

EN Liquid N-geneous™ Lipase Calibrator

INTENDED USE

For the calibration of the Liquid N-geneous™ Lipase assay.

SUMMARY AND PRINCIPLE

See the Liquid N-geneous™ Lipase Reagent package insert.

REAGENTS/COMPOSITION

The Liquid N-geneous™ Lipase calibrator is a human pancreatic matrix with an assigned concentration of lipase.

Precautions and Warnings

1. For In Vitro Diagnostic Use.
2. Do not use the calibrator beyond the expiration date printed on the label.
3. **Warning:** Human source material. Treat as potentially infectious. Each plasma donor unit used in the preparation of this product has been tested by an FDA- approved method and found to be non-reactive for HBsAg, HCV, HIV 1 & 2 and HIV-1 antigen. Because no known test method can offer complete assurance that Hepatitis B virus, Human Immunodeficiency Virus (HIV) or other infectious agents are absent, all human-based products should be handled in accordance with good laboratory practices using appropriate precautions.¹
4. Do not pipette by mouth.

Preparation of Calibrator

Bring all components to room temperature (20 - 25°C) prior to reconstitution. Reconstitute each vial with 3.0 mL of distilled, deionized, Type II water or equivalent.² Replace the cap/stopper and swirl gently until completely dissolved. Keep the calibrator at 20 - 25°C for 10 minutes and invert to mix before use. Mix gently by inversion before use.

DO NOT SHAKE.

Storage and Stability

Unopened calibrator is stable until the expiration date shown on the label when stored at 2 - 8°C.

Once prepared, the calibrator is stable up to 28 days at 2 - 8°C.

Reconstituted stability of the calibrator may be extended by aliquotting and freezing the reconstituted calibrator at -20°C for up to 4 months. FREEZE ONLY ONCE.

Indications of Deterioration

Presence of turbidity or microbial growth may indicate deterioration.

PROCEDURE

Materials Provided

Description	Configuration	Catalog Number
Liquid N-geneous™ Lipase Calibrator	3 x 3 mL	80-6691-00

Materials Required but not Provided

Description	Configuration	Catalog Number
Liquid N-geneous™ Lipase Reagent 1	5 x 26 mL	80-6687-00
Liquid N-geneous™ Lipase Reagent 2	5 x 13 mL	80-6688-00

- Volumetric pipette or calibrated single channel pipette.
- Distilled, deionized, Type II water or equivalent.²
- Quality Control materials.
- Analyzer capable of running two reagent chemistries.

Calibration


Refer to the instrument operator's manual for analyzer specific calibration procedures and for guidance in determining calibration frequency.










Quality Control values should be within the expected ranges.

References

1. Richardson JH and Barkley WE eds. Biosafety in Microbiological and Biomedical laboratories, U.S. Dept. of Health and Human Services, Public Health Service, HHS Publication No. (CDC) 84-8395, Washington, D.C., (1984).
2. National Committee for Clinical Laboratory Standards. Preparation and Testing of Reagent Water in the Clinical Laboratory, 3rd Edition: Approved Guideline. NCCLS Document C3-A3. Villanova, PA: 1997.

Definitions for Symbols

 This product fulfills the requirements of the European Directive for In Vitro Diagnostic Medical Devices.

 Catalog number	 For in vitro diagnostic use
 Temperature limitation	 Manufactured by
 Use by	 Batch code
 Consult instructions for use	 Caution, consult accompanying documents
 Authorized Representative in the European Community	

Manufactured by:

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