CytoRAL aerosol

CE IVD

REF. 361400-0150

Aerosol cytology fixative

IFU127A

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	Isopropylic 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.

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

Symbols	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
EC REP	Authorised Representative in the European Community
CH REP	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
STERILE R	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
CONT	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

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

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