TECO DIAGNOSTICS
1268 N. Lakeview Ave.
Anaheim, CA 92807
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MICROPROTEIN 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
Microprotein Calibrator is for calibration of the Microprotein Liquid assay

CONTENTS / MATERIALS PROVIDED
Microprotein Calibrator
It contains human serum. Sodium Azide (0.09 %) is added as preservative

MATERIALS REQUIRED BUT NOT PROVIDED:
Class A volumetric pipette for liquid transfer

STANDARDIZATION
The calibrator values were obtained by using Microprotein reagent and Certified Reference Material (CRM) NIST SRM 927c as the primary standard

CALIBRATOR STABILITY

Temperature-Conditions	Stability
Unopened at 2 - 8°C	Expiry date on the vial.
Opened and stored 2 - 8°C	30 days

PREPARATION OF CALIBRATOR
Calibrator is ready to use.

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.

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. 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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