

LIPASE COLOR CALIBRATOR

INTENDED USE

For calibration of the Lipase Color assay.

SUMMARY AND PRINCIPLE

See the Lipase Color Reagent package insert.

REAGENTS

Composition

The Lipase Color Calibrator contains human pancreatic lipase, serum albumin (bovine), and preservative.

Precautions and Warnings

1. For in Vitro Diagnostic Use.
2. Do not pipette by mouth.
3. Do not use the calibrator after the expiration date printed on the label.
4. **Warning:** Human source material. Treat as potentially infectious. Each serum donor unit used in the preparation of this product has been tested by an FDA approved method and found non-reactive for the presence of 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

Preparation

Reconstitute each vial with 3.0 mL of distilled, deionized, Type II water or equivalent using a Class A volumetric pipette.² Replace the cap/stopper and mix gently by inversion. Allow to stand for a minimum of 10 minutes at room temperature. Mix gently by inversion before use.

DO NOT SHAKE.

Storage and Stability

Unopened calibrator is stable until the expiration date printed on the label when stored at 2-8°C. Once reconstituted, 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 at least 4 months.

FREEZE ONLY ONCE.

Indications of Deterioration

Presence of extreme turbidity.

PROCEDURE

Assay

See The Lipase Color Reagent package insert.

Materials Provided

Description	Configuration	Catalog Number
Lipase Color Calibrator	1 x 3 mL	80-5295-00
Lipase Color Calibrator	20 x 3 mL	80-5627-00

Materials Required but Not Provided

Description	Configuration	Catalog Number
Lipase Color Reagent	5 x 30 mL	80-5290-00
Lipase Color Solvent	1 x 150 mL	80-5291-00
Lipase Color Activator	1 x 50 mL	80-5293-00

1. Class A Volumetric pipette.
2. Distilled or deionized water meeting specifications equivalent to USP purified water.
3. Lipase control sera or quality control material (see Quality Control in reagent package insert).

Calibration

The calibrator should be run in accordance with the instructions outlined in Genzyme's Lipase Color Reagent package insert. Refer to the instrument operator's manual for analyzer specific calibration procedures and for guidance in determining calibration frequency. For additional assistance please contact Genzyme Technical Marketing in the U.S. at (800) 332-1042 or in the U.K. at (+44) (0) 1732 220022.

REFERENCES

1. Centers for Disease Control/National Institute of Health Manual, "Biosafety in Microbiology and Biomedical Laboratories," 1988.
2. National Committee for Clinical Laboratory Standards, Preparation and Testing of Reagent Water in the Clinical Laboratory – Third Edition; Approved Guideline NCCLS Document C3-A3, 1997.

See the Lipase Color Reagent package insert for additional references.

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