

EA50 Papanicolaou solution

REF. 367600

Cytoplasmic staining for hormonal cytology



IFU120A-RAL

For professional use only.

Please read all information carefully before using this device.

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Intended use

EA50 Papanicolaou solution is intended to be used in combination with other staining devices for histo-cytology staining prior microscopic examination.

If applicable, RAL Diagnostics recommends using the associated RAL Diagnostics products and cannot guarantee that the expected results will be achieved if used in combination with products of other brands.

Principle

EA50 Papanicolaou solution is a cytoplasmic dye usually associated to the cytoplasmic dye OG6 and the nuclear dye haematoxylin for Papanicolaou staining.

Papanicolaou staining in its regressive and progressive variants is the most used technique for the diagnosis of cervical cancer.

In the regressive method haematoxylin, is applied in excess during a long-acting time (one to three minutes) contrary to progressive method in which haematoxylin is applied in sufficient quantity during a short acting time (one minute and thirty seconds).

Papanicolaou staining is also perform for spermatozoa morphological study (spermocytogram).

Device description

EA50 Papanicolaou solution

Clear green solution

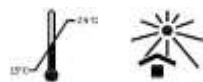
REF. 367600-0500	1 X 0.5 L
REF. 367600-1000	1 X 1.0 L
REF. 367600-2500	1 X 2.5 L

For a specific batch, refer to the analysis certificate of the batch available at my.ral-diagnostics.fr.

Storage

Storage temperature: 15-25°C away from light.

Bottle shelf life before and after opening: refer to expiry date on label.



Hazard classification and safety information

EA50 Papanicolaou solution

Danger: H225 - Highly flammable liquid and vapour. H302+H312+H332 - Harmful if swallowed, in contact with skin or if inhaled. H370 - Causes damage to organs.

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P261 - Avoid breathing dust/fume/gas/mist/vapours/spray. P264 - Wash hands thoroughly after handling. P280 - Wear protective gloves, protective clothing, eye protection, face protection. P308+P311 - IF exposed or concerned: Call a POISON CENTER or doctor. P312 - Call a POISON CENTRE or doctor if you feel unwell.



CONT CH3OH

Personnel qualification

All samples and products must be handled by qualified and authorized personnel, using individual or collective protection, in accordance with the national directives in force in the laboratories. Personnel must also be aware of the classification of hazardous materials indicated on the label and the safety data sheet (available at my.ral-diagnostics.fr).

The specimen must be treated in accordance with procedures available in the laboratory and required by national authorities.

The diagnosis must be conducted by qualified and authorized personnel, in accordance with the procedures in force within the laboratory.

Specific equipment and reagents required but not provided

Absolute ethanol, sodium bicarbonate, magnesium sulfate, hydrochloric acid 37%, ammonia 20%, microscope slides and these following RAL Diagnostics devices:

Haematoxylin stabilized solution according to Gill II REF. 362850

Harris haematoxylin REF. 361070

Harris Haematoxylin stabilized solution (mercury-free) REF. 361075

OG6 Papanicolaou solution REF. 361630

This equipment may vary depending on the protocol. Please refer to the relevant protocol (see the section operating procedure) to ensure that you have the necessary equipment to carry out tests.

Operating procedure

The equipment used for sample processing must comply with the supplier's instructions for use.

Sample preparation

Specimen must treat in accordance with procedures available in the laboratory and promulgated by national authorities.

For spermocytogram make a smear et let it air dry.

If the smear was fixed by cytofixer, remove cytofixer by dipping the slide in 50° ethanol during 20 to 30 minutes.

Reagents and instruments preparation

0,25%-hydrochloric acid solution: pour 6.757 mL of HCl 37% fill up to with 1 L of distilled water.

Ammonia alcohol solution: mix 3 mL of ammonia 20% and 97 mL of 70° ethanol

Acid-alcohol Solution: mix 300 ml of absolute ethanol with 2 ml of concentrated hydrochloric acid and 100 ml of distilled water.

Scott Solution: dissolve 3,5 g of sodium bicarbonate (NaHCO₃) and 20 g of magnesium sulfate (MgSO₄ 7H₂O) in 1 L of distilled water.

Protocols

The staining steps of the protocols indicated below consist of a successive dipping of the slides in the different staining baths.

