

Biohit Oyj

BIOHIT Lactase Control

Control solution for Lactose Intolerance quick test

INSTRUCTIONS FOR USE

REF 602018

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1. INTENDED USE

BIOHIT Lactase Control is an *in vitro* medical device and is intended to be a positive quality control for Lactose Intolerance quick test (REF 602010 and 602012). The product is used manually and is intended to be used by health-care professionals only.

2. WARNINGS AND PRECAUTIONS

Read all instructions before using BIOHIT Lactase Control.

Do not use BIOHIT Lactase Control beyond the expiration date.

Gloves must be worn.

If pipettes are used instead of the drop bottles, use a safety pipetting device for all pipetting. Never pipette by mouth.

The solution contains 0.002 % Thiomersal, and it should be disposed of according to local and national regulations.

3. PRODUCT CONTENTS AND STABILITY

Contents: 1 drop bottle containing 1.0 ml of lactase solution with 0.002% Thiomersal as preservative.

Preparation: Ready for use.

Stability: When stored as directed (at 2-8 °C), BIOHIT Lactase Control will remain stable until the labeled expiration date.

4. USE OF THE BIOHIT Lactase Control

The test procedure with BIOHIT Lactase Control is similar to the Lactose Intolerance quick test reaction, except BIOHIT Lactase Control is used instead of a biopsy sample. Please read the instructions carefully before starting the test procedure. Mix all the reagents before use by turning the bottles upside down a few times. Tap the bottles onto a table to ensure the liquid returns to the bottle. When adding the drops into the wells, hold the bottles in a vertical upside down position.

STEP I: LACTASE REACTION

1. Open the label covering the well on the plate. Add one drop (10 µl) of the BIOHIT Lactase Control solution into the well.
2. Add 2 drops (80 µl) of the substrate solution (Bottle 1) into the well. Close the label.
3. Turn the plate upside down twice by holding your thumb tightly on top of the well.
4. Incubate for 15 minutes at room temperature (20-25°C).

STEP II: SIGNAL REACTION

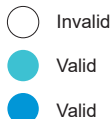
1. Open the label again. Add 1 drop (10 µl) of the chromogen solution (Bottle 2) into the well.
2. Immediately add 2 drops (80 µl) of the signal reaction solution (Bottle 3). Close the label.
3. Turn the plate upside twice by holding your thumb tightly on top of the well.
4. Incubate for 5 minutes at room temperature (20-25°C).

STEP III: RESULTS

After 5 minutes of the signal reaction, the result can be interpreted with the color chart also given in the Lactose Intolerance quick test.

Valid: The color of the solution is clearly blue (Mild or Normolactasia in the color chart).

Invalid: There is no color or the color of the solution is only slightly blue (Hypolactasia in the color chart).



If BIOHIT Lactase Control does not perform as expected, repeat the test or contact Biohit for technical assistance before testing patient samples. DO NOT use reagents beyond their labeled expiration dates.

Dispose of waste and residues in accordance with local authority requirements.

5. DATE OF ISSUE

BIOHIT Lactase Control kit insert
Version 4.1, 01-2024

6. WARRANTY





The Manufacturer shall remedy all defects discovered in any Product (the "Defective Product") that result from unsuitable materials or negligent workmanship and which prevent the mechanical functioning or intended use of the Products including, but not limited to, the functions specified in the Manufacturer's specifications for the Products. ANY WARRANTY WILL, HOWEVER, BE DEEMED AS VOID IF FAULT IS FOUND TO HAVE BEEN CAUSED BY MALTREATMENT, MISUSE, ACCIDENTAL DAMAGE, INCORRECT STORAGE OR USE OF THE PRODUCTS FOR OPERATIONS OUTSIDE THEIR SPECIFIED LIMITATIONS OR OUTSIDE THEIR SPECIFICATIONS, CONTRARY TO THE INSTRUCTIONS GIVEN IN THE INSTRUCTION MANUAL.

The period of this warranty for the Distributor is defined in the instruction manual of the Products and will commence from the date the relevant Product is shipped by the Manufacturer. In case of interpretation disputes the English text applies.

The product has been manufactured according to our ISO 9001 / ISO 13485 quality management protocols and have passed all relevant Quality Assurance procedures related to these products.

In case of any serious incident in relation to the product, contact the manufacturer.

7. EXPLANATION OF THE SYMBOLS USED IN LABELS

| | |
|-----------------------------------------------------------------------------------|-----------------------------------------|
|  | Catalogue number |
|  | Lot number |
|  | Use by |
|  | Temperature limitation. Store at 2-8 °C |

8. ORDERING INFORMATION

BIOHIT Lactase Control
REF 602018



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