# **BIOMÉRIEUX**

**REF** 607100

910078 V2.0 - en - 2017/02 **EN** 



# EndoGrade<sup>®</sup> 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 1

#### **Table of Contents**

1. General Information	2
1.1 Intended Use	
1.2 Specifications	
2. Components	
3. Warnings and Precautions	
4. Storage and Preparation	
5. Waste Disposal	
6. Quality Control	2
7. Index of Symbols and Abbreviation	
8. Limited Warranty	
9 Revision History	1

#### 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<sup>®</sup> 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		
REF	Catalog number		
	Manufacturer		
$\mathbb{A}$	Date of manufacture		
1	Temperature limit		
	Use by date		
LOT	Batch code		
(i	Consult Instructions for Use		

#### Abbreviations used:

EU

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



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)

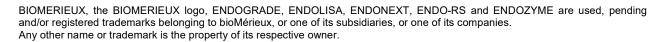
Correction Correction of documentation anomalies

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



Hyglos GmbH
- a bioMérieux company
Am Neuland 3
D-82347 Bernried am Starnberger See
Germany

HRB 178396, München Tel: +49 (0)8158 9060 0 Fax: +49 (0)8158 9060 210 www.biomerieux.com