TECO DIAGNOSTICS
1268 N. Lakeview Ave.
Anaheim, CA 92807
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LIPASE CALIBRATOR

INTENDED USE
Teco Lipase Calibrator is for calibration of the Lipase Liquid assay.

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.

STANDARDIZATION
The calibrator values were obtained by using Teco Lipase reagent and Certified Reference (CRM) NIST SRM 956 as the primary standard.

CALIBRATOR STABILITY

Temperature-Conditions	Stability
Unopened at 2-8°C	Expiry date on the vial.
Diluted and stored at 2-8°C	2 days
Frozen and stored 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 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, aliquot the calibrator into small quantities (150-250 microliters) into Eppendorf tubes or sample cups of the device and store at -20°C. For serums prepared in this way, it is necessary to leave the serum at 20-25°C for 30 minutes before dividing it into small quantities. Do not freeze after the serum is frozen and thawed once.
6. Calibrator serum precipitation is faster than normal serum. To avoid precipitation, the first and last part need to be fully homogeneous, perform the process as fast as possible during separation.
7. 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.
8. It is necessary to be careful against infectious agents in calibrator serum measurements.

PREPARATION
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 reagents.
Reagents with two different lot numbers should not be interchanged.
For professional use.
Follow Good Laboratory Practice (GLP) guidelines. Contains sodium azide.

REFERENCES
1. Council Directive (2000/54/EC). Official Journal of the European Communities No. L262 from Oct. 17, 2000.
2. EU-Dir 1999/11 Commission Directive of 8 March 1999 adapting to technical progress the principles of Good Laboratory Practice as specified in Council Directive 87/18/EEC
3. Clinical and Laboratory Standards Institute, H26-A2, Validation, verification, and quality assurance of automated hematology analyzers; Approved Guideline - Second Edition.
4. Gabbay, K.H., Hasty, K., Breslow, J.L., Ellison, R.C., Bunn, H.F., and Gallop, P.M., J. Clin. Endocrinol. Metab. 44, 859 (1977).
5. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, *Occupational Exposure to Bloodborne Pathogens*

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Manufactured by:

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