CryoRAL spray

CE IVD

REF. 361405-0500

Instant freezing spray for anatomical pieces

IFU128A

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

CryoRAL spray is intended to be used as instant freezing spray for anatomical pieces prior to cryosection.

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

The principle of the cryotomy is the hardening of tissue thanks to the freezing of the water that is contains. Cryotomy is practiced for extemporaneous examinations and for diagnostic confirmation during surgery when conventional inclusion methods are likely to affect the preservation of substances.

Device description

CryoRAL spray
Colorless gas
REF. 361405-0500 1 X 500 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

CryoRAL spray
Warning:
H229 - Pressurised container: May burst if heated.
P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P251 - Do not pierce or burn, even after use.
P410+P412 - Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.

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, CryoRAL spray aerosol is ready to use.

Protocols
Mount the cannula in the nozzle and spray the anatomical piece form a short distance until it gets hard.
Spay anatomical piece directly from a small distance until the necessary hardness for the anatomical specimen. The ideal temperature may vary according to the tissues section. The temperature of the tissues is linked to the spray time (minimum 55°C)

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
	Batch code
	Serial number
	Catalogue reference
	Date of manufacture
	Use up to
	Unique device identifier
	Manufacturer
	Importer
	Entity distributing the medical advice in the region concerned
	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

GABE M., *Techniques histologiques, Chapitre 3 : La fixation.* p.38-40.
LANGERON M., *Précis de microscopie*, Masson & Cie, 6ème éd., 1942, p. 554-555.

Changes tracking

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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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