

991-43701
1222D6

Intended use

The Wako Complement Control is intended for use as an assayed quality control serum in the clinical laboratory to monitor the accuracy and precision of complement testing utilizing the Wako Autokit CH50 test kit.

Reagents and ingredients

Complement Control L: 10 bottles x for 0.5 mL

Complement Control H: 10 bottles x for 0.5 mL

Contains human serum.

Reagent preparation

Accurately add 0.5 mL of distilled or deionized water to dissolve the contents of each of the Control.

Storage and stability

The Wako Complement Control will be stable until the expiration date on the vial label when stored unopened at -10 °C or lower. Once the Control is reconstituted, keep the solution on ice for at least 30 minutes. Store at 2–10 °C thereafter and use it within 8 hours.

Limitations

If there is evidence of microbial contamination or excessive turbidity in the reconstituted control, discard the vial.

Assignment of values

The values and acceptable ranges printed on the vial labels were derived from replicate analyses and are specific for this lot of Wako Complement Control. Since performance reflects instrument, reagent, technique and; method variations, it is recommended that each laboratory establish its own values and acceptable ranges. The values and acceptable ranges provided on the labels should be used only as a guide.

Warnings and precautions

- For *in vitro* diagnostic use.
- For professional use.
- Not to be used internally in humans and animals.
- Human serum material was used in the manufacture of this product. 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 this product 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.

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

Hazardous ingredients for labelling: boric acid

Signal word: danger

Pictograms

GHS08



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.

Ordering information

Code No.	Product	Package
991-43701	Complement Control	L: 10 x for 0.5 mL (Low) H: 10 x for 0.5 mL (High)

Manufacturer:

FUJIFILM Wako Chemicals Europe GmbH
Fuggerstr. 12 · 41468 Neuss · Germany
Telephone: +49 2131 311 272 · Fax: +49 2131 311 110
diagnostics_wkeu@fujifilm.com · wako-chemicals.de

Wako