

EndoGrade[®] Water, 16 x 100 mL

Ultra-pure water for reconstitution and dilution of samples, reagents and standards (<0.001 EU/mL).

Package Insert EndoGrade[®] Water, 16 x 100 mL

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1. General Information

1.1 Intended Use

Intended use EndoGrade® Water is recommended for endotoxin-free reconstitution and dilutions of reagents, samples and standards (CSE, RSE) used in endotoxin testing.

1.2 Specifications

Material Water, manufactured in GLP and DIN EN ISO 9001/13485 certified facilities.

Endotoxin content EndoGrade® Water contains less than 0.001 EU/mL of endotoxin.

Sterility EndoGrade® Water contains no detectable gram-negative bacteria.

2. Components

Quantity 16 bottles per packaging unit

Volume Each bottle contains 100 mL

3. Warnings and Precautions

Warning For professional use only. Not for diagnostic or therapeutic use. Not for human or animal injection.

Endotoxin-free conditions Water contamination may affect experimental outcomes. Ultrapure water should be used for all experiments and quality control steps which could be subjected to environmental contamination causing unwanted artefacts, such as endotoxins.

4. Storage and Preparation

Storage and Stability Store EndoGrade® Water at 2 to 8°C. Opened bottles are stable until expiry date when stored at 2 to 8°C.

Preparation EndoGrade® Water is ready to use. All materials applied, such as containers or pipette tips, must be free of detectable levels of endotoxin in order to avoid contamination of the water.








5. Waste Disposal

Unused reagents may be considered as non hazardous waste and disposed of accordingly. Dispose of used reagents as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products. It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

6. Quality Control

EndoGrade® Water has been developed to meet the strictest quality requirements. The results of quality control are given on the quality control certificate available from our website (www.hyglos.com).

7. Index of Symbols and Abbreviation

Symbol	Meaning
	Catalog number
	Manufacturer
	Date of manufacture
	Temperature limit
	Use by date
	Batch code
	Consult Instructions for Use

Abbreviations used:

EU Endotoxin Unit (1 EU corresponds to 0.1 ng LPS (FDA RSE *E. coli* O113 EC-6))

8. Limited Warranty

Hyglos / bioMérieux warrants the performance of the product for its stated intended use provided that all procedures for usage, storage and handling, shelf life (when applicable), and precautions are strictly followed as detailed in the instructions for use (IFU).

Except as expressly set forth above, Hyglos / bioMérieux hereby disclaims all warranties, including any implied warranties of merchantability and fitness for a particular purpose or use, and disclaims all liability, whether direct, indirect or consequential, for any use of the reagent, software, instrument and disposables (the "System") other than as set forth in the IFU.

9. Revision History

Change type categories :

N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user

Minor typographical, grammar, and formatting changes are not included in the revision history.

Release date	Part Number	Change Type	Change Summary
2017/02	910078 V2.0	Administrative	All – change of template

Example Version

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