Protocol for Papanicolaou regressive variation staining - Manual bath method - Manual microscopic analysis

Processing time: 17 min

Steps	Reagent	Time [mm: ss]	Indications
Hydrate	80° ethanol	00: 30	Can be extended to 1 min
Hydrate	70° ethanol	00: 30	
Hydrate	50° ethanol	00: 30	
Hydrate	Distilled water	00:30	
Stain	Harris haematoxylin	01:00	Can be extended to 3 min
Rinse	Distilled water	00:30	Can be extended to 1 min
Differentiate	0,25 hydrochloric acid solution	No	Dips six times
Rinse	Tap water	06: 00	No
Rinse	Distilled water	00: 30	No
Dehydrate	50° ethanol	00: 30	Can be extended to 1 min
Dehydrate	70° ethanol	00: 30	
Dehydrate	80° ethanol	00: 30	
Dehydrate	95° ethanol	00: 30	
Stain	OG6 Papanicolaou solution	01: 30	No
Rinse	95° ethanol	01: 00	2 x 30 sec. Can be extended to 2 min (2 x 1min)
Stain	EA50 Papanicolaou solution	01: 00	No
Rinse	95° ethanol	01: 30	3 x 30 sec. Can be extended to 3 min (3 x 1min)
Dehydrate	Toluene or xylene	No	Pass slide in
Mount	Toluene or xylene base mounting media	No	No

Protocol for Papanicolaou progressive variation staining - Manual bath method - Manual microscopic analysis

Processing time: 17 min 30 s

Steps	Reagent	Time [mm: ss]	Indications
Hydrate	80° ethanol	00: 30	Can be extended to 1 min
Hydrate	70° ethanol	00: 30	
Hydrate	50° ethanol	00: 30	
Hydrate	Distilled water	00:30	
Stain	Haematoxylin stabilized solution	01: 30	Can be extended to 3 min
Rinse	Distilled water	01: 00	No
Rinse	Tap water	02: 30	
Rinse	Distilled water	01: 00	
Rinse	70° ethanol	01: 00	No
Differentiate	Ammonia alcohol solution	01: 00	No
Dehydrate	70° ethanol	01: 00	2 x 30 sec. Can be extended to 2 min (2 x 1min)
Dehydrate	95° ethanol	00:30	Can be extended to 1 min
Stain	OG6 Papanicolaou solution	01: 30	No
Rinse	95° ethanol	02: 00	2 x 1min
Stain	EA50 Papanicolaou solution	01: 00	No
Rinse	95° ethanol	03: 00	3 x 1min
Dehydrate	Absolute ethanol	01: 00	No
Dehydrate	Toluene or xylene	No	No
Mount	Mounting media	No	No

Protocol for spermcytograms Papanicolaou staining - Manual bath method - Manual microscopic analysis

Processing time: 35 min 03 s

Steps	Reagent	Time mm: ss]	Indications
Fix	Ether-Alcohol	05: 00	Can be extended to 15 min
Dry	No	No	Open air
Hydrate	80° ethanol	00: 10	10 x 1 sec
Hydrate	70° ethanol	00: 10	
Hydrate	50° ethanol	00: 10	
Hydrate	Distilled water	00: 10	
Stain	Harris haematoxylin	03: 00	No
Rinse	Tap water	03: 00	Can be extended to 5 min
Differentiate	Acid-Alcohol	00: 03	3 dips x 1 sec
Rinse	Tap water	03: 00	Can be extended to 5 min
Rinse	Scott solution	04: 00	No
Rinse	Distilled water	00: 10	10 x 1 sec
Dehydrate	50° ethanol	00: 10	
Dehydrate	70° ethanol	00: 10	
Dehydrate	80° ethanol	00: 10	
Dehydrate	95° ethanol	00: 10	
Stain	OG6 Papanicolaou solution	02: 00	No
Rinse	95° ethanol	00: 20	2 series of 10 x 1 sec
Stain	EA50 Papanicolaou solution	05: 00	No
Rinse	95° ethanol	00: 10	2 series of 5 x 1 sec
Dehydrate	Absolute ethanol	02: 00	No
Dehydrate	Absolute ethanol / toluene 50/50 mix	01: 00	No
Dehydrate	Toluene or xylene	05: 00	Pass slide in
Mount	Mounting media	No	No

Expected results

Papanicolaou regressive and progressive variations staining

Nuclei: more or less dark violet-blue

Eosinophilic cells cytoplasm: pink, sometimes red-pink or orange

Cyanophilic cells cytoplasm: blue, sometimes greenish

Orangeophilic cells cytoplasm: brilliant orangey

Spermocytograms Papanicolaou staining

Head piece -Nucleus: purple

Head piece-Acrosome: green blue

Flagellum: green

Midpiece: pale green

Assess in percentage:

- abnormalities of the head, midpiece and flagellum
- agglutinates
- leukocytes, erythrocytes, cells

If observed results vary from those expected, please contact RAL Diagnostics technical service through your usual supplier for assistance.

