Optitrol NAT Triplex

CE 2797

en-GB

INTENDED PURPOSE

Optitrol NAT Triplex is a multi-marker quality control (QC) sample intended to monitor the performance of *in-vitro* assays which are used for screening human blood, serum and plasma for presence of hepatitis B virus (HBV) DNA, hepatitis C virus (HCV) RNA and human immunodeficiency virus type 1 (HIV-1) RNA. This QC was manufactured as a positive control and may be helpful in determining the precision of testing systems and in identifying sources of variation. Optitrol NAT Triplex is an unassayed extraction and amplification control without target values. This control must not be used as a substitute for the mandatory manufacturer's kit controls provided with the assay. Optitrol NAT Triplex is an *in-vitro* diagnostic medical device for professional use.

CONTENTS

Optitrol NAT Triplex contains human serum as major component which was tested and found negative/nonreactive for anti-HIV 1/2, anti-HCV and HBsAg. The control was manufactured using human plasmas with intact HBV or HCV and cell cultures with HIV-1. HBV, HCV and HIV-1 stocks were inactivated by gamma radiation.

Optitrol NAT Triplex controls are traceable to the 3rd WHO International Standard for HBV (10/264), the 2nd WHO International Standard for HCV (96/798) and the 3rd WHO International Standard for HIV 1 (10/152).

Examples of possible reactivity (no target values) for this control can be found at http://www.seracare.com/resourcelibrary Users of Optitrol QC samples have access to EDCNet, an Internet-based QC results monitoring system at https://www.nrlquality.org.au/products-services/qconnect.

STORAGE AND STABILITY

Optitrol NAT Triplex:

- Stable until the expiration date when stored at -40 °C to -20 °C.
- Stable after thawing for 5 days when stored at 2 °C to 8 °C.
- Stable for 24 hours once opened provided it is closed tightly after use and returned to storage at 2 °C to 8 °C.
- Do not dilute.
- Always store vials upright.
- Do not use beyond the expiration date.

INSTRUCTIONS FOR USE

- Thaw at room temperature and use immediately or store at 2 °C to 8 °C.
- Mix contents briefly by vortexing before opening.
- After use, the control may be stored at 2 °C to 8 °C for up to 24 hours.
- Optitrol NAT Triplex should be treated using the same procedure as a patient sample, including the extraction and amplification steps.
- Follow the assay manufacturer's instructions for use.
- The expected values when using the control must be determined by the user for the respective assay.

LIMITATIONS

- Do not use this product if there is evidence of microbial contamination and/or high turbidity.
- Deviation from the recommended procedure may lead to unreliable results.
- This product is provided for quality assurance only and should not be used for calibration purposes.
- This product is not automated.
- Possible causes of variation in performance:
  - Different assay reagent lots
  - Different calibrator lots used
  - Different analyzers used
  - Different operators
  - Time of day when testing

PRECAUTIONS AND DISPOSAL INFORMATION

- Optitrol NAT Triplex is for *in-vitro* diagnostic use only and should be tested by trained personnel only.
- Optitrol NAT Triplex contains materials of human origin and should be considered potentially infectious. Observe universal precautions and handle this control like a patient sample.
- Wear protective gloves/ protective clothing.
- Do not pipette by mouth.
- Discard all materials in a safe manner that is in compliance with local and national regulations and in accordance with laboratory procedure for disposal of clinical waste.

REFERENCES

- Occupational Safety and Health Standards: Bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.
- Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.
- For further information, please refer to the appropriate instructions for use of the assays used.

For assistance, contact LGC Clinical Diagnostics Technical Support at +1 508.244.6400 / CDx-Info@LGCGroup.com.

Any serious incident that has occurred in relation to the device shall be reported to LGC Clinical Diagnostics Technical Support and, if in use in the EU, the competent authority of the Member State in which the incident occurred.

Date	Description of Change
October 2025	Update for IVDR

REF **PACKAGE SIZE**

Reference No.	Package size
NT01041	5 x 1.2 mL Positive
NT01042	10 x 1.2 mL Positive

Phone: +1 508.244.6400 | Toll Free (US Only) 800.676.1881
Fax: +1.508.634.3334 | SeraCare.com

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REF	CE	IVD	LOT								
Catalog Number	European Conformity	For *In-Vitro* Diagnostic	Lot Number	Use by Date	Product Logo	Warning / Attention	Biological risks	Consult Instructions for Use	Manufactured by	Importer	Temperature Limitation
CONTROL +	CONTROL −	EU REP									
Positive Control	Negative Control	Authorized Representative European Union									

EU REP **MediMark Europe Sarl.**
11 rue Emile Zola
38100 Grenoble. FRANCE
+33 (0) 4 76 86 43 22
info@medimark-europe.com

LGC Clinical Diagnostics, Inc. | 37 Birch Street, Milford, MA 01757 USA

Phone: +1 508.244.6400 | CDx-Info@LGCGroup.com

14659enGB-01 October 2025