Optitrol HEPR-1
Optitrol HEPR-2

CE 2797

en-GB

INTENDED PURPOSE
Optitrol HEPR-1 and Optitrol HEPR-2 are multi-marker quality controls (QC) intended to monitor the performance of *in-vitro* assays for determination of anti-HBs IgG, anti-HBe IgG, anti-HAV IgG and anti-HEV IgG antibodies 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 HEPR-1 QC is optimized for assays and platforms including DiaSorin LIAISON and Wantai ELISAs. Optitrol HEPR-2 QC is optimized for assays and platforms including ABBOTT ARCHITECT, ABBOTT Alinity i, Roche cobas, Siemens ADVIA Centaur and Microgen ELISAs. Optitrol QC samples are unassayed controls without target values. These controls must not be used as a substitute for the mandatory manufacturer's kit controls provided with the assay. Optitrol HEPR-1 and Optitrol HEPR-2 are *in-vitro* diagnostic medical devices for professional use.

CONTENTS
Optitrol HEPR controls contain 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-HIV, anti-HCV and HBsAg. If a negative quality control is required, Optitrol SeroNeg can be used. Examples of reactivity (no target values) for this control 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 HEPR:
- 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 HEPR 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 HEPR 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 HEPR is for *in-vitro* diagnostic use only and should be tested by trained personnel only.
- Optitrol HEPR 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 HEPR 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
October 2025	Update for IVDR

REF PACKAGE SIZE

Reference No.	Package size
SR12045 (HEPR-1)	1 x 1 mL Positive
SR12047 (HEPR-1)	2 x 2.5 mL Positive
SR12055 (HEPR-2)	1 x 1 mL Positive
SR12057 (HEPR-2)	2 x 2.5 mL Positive

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REF	CE	IVD	LOT								2°C 8°C
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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