

Optitrol Chagas-1 Optitrol Chagas-2



CE 2797

en-GB

INTENDED PURPOSE

Optitrol Chagas-1 and Optitrol Chagas-2 are single marker quality control (QC) samples intended to monitor the performance of *in-vitro* diagnostic assays for the determination of IgG antibodies to *Trypanosoma cruzi* (anti-T.cruzi - pathogen of Chagas) in human serum and plasma. These QCs were manufactured as positive controls and may be helpful in determining the precision of testing systems and in identifying sources of variation. Optitrol Chagas-1 samples are optimized for assays and platforms including ABBOTT ARCHITECT, ABBOTT Alinity i and DiaSorin LIAISON. Optitrol Chagas-2 samples are optimized for assays and platforms including Roche cobas and Elecsys. Optitrol QC samples are unassayed controls without target values. These controls must not be used as a substitute for any mandatory manufacturer's kit controls provided with the assays. Optitrol Chagas-1 and Optitrol Chagas-2 are *in-vitro* diagnostic medical devices for professional use.

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

Anti-*Trypanosoma cruzi* IgG

CONTENTS

Optitrol Chagas controls contain human plasma with sodium azide and ProClin 950 as preservatives.

Each plasma unit was separately tested and found negative/nonreactive for anti-HIV 1/2, anti-HCV and HBsAg. Examples of reactivity (no target values) for these controls on different test systems 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 Chagas:

- 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 Chagas 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 Chagas 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 Chagas is for *in-vitro* diagnostic use only and should be tested by trained personnel only.
- Optitrol Chagas 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 Chagas 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
March 2026	Update for IVDR

PACKAGE SIZE

Reference No.	Package size
SR16025 Chagas-1	1 x 1 mL Positive
SR16027 Chagas-1	2 x 2.5 mL Positive
SR16035 Chagas-2	1 x 1 mL Positive
SR16037 Chagas-2	2 x 2.5 mL Positive

Optitrol Chagas-1 Optitrol Chagas-2



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

EU REP MediMark Europe Sarl.
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