






# μTASWako DCP Calibrator Set

## Symbols in Product Labeling

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

### Intended use

The Wako μTASWako DCP Calibrator Set is designed to be used with the Wako μTASWako DCP Immunological Test System for the quantitative determination of DCP in human serum.

### Reagents and ingredients

μTASWako DCP Blank	3 × 2 mL
27 mmol/L Good's buffer, pH 6.0	
μTASWako DCP Calibrator 1	1 × 2 mL
27 mmol/L Good's buffer, pH 6.0	
Des-γ-carboxy-prothrombin	

Store at 2–10°C (Do not freeze)

### Accessory

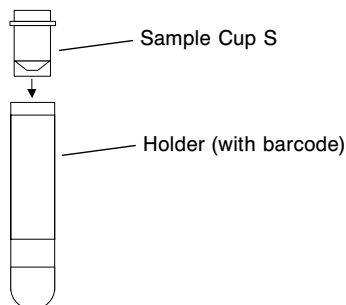
μTASWako DCP Blank Holder (with barcode)	1 piece
μTASWako DCP Calibrator 1 Holder (with barcode)	1 piece

### Reagent preparation

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

### Procedure

The concentrations of the analytes are supplied by the barcode attached to the holder included in the μTASWako DCP Calibrator Set. μTASWako i30 automatically obtains such information from the barcode when calibrators are supplied together with the holders on the QC rack of μTASWako i30. Refer to "μTASWako i30 Instruction Manual" for the details of calibration procedure. Sample cups are supplied separately.



### Determination of assigned values

Assigned values : See bottle labels.

Determination : Assigned values are determined by measuring a calibrator with the μTASWako DCP and the Wako 1<sup>st</sup> DCP standard<sup>(1)</sup>. The 1<sup>st</sup> standard was prepared by in-house purification and its protein concentration was determined by the BCA method<sup>(2)</sup>.

### Warnings and precautions

- (1) For in vitro diagnostic use.
- (2) Not to be used internally in humans or animals.
- (3) Do not use any calibrator holders other than those included in the same Calibrator Set.
- (4) Do not dispose the calibrator holders until the calibrators are consumed.
- (5) Do not use the calibrators for any other purpose than described herein.
- (6) Do not use the calibrators past the expiration date stated on each container label.
- (7) Do not use the calibrators 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 calibrators under the specified conditions.
- (9) Do not use the calibrators if they are frozen by mistake, since optimal results may not be obtained with frozen, then thawed calibrators.
- (10) Do not use the containers for any purposes other than those described herein.
- (11) If the calibrators 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 calibrators 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 bio-hazard precautions used for patient specimens.
- (13) Dispose of calibrators 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
999-61201	μTASWako DCP Calibrator Set	1 Set
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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