BIOGNOST®

LUGOL'S SOLUTION

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

Aqueous solution of iodine and potassium iodide

INSTRUCTIONS FOR USE

BASIC UDI-DI	385889212HPC4080299MCKA	
EMDN code	W0104080299	
REF **Catalog number**	**Volume**	**UDI-DI**
LUG-OT-100	100 mL	03858888824143
LUG-OT-250	250 mL	03858888824150
LUG-OT-500	500 mL	03858890000269

Intended use and test principle

Lugol's solution, named after the French physician J. G. A. Lugol, has an exceptionally wide range of 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. It is used in microbiology, where it forms one of the components of staining during the Gram staining method. Instead of the classic Lugol's solution for Gram staining, the use of stabilized Gram Lugol's solution is recommended, as it contains a stabilized form of iodine and contributes to reliable differentiation of Gram bacteria over a longer period of time. It is also used in parasitology for staining parasites in stool samples.

Product description

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

Applications of Lugol's solution:

- Microbiology (Gram staining)
- Parasitology (staining of parasites in stool samples)
- Cytology (staining of cell nuclei)

Example of using Lugol's solution in Gram staining of bacteria

Additional reagents and materials that can be used in the method

- VitroGnost slides and coverslips for use in histopathology and cytology
- BioGnost immersion media such as Immersion Oil, Immersion Oils types A, C, FF, 37, or Immersion Oil Tropical Grade
- Other BioGnost reagents required for Gram staining: Gram Crystal Violet 1% solution, Gram Decolorizer solution 2, and Gram Safranin solution
- Saline solution

Preparation of the sample for staining

- Transfer the sample to a clean glass slide using a sterilized microbiological loop
  Note: The sample can be body fluids, discharge, pus, and liquid or solid bacterial culture
- Spread the sample evenly on the slide with the help of 1-2 drops of saline solution
- After air drying, fix the sample above the flame of the Bunsen burner by passing the slide briefly through the flame cone 2-3 times
- Cool the slide and start the staining procedure

Sample staining procedure

Pour the reagents into glass staining jars (type Coplin, Hellendahl, or Schifferdecker) and return them to the original bottles after staining. Close well. Filter the reagents as needed.

1.	Stain the slide using Gram Crystal Violet 1% solution	1 min
2.	Remove excess dye from the slide	
3.	Carefully rinse the preparation with Lugol's solution	
4.	Fix the dye by treating the slide with Lugol's solution	1 min
5.	Rinse the slide carefully with distilled/demineralized water	5 s
6.	Treat the slide with Gram Decolorizer solution 2 Stop the procedure when the slide takes on a grayish-blue color	10-15 s
	Note: Excessive treatment with the decolorizer solution will wash away the dye from Gram-positive bacteria	
7.	Rinse the slide carefully with distilled/demineralized water	5 s
8.	Treat the slide with Gram Safranin solution	1 min
9.	Rinse the slide carefully with distilled/demineralized water	5 s
10.	Dry the slide with filter paper or leave it to air dry	
11.	Add a drop of Immersion oil to the slide	
12.	Observe the preparation under the immersion lens	

Result

Gram-positive bacteria - blue-purple color
Gram-negative bacteria - red color

Limitations

This product is intended for professional laboratory use for diagnostic purposes only. Deviations from the described sample preparation procedure and staining procedure in these Instructions for Use may cause differences in staining results.

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, sample preparation, staining procedure, and diagnosis may only be performed by qualified personnel. Use a microscope that complies with medical diagnostic laboratory standards. To avoid a false result, it is recommended to use a positive and negative control.
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 in accordance with 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 in 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. Sankaranarayanan, R. et al.(2003): Test characteristics of visual inspection with 4% acetic acid (VIA) and Lugol's iodine (VILI) in cervical cancer screening in Kerala, India, *Int.J. Cancer,* 106, pp.404-408.
4. Sargent, D. L. (1936): An improvement in staining technic for Protozoa, *Biotechnic and Histochemistry,* 11, pp.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.

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	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		

BioGnost Ltd.
Medjugorska 59, 10040 Zagreb, Croatia, EU, www.biognost.com

Version	Description / reason for change	Date
7	Revised in accordance with Regulation (EU) 2017/746 - IVDR	29.06.2026.