BIOGNOST®

LUGOL'S C SOLUTION

CE IVD *In vitro* diagnostic medical device Classification according to Regulation (EU) 2017/746 - **Class A** device

Enhanced formulation of aqueous solution of iodine and potassium iodide

INSTRUCTIONS FOR USE

Basic UDI-DI	385889212HPC4080299MCKA	
EMDN code	W0104080299	
REF **Catalog number**	**Volume**	**UDI-DI**
LUGC-OT-100	100 mL	03858890002171
LUGC-OT-110	250 mL	03858890008241
LUGC-OT-500	500 mL	03858890008258

Intended use and test principle

Lugol's solution, named after the French physician J. G. A. Lugol, has a wide range of medical applications. It is generally known as an antiseptic and disinfectant agent, as well as a starch indicator. The principle of Lugol's solution action on carbohydrate molecules is as follows: iodine binds to complex carbohydrates (starch in plant tissues and glycogen in animal tissues), thereby staining them. Lugol's solution is an aqueous solution of iodine and potassium iodide. Lugol's solution is used in parasitology for staining parasites in stool samples. In zoology, Lugol's solution is used for staining protozoa to enhance the contrast of internal structures (nuclei and glycogen vacuoles) and for the preservation of protozoa, while in microbiological examinations it serves as one of the components of the Gram staining method.

Product description

- **LUGOL'S C SOLUTION** - Aqueous solution of iodine and potassium iodide

Contains:

70 g/L iodine
140 g/L potassium iodide

Applications of Lugol's solution:

- Parasitology (staining of parasites in stool samples)
- Microbiology (Gram staining)
- Zoology (staining and preservation of protozoa)
- Cytology (staining of cell nuclei)

Limitations

This product is intended for professional laboratory use for diagnostic purposes only.

Sample preparation and diagnostics

Use only appropriate instruments for collecting and preparing the samples. Process the samples using modern technology and mark them clearly. It is necessary to follow the manufacturer's instructions for use. To avoid errors, diagnosis may only be performed by qualified personnel. Use a microscope that complies with medical diagnostic laboratory standards.
If a serious incident occurs during or as a result of the use of this product, please report it to the manufacturer and/or authorized representative and the competent authority.

Safety at work and environmental protection

Handle the product in accordance with occupational health and environmental protection guidelines. Used and expired solutions must be disposed of as special waste following national guidelines. Reagents used in this procedure can pose a danger to human health. The examined tissue samples are potentially infectious, therefore it is necessary to implement human health protection measures in accordance with good laboratory practice guidelines. It is mandatory to read and act according to the information and warning signs printed on the product label, instructions for use and in the safety data sheet, which is available on request.

Storage, stability, and shelf life

Upon receipt, store the product in a dry place and well-closed original packaging at a temperature of +15 °C to +25 °C. Do not freeze or expose to direct sunlight. After first opening, the product can be used until the specified expiry date, if stored properly. The production date and expiration date are printed on the product label.

References

1. Higdon, J. (2003): Micronutrient Information Center: Iodine, Linus Pauling Institute/Oregon State University.
2. Carson, F. L., Hladik, C. (2009): *Histotechnology: A Self-Instructional Text*, 3rd ed., Chicago: ASCP Press
3. Sargent, D. L. (1936): An improvement in staining technic for Protozoa, *Biotechnic and Histochemistry,* 11, p.49-52.

Warnings and precautions regarding the materials contained in the product:
Not a dangerous substance or mixture according to Regulation (EC) no. 1272/2008.

	Manufacturer	LOT	Batch code		Consult instructions for use	CE	European conformity
	Date of manufacture	REF	Catalogue number		Caution	UDI	Unique device identifier
	Use-by date	°C	Temperature limit	IVD	*In vitro* diagnostic medical device		

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Version	Description / reason for change	Date
5	Revised acc. to Regulation (EU) 2017/746 - IVDR	03.06.2026.