

MULTICONSTITUENT CALIBRATOR

En

REF 06R56-02

FOR USE WITH
ARCHITECT

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package.

INTENDED USE

Archem Multiconstituent Calibrator is for calibration of the parameters stated in the value sheet.

CONTENTS / MATERIALS PROVIDED

Multiconstituent Calibrator

REF: 06R56-02

Package: 5 x 5 mL Lyophilized

06R56-02 contain the human serum

Sodium Azide (0,09 %) is added as preservative.

Materials Required But Not Provided:

1. Class A volumetric pipette for liquid transfer
2. Distilled or deionized water meeting the specifications equivalent to USP (United States Pharmacopeial Convention) purified water.

PREPARATION OF CALIBRATOR AND CONTROL

Lyophilized serum calibrator should be reconstituted by adding distilled or deionized water with the amount stated on the label. Close the vial and wait for 30 minutes. Dissolve the contents of the vial by swirling gently to avoid the formation of foam. Do not shake

CALIBRATOR AND CONTROL STABILITY

| Temperature-Conditions | Stability |
|---|--------------------------|
| Dry form and stored in a dark place at +2/+8°C | Expiry date on the vial. |
| Diluted and stored in a dark place at +25°C | 8 hours |
| Diluted and stored in a dark place at +2/+8°C | 2 days |
| Diluted, stored in a dark place and frozen at -20°C | 30 days |

LIMITATIONS

1. Please open the vial caps carefully. When you open, be careful not to scatter any powdery substance around or to escape from the vial.
2. Dissolve with distilled water with volume stated on the vial. Injector should not be used for the transfer process since

there may be errors between 5-20% in liquid transfer with the injector. Use calibrated micropipettes.

3. Temperature of dry serum in the vial and distilled water must be +20/+25°C. After adding distilled water, close the vial cap tightly and store at +25°C around 5-10 minutes.
4. Wait for 30 minutes for dissolving process and mix thoroughly by gently inverting the vial at regular intervals, do not shake. Avoid formation of bubbles or foam. Protect from light. It is recommended to use a rotational mixer for routine mixing procedures.
5. After reconstitution, the calibrator is aliquoted into eppendorf tubes or sample cups of the device and stored in the deepfreeze. Do not refreeze after the calibrators are frozen and thawed once.
6. Calibrator precipitation is faster than normal serum. In order for the first and last parts to be homogeneous and to avoid precipitation, perform the process as fast as possible during separation.
7. Alkaline phosphatase value increases by %2 within 24 hours in diluted calibrators.
8. Bilirubins are stable in the dark, and if the serum is exposed to light, bilirubin activity decreases (Bilirubins are affected by light in powdered, frozen and thawed sera forms).
9. Bilirubins are stable in dark environment for 8 hours at +2/+8°C after dissolving.
10. Bilirubin calibrator cannot be refrozen and cannot be stored at +15/+25°C.
11. After being dissolved, bicarbonate in the serum is stable for 8 hours in closed cap and 1 hour in open cap.
12. The quality of the distilled water to be used in the dilution of the calibrator is very important. There may be significant deviations in the values due to bacterial contamination.
13. It is necessary to be careful against infectious agents in calibrator measurements.

INDICATIONS OF INSTABILITY OR DETERIORATION

Presence of extreme turbidity or microbial growth may indicate deterioration.

PRECAUTIONS



Human source material. Treat as potentially infectious material. Each plasma donor used in the preparation of this product has been tested by an FDA-approved method and found negative for the presence of HIV 1/2 HBsAg, HCV, HIV-Ag antibodies.

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However, none of the known testing methods can offer complete assurance that the hepatitis B virus, Human Immunodeficiency Virus (HIV) or infectious agents are not present. All human-based products should be handled in accordance with Good Laboratory Practice (GLP) principles using appropriate precautions. Safety data sheets are available at www.archem.com.tr or you may contact your local representative.

WARNINGS

IVD: For in Vitro Diagnostic use only.
Do not use expired reagents.
Reagents with two different lot numbers should not be interchanged.
For professional use.
Follow Good Laboratory Practice (GLP) guidelines.
Contains sodium azide.

CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

Danger

H317 :May cause allergic skin reaction.

Precaution

P280 :Use protective gloves / clothes / glasses / mask.
P264 :Wash your hands properly after using.
P272 :Contaminated work clothes should not be allowed to be used outside of the workplace.

Intervention

P302+P352 :Wash with plenty of water and soap if it contacts with skin.
P333+P313 :Seek medical help if it irritates your skin or develops rash.
P362+P364 :Remove contaminated clothes and wash properly before using.

Disposal

P501 :Dispose the vials and contents according to the local regulations.

REFERENCES

1. Burtis CA, Ashwood ER, Bruns DE, editors. Tiets Textbook of Clinical Chemistry and Molecular Diagnostics, 4th ed. St. Louis, MO, Elsevier Saunders; 2006:2263.
2. S.Dean Allison, Mark C.Manning, Theodore W.Randolph, Kim Middleton, Ashley Davis, John F.Carpenter. Optimization Of Storage Of Lyophilized Actin Using Combinations Of Disaccharides And Dextran. Journal Of Pharmaceutical Sciences.89/2,199- 214(2000)

TRADEMARKS

Archem Clinical Archem Multiconstituent Calibrator trademarks of ARCHEM Sağlık Sanayi ve Tic. A.Ş. in various jurisdictions.



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DIAGNOSTICS

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| SYMBOLS | |
|---|---|
| IVD | In Vitro Diagnostic Medical Device |
| LOT | Lot Number |
| CAL | Calibrator |
| CONTROL | Control |
| GTIN | Global Trade Item Number |
| REF | Reference Number |
| FOR USE WITH | Identifies Products to Be Used Together |
| PRODUCT OF TURKEY | Product of Turkey |
|  | Manufacturer |
|  | Expiration Date |
|  | Temperature Limits |
|  | Consult Instructions for Use |
|  | Caution |
|  | Number of Tests |

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