



Papanicolaou Harris hematoxylin

Nuclear staining



In-vitro diagnostic medical device

EMDN : W01030708

BASIC UDI: 080339762W01030708X8

IVD in **Classe A**, Reg. UE 2017/746

Catalog number	Unit size	UDI-DI
05-12011	500 ml	08033976232665
05-12011/L	1 l	08033976232672
05-12011E	2,5 l	08033976232689

Packaging

05-12011E

Primary container: white bottle in polyethylene terephthalate (PET). Useful capacity 2.5 liters. HDPE cap.

Tamper evident cap.

The polyethyleneterephthalate is a thermoplastic polymer of the polyester family. PET is an optimal oxygen, carbon dioxide and other gasses barrier. This material has a high resistance to ultraviolet radiation and an inertia toward the mainly chemical agents (solvents: xylene, limonene, liquid paraffines, alcohols, acids, bases etc.). It is biologically inert. It constitutes a good water and humidity barrier. It shows a great hardness and mechanical resistance.

The bottle has an optimal grip. The absence of the handles reduces space for storage. The anti-dropping cap permits a precise and clean use.

Secondary container: carton box.

05-12011/L

Primary container: white bottle in High Density Polyethylene (HDPE). Useful capacity 1 l. HDPE cap. Tamper evident cap.

05-12011

Primary container: white bottle in High Density Polyethylene (HDPE). Useful capacity 500 ml. HDPE cap. Tamper evident cap.

Wear, water, alcohol and solvents resistant PVC label. Scratchproof ink resistant to water and alcohol.

Expected aim

Product for the preparation of: gynecological specimens, urine cytology, fine needle specimens, sputum and bronchial washings, to be examined by optical microscopy.

Application

Nuclear stain for Papanicolaou method.

For the execution of the staining method is required the use of reagents Papanicolaou

EA50 and Papanicolaou OG6.

Principle A highly selective blue nuclear stain, Harris' hematoxylin, is combined with EA65 polychromic mixture, a subtle cytoplasmic stain which differentiates cyanophil cells from eosinophil ones. The last ingredient is OG6 solution, which stains keratinized elements.

Method

- 1) Ethanol 95°, 2 minutes
- 2) Distilled water, 2 minutes
- 3) Harris Hematoxylin, 1 minute
- 4) Tap water, 5 minutes
- 5) Ethanol 95°, 15 seconds
- 6) OG 6, 2 minutes
- 7) Ethanol 95°, 15 seconds (twice)
- 8) EA 65, 5 minutes
- 9) Ethanol 95°, 15 seconds
- 10) Absolute Ethanol, 30 seconds (twice)
- 11) Xilene or Bio Clear, 2 minutes (twice)

Results

Nuclei : Blue-purple
 Cyanophil cytoplasm : Blue-green
 Eosinophil cytoplasm : Pink
 Keratinized cytoplasm : From pink to orange

Components

Components	CAS	CE	Index
Certified Hematoxylin	517-28-2	20822373	-
Aluminium sulfate	7784-31-8	2331350	-
Potassium iodate	7758-05-6	2318319	-
Acetic acid	64-19-7	2005807	607-002-00-6
Stabilizers			

Warning and precaution

The product is intended for professional laboratory use for healthcare professionals. Carefully read the information on the label (danger symbols, risk and safety phrases) and always consult the safety data sheet. Do not use if the primary container is damaged. In the event of a serious accident, we recommended that you immediately inform Bio-Optica Milano S.p.A and the competent authorities.

Storage

Store the preparation at 15-30°C. Keep the containers tightly closed.

Stability

After the first opening, the product is reusable until the expiry date, if correctly stored. Validity: 2 years.

Disposal

Hazardous preparation: observe all state and local environmental regulations regarding waste disposal.

REVISION N°	REASON	REVISION DATE
001	Regulation adjustment UE 2017/746 - IVDR	16/05/2022