

μTASWako DCP Control H

Symbols in Product Labeling

REF	Catalog number		Consult instructions for use
IVD	In vitro diagnostics medical device		Use by (last day of the month)
CONT.	Contents of kit		Caution
AC.	Accessory		Manufacturer
Adaptor	Adaptor		Temperature limitation
Holder	Holder		
LOT	Batch code		
EC REP	Authorized Representative in the European Community		
BL	Blank		
CAL	Calibrator		
CONTROL	Control		
CONC.	Assigned value		

Intended use

The Wako μTASWako DCP Control H is designed to be used as a quality control material for the quantitative determination of DCP in human serum using the Wako μTASWako DCP Immunological Test System.

Reagents and ingredients

μTASWako DCP Control H 4 × 2 mL
 27 mmol/L Good's buffer, pH 6.0
 Des-γ-carboxy-prothrombin

Store at 2–10°C. (Do not freeze)

Accessory

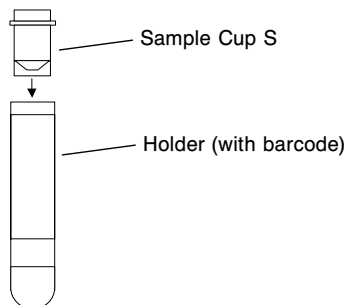
DCP Control H Holder (with barcode) 1 piece

Reagent preparation

Use the controls as supplied. Controls are stable until the expiration date printed on the label when stored at 2–10°C. (Do not freeze)

Procedure

The concentration of the analyte is supplied by the barcode attached to the holder included in the μTASWako DCP Control H. μTASWako i30 automatically obtains such information from the barcode when control is supplied together with the holder on the QC rack of μTASWako i30. Refer to μTASWako i30 Instruction Manual for the details of QC procedure. Sample cups are supplied separately.



Determination of assigned values

Assigned values : See bottle labels.

Determination : The assigned values are determined by measuring a control with the μTASWako DCP and calibrators for DCP whose DCP levels are traceable to the Wako 1st DCP standard. The 1st standard was prepared by in-house purification and its protein concentration was determined by the BCA method. (2)

Warnings and precautions

- (1) For in vitro diagnostic use.
- (2) Not to be used internally in humans or animals.
- (3) Do not use any control holder other than that included in the same Control H package.
- (4) Do not dispose the control holder until the control is consumed.
- (5) Do not use the controls for any other purpose than described herein.
- (6) Do not use the controls past the expiration date stated on each container label.
- (7) Do not use the controls in any other procedures than those described herein. Refer to the package insert of the μTASWako DCP and the μTASWako i30 Analyzer Instruction Manual for additional information on the procedure.
- (8) Store the controls under the specified conditions.
- (9) Do not use the controls if they are frozen by mistake, since optimal results may not be obtained with frozen, then thawed controls.
- (10) Do not use the containers for any purposes other than those described herein.
- (11) If the controls come in contact with the mouth, eye, or skin, wash the exposed area immediately with a large amount of water. Contact a physician if necessary.
- (12) The controls contain some human origin materials. The materials have been tested and found negative for HBsAg, anti-HIV-1/HIV-2 antibodies, and anti-HCV antibody. Because no test can offer complete assurance that products derived from human will not transmit infectious agents, it is recommended that this product should be handled with the same biohazard precautions used for patient specimens.
- (13) Dispose of controls according to your local or national regulations.
- (14) FDA UDI (Unique Device Identification) is on the box. Keep box until reagent is finished.

This product contains components classified as follows according to the European Regulation :

Hazard designation of product



Mixture containing:

5-Chloro-2-methyl-2H-isothiazol-3-one [EC No 247-500-7] and 2-Methyl-2H-isothiazol-3-one [EC No 220-239-6] (3:1)

Information pertaining to particular dangers for man and environment**Hazard statement**

May cause an allergic skin reaction.

Precautionary statement

Avoid breathing vapours/spray.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/ protective clothing/ eye protection.
If on skin : Wash with plenty of soap and water.
If skin irritation or rash occurs : Get medical advice/attention.
Wash contaminated clothing before reuse.
Dispose of contents or container in accordance with local/regional/national/international regulation.

References

- (1) Bajaj SP, et al. : J Biol Chem. Apr 10 ; 257(7) : 3726-3731, 1982
(2) Smith PK, et al. : Anal Biochem. Oct ; 150(1) : 76-85, 1985

Ordering information

Code No.	Product	Package
991-61401	μTASWako DCP Control H	4 × 2 mL
452-00501	Sample Cup S	1000 Pieces

Revision Date ; July. 2, 2018



μTASWako i30, its IVD reagent kits and the consumables developed by Wako use Wako's proprietary LBA-EATA assay technologies and microfluidic technologies licensed from Caliper Life Sciences, Inc.

Manufactured by
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