

# ALCIAN YELLOW TOLUIDINE BLUE KIT



IVD In vitro diagnostic medical device

Classified acc. to Regulation (EU) 2017/746 - Class A device

## Six-reagent kit for staining *Helicobacter pylori* in gastric biopsy samples

### INSTRUCTIONS FOR USE



<b>BASIC UDI number</b>	385889212HPC30708STARVF		
<b>EMDN code</b>	W01030708		
<b>REF</b> <b>Catalog number</b>	<b>Volume</b>	<b>UDI-DI number</b>	
AYTB-100T	Za 100 testiranja	03858892121023	

#### Intended use and test principle

Histology, cytology and other related scientific disciplines study the microscopic anatomy of tissues and cells. In order to achieve a good tissue and cellular structure, the samples need to be stained in a correct manner. Alcian Yellow Toluidine Blue is used for visualization of *H. pylori* found in endoscopic and surgical stomach samples. In first step Alcian Yellow dye is specifically bound for previously oxidized mucins; gastric bacteria are stained afterward, as well as cellular nuclei and other structures using Toluidine Blue dye. This provides excellent contrast between dark blue stained bacteria placed on yellow surface and extracellular foveolar mucins.

#### Product description

- **ALCIAN YELLOW TOLUIDINE BLUE KIT** - Six-reagent kit for staining *Helicobacter pylori* bacteria in gastric biopsy samples

The kit contains:	100 tests (AYTB-100T)	Storage temperature
Periodic acid, 1% solution	30 mL (PK1-OT-30)	15-25°C
HCL reagent, A.T.	30 mL (HCLAT-OT-30)	15-25°C
Sodium metabisulphite, solution	30 mL (NM-OT-30)	15-25°C
Alcian Yellow, solution	30 mL (AY-OT-30)	15-25°C
Buffer solution, A.T.	30 mL (PO-OT-30)	15-25°C
Toluidine Blue reagent	30 mL (TBR-OT-30)	15-25°C

#### Additional reagents and materials that can be used in the method:

- Fixatives such as BioGnost's neutral buffered formaldehyde solutions: Formaldehyde NB 4%, Formaldehyde NB 10%
- Dehydrating/rehydrating agent, such as BioGnost's alcohol solutions: Histanol 70, Histanol 80, Histanol 95 and Histanol 100
- Clearing agent, such as BioClear xylene or its aliphatic hydrocarbon substitutes, such as BioClear New
- Infiltration and embedding agent, such as BioGnost's granulated paraffin BioWax Plus 56/58, BioWax 56/68, BioWax Blue
- Covering agents for microscopic sections and mounting cover glass, such as BioGnost's BioMount, BioMount High, BioMount M, BioMount New, BioMount DPX, BioMount DPX High, BioMount DPX Low, BioMount C, BioMount Aqua
- VitroGnost slides and coverslips for use in histopathology and cytology
- BioGnost's immersion oils, such as Immersion oil, Cedarwood oil, Immersion oils types A and C, FF, 37 or Tropical Grade

#### Preparation of histological sections for staining

- Fix (Formaldehyde NB 4%, Formaldehyde NB 10%) and process the tissue sample
- Embed the tissue in a paraffin block (BioWax 52/54, BioWax 56/58, BioWax Plus 56/58, BioWax Blue)
- Cut the paraffin block into 4-6 µm thin slices and mount on a VitroGnost microscope slide

#### NOTE

Apply the reagent so it completely covers the section.

#### Sample staining procedure

1.	Deparaffinize in xylene (BioClear) or xylene substitute (BioClear New)	3 exchanges, 5 min each
2.	Rehydrate in 100% alcohol (Histanol 100)	2 exchanges, 5 min each
3.	Rehydrate in 95% alcohol (Histanol 95)	2 min
4.	Rehydrate in distilled/demineralized water	2 min
5.	Add 6 drops of Periodic acid, 1% solution	let it set for 10 min
6.	Rinse with distilled/demineralized water thoroughly	
7.	Add 3 drops of HCL reagent, A. T. and 3 drops of Sodium metabisulfite, solution, then gently mix the solutions on the section	let it set for 5 min
8.	Rinse with distilled/demineralized water thoroughly	
9.	Add 6 drops of Alcian Yellow, solution	let it set for 5 min
10.	Rinse with distilled/demineralized water thoroughly	
11.	Add 6 drops of Buffer solution, A.T. and 2 drops of Toluidine Blue reagent, gently mix the solutions on the section	let it set for 3 min
12.	Rinse with distilled/demineralized water thoroughly	
13.	Let the sections dry on air until the tissue changes color from purple to blue	20-30 min
14.	Clear the section in xylene (BioClear) or in a xylene substitute (BioClear New)	3 exchanges, 2 min each

Immediately after clearing apply an appropriate BioMount medium for covering/mounting on the section. If BioClear xylene was used, use one of BioGnost's mounting xylene-based media (BioMount, BioMount High, BioMount M, BioMount DPX, BioMount C, or universal BioMount New). If BioClear New xylene substitute was used, the appropriate covering agent is BioMount New. Cover the section with VitroGnost cover glass.

### Result

Bacteria – blue-black

Mucins – yellow to green

Nuclei and other cellular structures - hues of blue

### Limitations

This product is intended for professional laboratory use for diagnostic purposes only. Deviations from the staining procedure described in this Instruction 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. Be sure to follow the manufacturer's handling instructions. To avoid errors, staining and diagnosis can only be carried out by qualified personnel. Use a microscope equipped according to medical diagnostic laboratory standards. To avoid an incorrect staining result, it is advised to use a positive and negative control.

If a serious incident occurs during use of this product or as a result of its use, please report it to the manufacturer or authorized representative and 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, and it is necessary to take the measures needed to protect human health in accordance with the guidelines of good laboratory practice. It is mandatory to read and act according to the information and warning signs printed on the product label 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 expiration date is printed on the product label.

### Reference

1. Prophet, E.B., Mills, B., Arrington, J., Sobin, L. (1968) Laboratory methods in histotechnology. McGraw Hill, Washington D.C.
2. Bancroft, J.D., Gamble, M. (2002) Theory and practice of Histological Techniques. Churchill Livingstone, New York.
3. Kiernan, J.A. (2015) Histological and Histochemical Methods, Theory and Practice, 5<sup>th</sup> ed. Bunbury, Oxford, UK.

Warnings and precautions regarding the materials contained in the product:	
	<p>H360FD May damage fertility or the unborn child.            H319 Causes serious eye irritation.            H225 Highly flammable liquid and vapor.</p> <p>P201 Obtain special instructions before use.            P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.            P233 Keep container tightly closed.            P280 Wear protective gloves/protective clothing/eye protection/face protection.            P305 + P351 + P338 IF IN EYES: rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.            P308 + P313 IF exposed or concerned: get medical advice/attention.</p>

AYTB-IFU\_ENV5, 19.02.2026. IŠP

 Manufacturer	 Batch code	 Consult instructions for use	 Contains sufficient for <n> tests	 Contains hazardous substances
 Date of manufacture	 Catalogue number	 Caution	 European conformity	 Fragile, handle with care
 Use-by date	 Temperature limit	 <i>In vitro</i> diagnostic medical device	 Unique device identifier	

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Version	Description / reason for change	Date
5	Correction of „fitting“ to „embedding“	19.02.2026.