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EU rev. CL-BHCG-030324

CL AIA-PACK® βHCG ADJUSTER SET

NAME AND INTENDED USE

CL AIA-PACK βHCG ADJUSTER SET is a single use reagent, designed for IN VITRO DIAGNOSTIC USE ONLY, by healthcare professionals, for adjusting the Master curve of the CL AIA-PACK βHCG TEST CUP using the automated Tosoh AIA®-CL Analyzers, for the quantitative measurement of Human Chorionic Gonadotropin (total beta hCG or βHCG) in human subjects.

SUMMARY AND EXPLANATION

The CL AIA-PACK βHCG ADJUSTER SET contains protein matrix with assigned levels of βHCG. Adjusting the Master curve of CL AIA-PACK βHCG TEST CUP should be performed according to the schedule indicated in the Tosoh AIA-CL Analyzer Operator's Manual.

MATERIAL PROVIDED

Cat. No. 0029228
24 cups 12 cups x 2 levels
CL AIA-PACK βHCG ADJUSTER (1) 10mIU/mL (approx.)
CL AIA-PACK βHCG ADJUSTER (2) 3,000mIU/mL (approx.)
Lyophilised protein matrix containing the assigned concentration of βHCG.

WARNINGS AND PRECAUTIONS

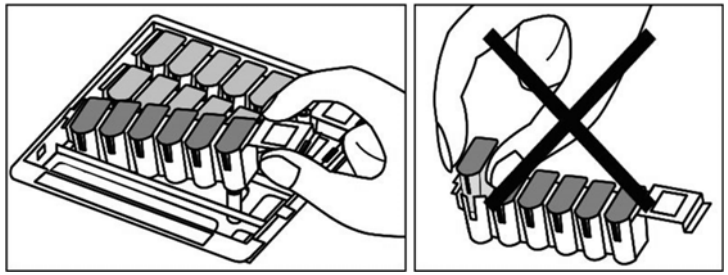
1. The CL AIA-PACK βHCG ADJUSTER SET is intended for in vitro diagnostic use only.
2. Inspect the packaging and the exterior of the aluminium pouch for any sign of damage before use. If any damages are visible, contact your local Tosoh sales representative.
3. The cups shall not be mixed within a strip nor between/among strips.
4. The adjuster material has been tested by FDA-approved methods and found negative for the presence of HBsAg, antibody to HIV-1/2 and HCV. Since no test method can offer complete assurance that products derived from human sources will not transmit infectious agents, it is recommended that this product be handled with the same precautions as used for patient samples.
5. Do not use beyond the expiry date.
6. For safe waste disposal, it is recommended that each laboratory complies with the established laboratory procedures and local, state, and federal regulations.
7. Tosoh recommends that a new pouch of the CL AIA-PACK βHCG TEST CUP be used for Master curve adjustment.
8. Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the regulatory authority (e.g. EU competent authorities) in the country where the user and/or patient is established.
9. Handle the cups with care and do not use any cups that have been dropped, or that have fallen down, which could cause erroneous results.

PREPARATION OF REAGENTS

1. Open the aluminium pouch and take out the tray (the Multi-purpose tray). Place the individual strips in the appropriate position on the instrument.
2. The CL AIA-PACK βHCG ADJUSTER SET is automatically reconstituted by the instrument.

< Handling of the Multi-purpose tray >

1. Since the names of the cups in a strip and their lot numbers are recognized by the test cup sorter of the instrument using the QR code® label on the strip, the individual strip can be set one by one.
2. When not being set on the instrument, the remaining individual strips should be stored at 2-8 °C.
3. After all the cups in a strip are used, the strip can be replaced with a new strip manually.
4. When replacing with a new strip, do not replace single cups in a strip as it causes a mismatch between the QR codes. Replace the entire strip with a new strip.
5. In one Multi-purpose tray, up to four different strips can be placed.



Refer to the Tosoh AIA-CL Analyzer Operator's Manual for additional handling information of the Multi-purpose tray.

STORAGE AND STABILITY

- While unopened and refrigerated at 2°-8 °C, the CL AIA-PACK βHCG ADJUSTER SET will remain stable until the expiry date on the label.
- Once the aluminium pouch is opened, the CL AIA-PACK βHCG ADJUSTER SET can be left on-board in the test cup sorter of the Tosoh AIA-CL Analyzers (kept at 2°-15 °C) for up to 180 days, unless its expiry date has passed.
- After opening the aluminium pouch, if the tray or remaining strips of the CL AIA-PACK βHCG ADJUSTER SET are stored refrigerated at 2°-8 °C, the product will be stable until the expiry date. If leaving the CL AIA-PACK βHCG ADJUSTER SET at 18-25 °C, the cups should be used within 24 hours.

PROCEDURE

Refer to the Instructions For Use of the CL AIA-PACK βHCG TEST CUP and the Tosoh AIA-CL Analyzer Operator's Manual for detailed instructions.

1. Place a sufficient quantity of the CL AIA-PACK βHCG TEST CUP and the CL AIA-PACK βHCG ADJUSTER SET on the instrument.
2. When using a new lot of the Adjuster Set, scan the QR code printed on the box label to enter the concentration values and lot number of the Adjuster Set into the Tosoh AIA-CL Analyzers. Refer to the Tosoh AIA-CL Analyzer Operator's Manual for details.
3. Select START. The Adjuster Set is automatically reconstituted and measured as a sample by the Tosoh AIA-CL Analyzers.

ASSIGNMENT OF VALUES

The CL AIA-PACK βHCG ADJUSTER SET contains the assigned concentrations of βHCG. The assigned values are determined on a lot-by-lot basis and are standardized against the WHO 5th International Standard Chorionic Gonadotropin, NIBSC Code 07/364.

RESULTS

The replicate values should be within a 10 % range.

LIMITATIONS

The CL AIA-PACK βHCG ADJUSTER SET is designed solely for use with CL AIA-PACK βHCG assay procedures on Tosoh AIA-CL Analyzers only.

TOSOH CORPORATION
2-2-1 Yaesu, Chuo-ku, Tokyo 104-0028 Japan
Phone: +81 3 6636 3734
Fax: +81 3 6636 3627

TOSOH EUROPE N.V.
Transportstraat 4
3980 TESSENDERLO, BELGIUM
Tel.: +32 (0)13 66 88 30 Fax: +32 (0)13 66 47 49

TOSOH BIOSCIENCE LIMITED
Lytchett House, 13 Freeland Park,
Wareham Road, Poole, Dorset, BH16 6FA, UK
Phone :+44 1527 592901
Fax :+44 1527 471680

TOSOH BIOSCIENCE SA
Ankerstrasse 24
8004 Zürich
Switzerland