Optitrol HIV 2

CE 2797

en-GB

INTENDED PURPOSE

Optitrol HIV 2 is a single marker quality control (QC) sample intended to monitor the performance of in-vitro assays for determination of anti-HIV 2 IgG antibodies in human serum and plasma. 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 HIV 2 is optimized for assays and platforms including ABBOTT ARCHITECT and PRISM, DiaSorin LIAISON, Roche cobas/ Elecsys and Siemens ADVIA Centaur and is an unassayed 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 HIV 2 is an in-vitro diagnostic medical device for professional use.

Optitrol HIV 2 will provide a positive reaction in assays that detect the following analyte:

Anti-HIV 2 IgG

CONTENTS

Optitrol HIV 2 contains human plasma with sodium azide and ProClin 950 as preservatives. Each plasma unit used to manufacture this product was separately tested and found negative/non-reactive for anti-HCV and HBsAg.

Examples of possible reactivity (no target values) for this control can be found at https://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 HIV 2:

- Stable until the expiration date when stored at 2-8 °C.
- Stable for 90 days once opened provided it is closed tightly after use and returned to storage at 2-8 °C.
- Always store vials upright.
- Do not use beyond the expiration date.

INSTRUCTIONS FOR USE

- Optitrol HIV 2 is ready-to-use.
- Mix thoroughly by gentle swirling prior to use.
- For automated analyzers, label the vial with the barcode provided and then place the Optitrol QC in a sample rack as per routine samples.
- Return vials to 2-8 °C storage after use.

LIMITATIONS

- Do not use this product beyond the expiration date.
- Do not use this product if there is evidence of microbial contamination and/or high turbidity.
- Use Optitrol HIV 2 as per assay manufacturer's instructions for use.
- 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 Optitrol QC performance:
  - Different assay reagent lots
  - Different calibrator lots used
  - Different analyzers used
  - Different operators
  - Time of day when testing

PRECAUTIONS AND DISPOSAL INFORMATION

- Optitrol HIV 2 is for in-vitro diagnostic use only and should be tested by trained personnel only.
- Optitrol HIV 2 contains materials of human origin and should be considered potentially infectious. Observe universal precautions for prevention of transmission of infectious agents when handling this product.
- Do not pipette by mouth.
- The preservative sodium azide may react with copper or lead to form dangerous compounds. Although Optitrol HIV 2 contains only a small amount of sodium azide, please dilute with a sufficient amount of water when disposing these products into waste water systems.
- This product also contains methylisothiazolones, which are a compound of ProClin. Methylisothiazolones are classified per applicable European Community (EC) Directives as: skin sensitization.
- Discard all material in a safe manner that is in compliance with local and national regulations and in accordance with laboratory procedure for disposal of clinical waste.

WARNING: Contains methylisothiazolones.
H317 May cause an allergic skin reaction.

Prevention:
P261 Avoid breathing mist/ vapours/ spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/ protective clothing.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P363 Wash contaminated clothing before reuse.

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
September 2026	Update for IVDR

REF PACKAGE SIZE

Reference No.	Package size
SR11113	4 x 2.5 mL Positive
SR11115	1 x 1 mL Positive
SR11117	2 x 2.5 mL Positive

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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.**
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14639enGB-01 September 2026