

## Metachromatic dye solution for cytological specimens

### Instructions for Use

**Product Name:** BlueStain®

**REF** DIAG02-1L / DIAG02-5L

#### **Packaging:**

Primary packaging: High-density Polyethylene bottle (HDPE) with tamper-proof cap, nominal content 1 L

Primary packaging: High-density Polyethylene (HDPE) Jerrycan with tamper-proof cap, nominal content 5 L

**Intended Purpose:** Metachromatic dye solution for cytological specimens, whose purpose is the morphological analysis of cells.

#### **Components:**

- Toluidine blue, CAS: 64-17-5
- Alcohol, CAS: 92-31-9
- HDPE packaging
- PVC label resistant to water, alcohol, and solvents

#### **Overview and Principles:**

When BlueStain dye solution is applied to cytological specimens, its metachromatic characteristic will show the different morphological structures from purple to blue of various shades, with special affinity for basophilic structures.

This in-vitro diagnostic medical device meets the performance requirements for in-vitro diagnostic use, in the scope of Regulation (EU) 2017/746.

**Type of Specimen:** Cytology specimens. The specimen is taken by a duly qualified healthcare professional.

#### **Procedure**

Slides are to be stained according to the following **BlueStain Method®**:

1. Dip the slide in BlueStain dye for 2 minutes.
2. Remove excess dye from the slide with tap water.
3. Allow the slide to air-dry completely  
Fit the slide (place the mounting medium and coverslip)

#### **Non-supplied Materials:**

The following materials and equipment are necessary for the completion of the staining, but are not supplied with BlueStain:

- Dropper/pipette
- Slide
- Coverslip
- Microscope
- Personal Protective Equipment (PPE)

#### **Expected Result:**

- Nucleus: Purple
- Nucleolus: Dark blue
- Cytoplasm: Light blue
- Metachromatic substances: Dark blue

#### **Precautions:**

- Read the Instructions for Use carefully
- Professional use for in-vitro diagnostics
- Act according to the hazard signs and warnings shown on the label, as well as safety data available on the device Safety Data Sheet
- Handling of the product in accordance with good work protection practices.
- It is to be used exclusively by qualified and trained professionals.
- Do not use after the expiry date.
- Respect the handling and storage conditions.
- Do not use if packaging is damaged.

**Warnings:** Any serious incident occurring in relation to the device should be communicated to the manufacturer and the competent authority of the Member State in which the users and/or patients are based.

#### **Quality Control:**

- Each batch is subjected to an internal quality inspection before its



release, so as to ensure compliance with the product requirements.

- The product and raw materials are constantly monitored, enabling the traceability between the Batch no. of each product and its materials and raw materials.

**Limitations:**

The results obtained depend on the attainment of quality cytological material which is directly related to the adequacy of the specimen, its fixation, slide assembly, as well as well as the effectiveness of microscopic illumination.

**Stability, Handling Conditions, and Storage.**

- Store between 15°C and 25°C, away from light
- Close well after each use
- Store in an upright position.
- Expiry date: After opening for the first time, the product is stable until its expiry date - 4 years after manufacture, indicated on the device label
- Do not freeze.

**Instructions for disposal:**

- The expired and/or used product must be disposed of in accordance with the local and national legislation in force.
- Do not dispose of in the drain system or in the environment







**Bibliographical references:**







- Alves PM, Ferreira F, Oliveira T, Alves D, Canberk S, Schmitt F. a new cytology staining method – a fast approach for rapid on-site

evaluation on thyroid fine needle aspiration cytology. *acta cytologica*.

- Hewer E, Schmitt AM. Ultrafast toluidine blue staining for rapid on-site evaluation of cytological smears. *Acta Cytologica*. 2020;64(4):375–7.
- Saba K, Niazi S, Bukhari MH, Imam SF. Use supravital toluidine blue staining to improve the efficiency of fine-needle aspiration cytology reporting in comparison to Papanicolaou stain. *Pakistan Journal of Medical Sciences*. 2015;31(5).
- Ammanagi AS, Dombale VD, Patil SS. On-site toluidine blue staining and screening improves efficiency of fine-needle aspiration cytology reporting. *Acta Cytologica*. 2012;56(4):347–51.

**Symbol Glossary:**

	Read the instructions for use
	Batch
	Medical Device for In-vitro diagnostics
	Expiry date
	Name and address of manufacturer
	Reference

	Store away from sunlight
	Keep in a dry place
	Temperature Limits
	Do not use if packaging is damaged
	CE Marking
	Caution/Warning



Date of Review	Identifier of the Review	Description of the modifications
17/10/2022	01	1 <sup>st</sup> edition

