

Pack Dropstand Immersion 30 RAL

C€ IVD

REF. 340032-0000

Immersion oil for microscopy

IFU035A-RAL

For professional use only.

Please read all information carefully before using this device.

Table of contents

| ntended Use | 1 |
|---|---|
| Principle | 1 |
| Kit description | 2 |
| Storage | 2 |
| Active components | 2 |
| Hazard classification and safety information | 2 |
| Personnel qualification | 2 |
| Specific equipment and reagents required but not provided | 2 |
| Operating procedure | |
| Expected results | 3 |
| Performance | 3 |
| Jser quality Control | |
| Other products | |
| Recommendations, notes, and troubleshooting | 4 |
| Table of symbols and abbreviations | 5 |
| Bibliography | 5 |
| Change tracking | 5 |
| | |

Intended Use

Pack Dropstand Immersion 30 RAL is intended to be used for the optimization of biological specimen examinations with immersion-objective equipped microscopes.

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

In microscopy, the image quality is related to the optical properties of the immersion oil used. To increase the resolution (the shortest distance between two objects distinguishable through a microscope), one should use an immersion oil presenting the same refraction index as glass (approximately 1,515). This colorless oil replaces air between the object and the objective and eases the spreading of light at the same speed as in glass, avoiding any image distortion



Kit description

Pack Dropstand Immersion 30 RAL

Clear colorless liquid REF. 340032-0000

2 X 15 mL + 1 DropStand

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 the expiry date on the label.



Active components

Pack Dropstand Immersion 30 RAL

Oil synthesis: 100%

Hazard classification and safety information

Pack Dropstand Immersion 30 RAL

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

Immersion-objective equipped microscopes.

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.

Reagents and instruments preparation

No preparation needed. The oil is ready to use.

Protocols

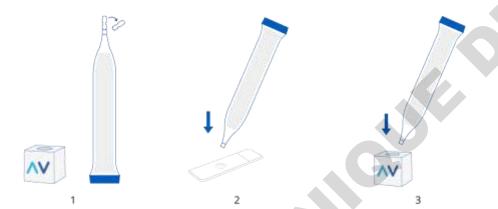


Figure 1. Schematic representation of DropStick and DropStand use 1-3: steps 1 to 3

- 1 Break the breakable tip, pointing upwards, to chase the air.
- 2 Lay a drop of the immersion oil on the slide
- Put the DropStick into the DropStand. Keep the DropStick in its support until the next use.

It is advisable to clean the DropStand with a cleaning solution before using it with a new DropStick.

Microscopic observation with immersion objective:

STEP 1: Make a pinpointing on the preparation to be observed with the lowest objectives

STEP 2: Turn to the immersion objective of the optical microscope

STEP 3: Lower the immersion objective close to the slide, so that the objective touches the immersion oil

STEP 4: Pull up slowly the objective until the preparation becomes sharp and clear

STEP 5: Once the examination is finished, clean the objective carefully with a soft duster impregnated with a cleaning solution for immersion objectives.

Expected results

Depend on the observed slides.

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.

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

Do not move from the immersion objective directly to dry objective but pull up the immersion objective and clean it carefully with a soft duster, impregnated with a cleaning solution for immersion objectives. This step is essential to avoid any contamination of the dry objectives by the oil. The risk is that the oil would seep through the objectives and so make them unusable.

Never mix up immersion oils coming from different brands, because they are not systematically miscible: always clean the objective carefully before changing oil

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

No applicable

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 |
| (b) | Flammable |
| © | Oxidizer |
| \Diamond | Compresses gas |
| 0 | Corrosive |
| (4) | Taxic |
| 1 | Harmful |
| & | Health Hazard |
| 1 | Environmental Hazard |
| \Diamond | No labelling applicable |

| SYMBOL | INTERPRETATION |
|------------|--|
| LOT | Batch code |
| SN | Serial number |
| REF | Catalogue reference |
| Conf | Date of manufacture |
| Ω. | Use up to |
| UDI | Unique device identifier |
| - | Manufacturer |
| 1980 | Importer |
| 100 | Entity distributing the medical advice in the region concerned |
| CE | CE marking device |
| IVD | In vitro diagnostic medical device |
| BE REP | Authorised Representative in the European Community. |
| (in ner | Authorised Representative in Switzerland |
| UK CA | Complies with UK guidelines |
| (58 | Do not use if packaging is damaged |
| * | Keep away from light |
| 1 | Temperature limit: 15-25°C |
| | Temperature limit: 15-30°C |
| 7 | Keep dry |
| 11 | Box: handling upwards |
| • | Fragie |
| present in | Sterilised by irradiation |
| 0 | Single sterile barrier system with outer protective packaging |
| (| Sterile and radiation-sterilised barrier suit |
| 2 | Do not reuse |
| 8 | Do not resterilize |
| E. | Contents sufficient for n tests |
| 1000 | Hazardous material contained |
| []6] | Consult instructions for use |
| USE | Use |
| 5 | After opening, use within XX months |
| 8 | 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 a endocrine disruptors |

Bibliography

M.LANGERON, Précis de microscopie - Technique. Expérimentation. Diagnostic, Masson, Paris, 7ème édition, (1949) p. 81-87; p. 165A.

POLICARD - M.BESSIS - M.LOCQUIN, Traité de microscopie - Instruments et techniques, Masson, Paris, 7ème édition (1957), p. 37

Change tracking

| Date | Version | Changes |
|---------|-------------|-------------------------------|
| 05/2022 | IFU035A-RAL | IVDR (EU) 2017/746 compliance |



RAL Diagnostics - Site Montesquieu - 33650 Martillac - France T+33(0)5 57 96 04 04 - F +33 (0)5 57 96 04 55 - ral-diagnostics.fr / cellavision.com