



BIOLABO
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LIPASE Calibrator

For calibration of Lipase [EC 3.1.1.3] determination
with BIOLABO Lipase Reagents **REF** 99881, **REF** 99891

REF 95801 R1 1 x 3 mL R2 1 x 5 mL

TECHNICAL SUPPORT AND ORDERS

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IVD IN VITRO DIAGNOSTIC USE

INTENDED USE

BIOLABO Lipase Calibrator is a preparation of pancreatic human lipase to calibrate during Lipase activity measurement with Lipase reagent BIOLABO **REF** 99881 or **REF** 99891.

The Lipase value is traceable to reference method for determination of Lipase and is around the medical decision level.

REAGENTS COMPOSITION

Vial R1 LIPASE CALIBRATOR

Pancreatic lipase (human origin)
BIOLABO Lipase Calibrator contains human pancreatic lipase, serum albumin (bovine), and preservative.

Vial R2 DILUENT

Refer to the label of the vial to know the exact value of the Lipase Calibrator.

MATERIAL REQUIRED BUT NOT PROVIDED

- Basic medical analysis laboratory equipment.
- BIOLABO Lipase reagent **REF** 99881 or **REF** 99891
- Lipase control (human origin).

PREPARATION

- Open the vial carefully, avoiding any loss of lyophilised material.
- Using a volumetric class A pipette or equivalent, reconstitute with exactly 3 mL (3000 µL) demineralised water.
- Close the vial and allow standing for 10 minutes at room temperature.
- Dissolve completely the contents by swirling gently before use.

Do not shake (to prevent foam formation).

CALIBRATION

The calibrator should be used in accordance with the instructions described in the package insert of BIOLABO Lipase reagent **REF** 99881 or **REF** 99891.

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



STABILITY AND STORAGE

Store at 2-8°C, well recapped in the original vial and away from light.

- Unopened calibrator is stable until expiry date stated on the label of the kit.
- When free from contamination, reconstituted Calibrator is stable for :
 - ✓ 14 days at 2-8°C
 - ✓ 4 months at -20°C (**freeze once only**).
- Discard any calibrator if cloudy or contaminated.
- Don't use reconstituted calibrator after the expiry date stated on the label of the kit.

SAFETY CAUTIONS (1)

BIOLABO reagents are designated for professional, in vitro diagnostic use.

- Caution: Human origin.** Each component of this product has been tested with FDA-approved methods and found non reactive for the presence of HBsAg, HCV and antibodies to HIV1/2. Because no known test method can offer complete assurance that infectious agents are absent, this material should be handled as potentially infectious.
- Use adequate protections (overall, gloves, glasses).
- Do not pipette by mouth.
- In case of contact with skin or eyes, thoroughly wash affected areas with plenty of water and seek medical advice.
- Reagent contains sodium azide (concentration < 0.1%) which may react with copper and lead plumbing. Flush with plenty of water when disposing.
- Material Safety Data Sheet is available upon request.
- Waste disposal : Respect legislation in force in the country.

All specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.

REFERENCES

- Centers for Diseases control/National Institutes of Health Manual, "Biosafety in Microbiological and Biomedical Laboratories", 1988.
- See the BIOLABO Lipase Reagent **REF** 99881 (3 x 10 mL) or **REF** 99891 (5 x 30 mL) package insert for additional references