Performance

This medical device is state of the art. Its analytical performance, scientific validity and medical relevance are assessed in the CE marking review.

To ensure product performance, use clean and dry laboratory equipment.

The laboratory is responsible for notifying the manufacturer and state competent authority of any serious incident relating to the medical device uses.

User quality Control

Users remain responsible for determining the appropriate quality control procedures for their laboratory and for complying with applicable laboratory regulations.

RAL Diagnostics recommend quality control at reagents renewal and for the first staining cycle of each day. Slides stained for quality control purposes should be checked to ensure that they are satisfactory for intended test (properly stained and free of precipitate). Staining results for each cell type must also be compliant with this manual expected results.

These quality controls depend on the authorization by qualified personnel.

Other products

For more information contact your usual supplier.

Recommendations, notes, and troubleshooting

Products appearance

If the appearance of the products differs from the description above, do not use it and contact RAL Diagnostics technical service through your usual supplier for assistance.

Procedures notes

To prevent products degradation, please comply with the storage and handling recommendations specified in this manual.

Reagent may present crystals. RAL Diagnostics recommend filtering the necessary amount of product for the staining before use.

Staining times may vary according to the nature of the smear or may be modified depending on the frequency of use, the desired staining intensity and the staining material used.

To avoid any detachment of the smear for the spermocytograms application, make a smear that would be neither too fine, nor too thick and allow it to dry well (during several hours in air or on a hot plate).

According to the thickness of the smear, it may be necessary to increase the fixative time in a bath of 70° ethanol, to 1 hour.

Products stability

Every RAL Diagnostics product can be used until the expiry date indicated on, in its original packaging if it is still hermetically sealed.

Staining stability

Staining quality and reproducibility depend on the correct use of the products.

RAL Diagnostics recommends mounting the stained slides with a coverslip using a suitable mounting liquid and to store them in a light and dustproof container.

Instructions for cleaning and waste disposal

All biological samples, effluents and used consumables should be considered potentially hazardous.



To avoid any risk, apply the following instructions: dispose of samples, effluents and consumables in accordance with laboratory standards and applicable national and local standards and regulations.

Chemical and biological waste must be collected and processed by specialized, registered companies.

Table of symbols and abbreviations

Depending on the product, you may find the following symbols on the device or the packaging material.

GHS PICTOGRAMS	INTERPRETATION	SYMBOL	INTERPRETATION
	Explosive		Batch code
	Flammable		Serial number
	Oxidizer		Catalogue reference
	Compressed gas		Date of manufacture
	Corrosive		Use up to
	Toxic		Unique device identifier
	Harmful		Manufacturer
	Health Hazard		Importer
	Environmental Hazard		Entity distributing the medical advice in the region concerned
	No labelling applicable		CE marking device
			In vitro diagnostic medical device
			Authorized Representative in the European Community
			Authorized Representative in Switzerland
			Complies with UK guidelines
			Do not use if packaging is damaged
			Keep away from light
			Temperature limit: 15-25°C
			Temperature limit: 15-30°C
			Keep dry
			Box: handling upwards
			Fragile
			Sterilised by irradiation
			Single sterile barrier system with outer protective packaging
			Sterile and radiation-sterilised barrier suit
			Do not reuse
			Do not resterilize
			Contents sufficient for n tests
			Hazardous material contained
			Consult instructions for use
			Use
			After opening, use within XX months
			The product must not be used in conjunction with an automatic colouring machine
			Indicates a medical device that contains potentially carcinogenic, mutagenic or reprotoxic (CMR) substances, or substances classified as endocrine disruptors

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Procedure modified by Service de Biologie de la Reproduction, Hôpital Pellegrin - Bordeaux - FRANCE.

Change tracking

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