

Kit Vita-Eosine

REF. 380420-0000

Fast staining for spermograms



IFU093A-RAL

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

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Intended use

Kit Vita-Eosine is intended to be used for fast staining for spermograms 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

This kit helps assess the percentage of dead and living spermatozoa.
Only dead spermatozoa stain pink by Eosin.
Living spermatozoa remain colorless, except their outlines stain dark blue by Nigrosin.

Kit description

Eosin solution

Clear red solution
REF. 363200-0100 1 X 100 mL

Nigrosin solution

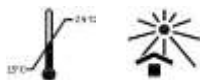
Clear black solution
REF. 363210-0100 1 X 100 mL

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

Eosin solution

No labelling applicable

Armand solution

No labelling applicable

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

Microscope slides.

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

Liquefying sperm before staining.

Reagents and instruments preparation

No preparation needed. The solutions are ready to use.

Protocols

Protocol for spermogram staining - Manual method - Manual microscopic analysis

Liquefying sperm before staining.

Processing time: 01 min

Steps	Reagent	Time [mm: ss]	Indications
Stain	Eosin solution	00:30	Mix 1 drop of sperm + 1 drop of Eosin solution and shake
Stain	Nigrosin solution	No	Add 2 drops and mix
Smear	The mix	No	No
Dry	No	No	Air dry

Microscopic examination is performed with x40-objective microscope between slide and cover-slide.

Expected results

Dead Spermatozoa: pink

Living Spermatozoa: colorless (Nigrosin shows up their outlines).

Background of preparation: dark blue

Assess the percentage of dead spermatozoa and living spermatozoa: On average, one can observe:

After 3 hours: 75 to 85% of living forms.

After 6 hours: 55 to 65% of living forms.

After 24 hours: 25 to 40% of living forms.

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

RAL Diagnostics recommend using a positive smear and a negative smear from different patient samples 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 control procedures should only be performed 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.

When the concentration of sperm is low (oligozoospermia), the dilution (Sperm/Eosin/Nigrosin) may be too high and the examination long and hard to read because there are so few living forms. In such cases, we recommend staining the sample with Eosin solution only.

Nigrosin solution can gel over time without affecting the staining quality.

Microscopic examination is performed with x40-objective microscope between slide and cover-slide.

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.

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 re-sterilize
			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

Bibliography

AUGER J., JOUANNET P., Manuel de laboratoire de l'OMS, Analyse du sperme humain et de l'interaction des spermatozoïdes avec le mucus cervical, INSERM, 3ème éd., 1993, p. 55-56.

DIEUSAERT P., Rôle du laboratoire dans l'exploration masculine du couple stérile, Rubrique de l'interne, Option Bio, n°120, 1994, p. 1-8.

Change tracking

Date	Version	Changes
05/2022	IFU093A-RAL	IVDR (EU) 2017/746 compliance

