TECO DIAGNOSTICS
1268 N. Lakeview Ave.
Anaheim, CA 92807
1-800-222-9880

ARCAL AUTO CALIBRATOR

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

INTENDED USE
Auto Calibrator is for calibration of the parameters stated in the value sheet.

CONTENTS / MATERIALS PROVIDED
Auto Calibrator
It contains 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.

CALIBRATOR 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 20-25°C for around 5-10 minutes.
4. Wait for 30 minutes for the 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 serum is usually divided into small quantities (150-250 microliters) into Eppendorf tubes or sample cups of the device and stored for freezing process. For serums prepared in this way, it is absolutely necessary to leave the serum at 20-25°C for 30 minutes before dividing it into small quantities. Do not refreeze after the serum is frozen and thawed once.
6. Calibrator serum 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 level increases during the wait after mixing. Therefore, the diluted or dissolved calibrator serum should be kept at 20-25°C for 1 hour before ALP measurement.
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 serums 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 serum 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 serum. Refer to precautions/warning section.

PREPARATION OF CALIBRATOR
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.

INDICATIONS OF INSTABILITY OR DETERIORATION
The 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. 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.

WARNINGS
IVD: For in Vitro Diagnostic use only. Do not use expired calibrators.
Calibrator 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.

REFERENCES
1. Burtis CA, Ashwood ER, Bruns DE, editors. Tietz Textbook Of Clinical Chemistry and Molecular Diagnostics, 4th ed. St. Louis, MO, Elsevier Saunders; 2006:2263.
2. S.Dean Allıson, Mark C.Mannıng, Theodore W.Randolph, Kım Middleton, Ashley Davıs, John F.Carpenter. Optimization Of Storage Of Lyophilized Actin Using Combinations Of Disaccharides And Dextran. Journal Of Pharmaceutıcal Scıences.89/2,199-214(2000)

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Manufactured by:

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1268 N. LAKEVIEW AVE.
ANAHEIM, CA 92807
U.S.A.