional regulation and legislation also.
- Clinical diagnosis must be determined with clinical symptoms and other test results by a physician.
- The CH50 Calibrator has been prepared from human serum that was tested for HBsAg, anti-HIV antibodies and anti-HCV antibodies and found negative. 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.
- When discarding the reagents, dispose of them according to local or national regulations.

CH50 Calibrator contains components classified as follows according to Regulation (EC) No. 1272/2008:

Hazardous ingredients for labelling: boric acid

Signal word: danger

Pictograms

GSH08



Hazard statements

H360FD May damage fertility. May damage the unborn child (if swallowed).

Precautionary statements

P201 Obtain special instructions before use.

P280 Wear protective gloves/protective Clothing/eye protection/face protection/hearing protection.

P308+P313 IF exposed or concerned: Get medical advice/attention.

References

1. Mayer MM. Complement and complement fixation. In: Kabat EA, Mayer MM, eds. Experimental immunochemistry, 2nd ed. Springfield, IL: Charles C Thomas, 1967: 133-240

Bestellinformation

Bestellnummer	Produkt	Packung
997-43801	CH50 Calibrator	CAL: 5 Konz. x für 0,5 ml