






μTASWako AFP-L3 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 AFP-L3 Control H is designed to be used as quality control material for the quantitative determination of AFP-L3% in human serum using the Wako μTASWako AFP-L3 Immunological Test System.

Reagents and ingredients

μTASWako AFP-L3 Control H 4 × 2 mL
 51 mmol/L Phosphate buffer, pH 6.0
 Human AFP-L1 and L3 fractions

Store at 2–10°C. (Do not freeze)

Accessory

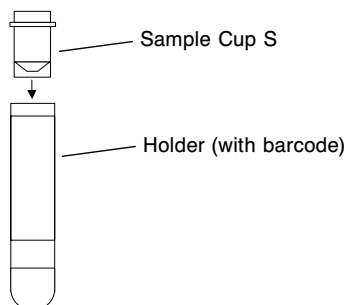
AFP-L3 Control H Holder (with barcode) 1 piece

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 AFP-L3 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 : A control is mixture of pure human AFP-L1 and L3 fractions. The assigned values are determined by measuring the control with μTASWako AFP-L3 and calibrators for AFP-L1 and L3 whose AFP levels are traceable to the 1st international standard for alpha-fetoprotein from NIBSC. Purity of AFP-L1 and L3 fractions is recognized by the method combining lectin-affinity electrophoresis and antibody-affinity blotting⁽¹⁾.

Warnings and precautions

- (1) For in vitro diagnostic use.
- (2) Not to be used internally in human 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 μTASWako AFP-L3 and μTASWako i30 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 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.

Reference

- (1) Establishment of assay kits for the determination of microheterogeneities of alpha-fetoprotein using lectin-affinity electrophoresis. Shimizu K., et al., Clin. Chim. Acta, **214**, 3-12, 1993

Ordering information

Code No.	Product	Package
993-61101	μTASWako AFP-L3 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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