OG6 Papanicolaou solution

REF. 361630

Cytoplasmic staining for hormonal cytology

CE IVD

IFU119A-RAL

For professional use only.
Please read all information carefully before using this device.

Table of contents

Intended use

OG6 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

OG6 Papanicolaou solution is a cytoplasmic dye usually associated to the cytoplasmic dye EA50 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

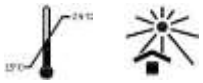
OG6 Papanicolaou solution
Clear orange solution

REF. 361630-1000	1 X 1.0 L
REF. 361630-2500	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

OG6 Papanicolaou solution

Danger: H225 - Highly flammable liquid and vapour.
P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

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
EA50 Papanicolaou solution REF. 367600

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 spermocyogram 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 ($NaHCO_3$) and 20 g of magnesium sulfate ($MgSO_4\ 7H_2O$) 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 spermocytograms 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 variation 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
	Explosive
	Flammable
	Oxidizer
	Compresses gas
	Corrosive
	Toxic
	Harmful
	Health Hazard
	Environmental Hazard
	No labelling applicable

SYMBOL	INTERPRETATION
LOT	Batch code
SN	Serial number
REF	Catalogue reference
	Date of manufacture
	Use up to
UDI	Unique device identifier
	Manufacturer
	Importer
	Entity distributing the medical advice in the region concerned
CE	CE marking device
IVD	In vitro diagnostic medical device
	Authorised Representative in the European Community
	Authorised Representative in Switzerland
UK CA	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	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

Bibliography

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

Change tracking

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