

CytoRAL aerosol

REF. 361400-0150

Aerosol cytology fixative



IFU127A

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For professional use only.

Please read all information carefully before using this device.

IFU content may change, make sure you have the latest version available at my.ral-diagnostics.fr.

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Intended use

CytoRAL aerosol is intended to be used as aerosol cytology fixative for fixation of swab specimens.

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

Principle

Fixation is essential, for cytologic samples, to maintain the shape and structure of cellular constituents.

CytoRAL aerosol allows a quick fixation of smear, in fifteen seconds. It can be sprayed as soon as the smear is performed. CytoRAL can be used for fixation of vaginal, cervical, buccal, bronchial and other smears from swabs.

Device description

CytoRAL aerosol

Colorless solution

REF. 361400-0150

1 X 150 mL

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

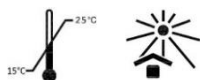
Storage and use conditions

Storage and use temperature: 15-25°C.

Storage and use conditions: away from light and heat sources.

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

Bottle shelf life after opening: refer to expiry date on the label and if the "period after opening" symbol is present take it into account.



Hazard classification and safety information

CytoRAL aerosol

Danger:

H222 - Extremely flammable aerosol.

H229 - Pressurised container: May burst if heated.

H319 - Causes serious eye irritation.

H336 - May cause drowsiness or dizziness.

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P211 - Do not spray on an open flame or other ignition source.

P251 - Do not pierce or burn, even after use.



P271 - Use only outdoors or in a well-ventilated area.

P410+P412 - Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.

CONT Isopropyl alcohol

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 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

NA

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

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

Reagents and instruments preparation

No preparation needed, CytoRAL aerosol is ready to use.

Protocols

Prepare the smear then shake the aerosol before use.

Spray straight onto the slide from about 15 cm. Lay flat 3 min for smear to dry and to be fixed. Proceed by short pressure without prolonged pulverization.

Expected results

NA

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.

These quality control procedures should only be performed by qualified personnel.

Other products

For more information, please 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 CellaVision RAL Diagnostics technical service through your usual supplier for assistance.

Procedure notes

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

Product stability

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

Staining stability

NA

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.

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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	Symbols	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
			Authorised Representative in the European Community
			Authorised 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

Bibliography

HOULD R., *Techniques d'histopathologie et de cytopathologie*, ed. Maloine (Paris) – Décarie (Montréal), 1984, p. 33 and 311-312.

Changes tracking

Date	Version	Changes
02/2023	IFU127A	IVDR (EU) 2017/746 compliance

Legal representatives

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United Kingdom	QAvis UK Ltd, company N° SC679796, 56-66 Frederick Street Edinburgh, EH21LS, United Kingdom
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