



**IVD** MEDICAL DEVICE FOR IN VITRO DIAGNOSTICS **CE**

**NAME PAPANICOLAOU REAGENT**

**European Medical Device Nomenclature (EMDN) W01030708 STAIN SOLUTIONS (HISTOLOGY/CYTOLOGY)**

**Packaging available**

446461	Papanicolaou hematoxylin according to Harris	Bottle 1 l
446462	Papanicolaou hematoxylin according to Harris	Bottle 500 ml
446463	Papanicolaou hematoxylin according to Harris	Bottle 2.5 l
467781	Solution de Papanicolaou EA50	Bottle 1 l
467782	Solution de Papanicolaou EA50	Flacon 500 ml
467783	Solution de Papanicolaou EA50	Bottle 2.5 l
467791	Solution de Papanicolaou OG6	Bottle 1 l
467792	Solution de Papanicolaou OG6	Flacon 500 ml
467793	Solution de Papanicolaou OG6	Bottle 2.5 l

**Intended use**

Preparation for staining of histological samples to be examined by light microscopy.

**Principle**

Mainly applicable to the study of desquamation of cells of the vaginal epithelium, it is also used for prostate secretions and other body fluids; Allows the obtaining of slides in which the cells are transparent, to easily observe the structure of the cellular components thus allowing to detect the appearance of cancer cells.

With Hemoxylin according to Harris, it is possible to obtain an excellent coloration of the nuclei and their fine structures. Transparent staining of the cytoplasm is obtained with OG6 solution and with Polychrome EA50 solution.

Polychrome solutions are distinguished by the different concentrations of dyes, especially the EA 50 solution, used in gynecology mainly for the evaluation of cancer and ovarian cycle disorders, stains the plaques and cytoplasm with different intensities.

**Warnings and precautions**

The product is intended for specialized technical personnel.

The product is ready for use.

Read the information on the indications of danger and precautionary statements on the label carefully. Always **consult the safety data sheet** (accessible from the website at <https://www.carloerbareagents.com/cerstorefront/cer-fr/> ) where you can find information on the risks presented by the product, the precautionary measures to be taken during use, first aid measures and the response measures in case of accidental release.

Do not use if primary container is damaged.

Reagents shall be produced with uniform methods in accordance with bibliographic references and verified in accordance with quality control specifications.



### Procedure

- 1) Ethyl alcohol 96% , rinse
- 2) Ethyl alcohol 80%, rinse
- 3) 70% Ethyl Alcohol, rinse
- 4) Ethyl alcohol at 50%, rinse (these 4 phases for a total of 3 minutes)
- 5) Rinse with distilled water
- 6) Harris Hematoxylin for 2 to 3 minutes
- 7) Rinse with a thin trickle of running water for 10 minutes
- 8) Ethyl alcohol 50% for 5 minutes
- 9) Ethyl alcohol 70%, rinse
- 10) Ethyl alcohol 80%, rinse
- 11) Ethyl alcohol 96%, rinse
- 12) OG6 solution for 2 minutes
- 13) Ethyl alcohol 96%, rinse 2-3 times
- 14) EA50 Polychrome solution for 30 seconds to 2 minutes depending on the freshness of the solution
- 15) Ethyl alcohol 96%, rinse vigorously 2-3 times
- 16) Absolute Alcohol for 5 minutes
- 17) Absolute Alcohol and Xylene (50:50) for 5 minutes
- 18) Xylene, vigorously rinsed
- 19) Mount the blades

### Results

Preventive cytological examination - Pap smear plan:

PAP Group	Results	Diagnosis
I	Only normal/non-suspect cells	Negative
II	Light/non-suspicious abnormalities	Negative
III	Abnormal cells, suspicious enough to be cancerous	Doubt - Repeat
IV	Some atypical cells	Positive - Histology
V	Many atypical cells	Positive - Histology

### Diagnosis of ovarian cycle

Results with	EA50
Cyanophilic cytoplasm	Blue – green
Eosinophilic pink cytoplasm (acidophilic)	Rose
Erythrocyte	Red
Keratinized plasma	From Rose to Orange
Nucleus	Blue, dark purple, brown

### Remark

If in doubt about the scan result repeat the above procedure

### Stability

The product is stable under normal storage conditions.

There is no particular risk of reaction with other substances under normal conditions of use.

### Shelf life of the product

The product has a shelf life of 2 years, in unopened and properly stored packaging.

Close the bottle after use.

After the first opening, the product can be used for 6 months or within the limit of the total shelf life.

### Storage conditions

Products are packaged in appropriate containers, with a sealed cap; They must be kept tightly closed, protected from light, in a cool, dry place.

Recommended temperature range for storage: 5-30°C

**Warning:** In case of precipitation of dyes, the solution can be restored by heating in a water bath for a few minutes at 60 ° C; the formation of a "mirror" on the walls of the bottle indicates that the product has aged and therefore it is advisable to get rid of it.

### Waste disposal





For more information on disposal, please refer to the safety data sheet. It is advisable to follow appropriate safety precautions when handling, processing and disposing of all clinical specimens, as pathogenic organisms may be present

**References**

Valdo Mazzi – Manuale di Tecniche Istologiche e Istochimiche – Piccin Editore, Padova.

Staining Procedures – Edited by G.Clark 4th Edition – Williams & Wilkins Baltimore, London.

**English version**

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