

Kit RAL 555 (3x500mL)**REF.361555-0000**

Fixation and differential staining of cellular structures

**IFU023B**

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|-----------------------------|----|
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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

Kit RAL 555 is intended to be used for the fixation and the differential staining of biological samples and cellular structures prior microscopic examination.

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

Kit RAL 555 is a fast-acting variation of May-Grünwald Giemsa staining.

In an aqueous buffered medium, this kit enables:

- A differential staining of blood smears (differential blood cell counting, morphological study of leukocytes, study of parasites) and medullary smears (myelograms)
- The detection of tissular and blood parasites in medical and in veterinary mycology
- The cytological and structural study of fixed and paraffin embedded tissue sections as well as fluids and punctions
- The cytological study of urines, spinal, and other fluids

The analysis of smears is identical to the one carried out with standard MGG staining.

Kit description

FIX-RAL 555

Clear purple solution

REF. 362870-0500 1 X 500 mL

EOSIN-RAL 555

Clear orange red solution

REF. 361640-0500 1 X 500 mL

BLUE-RAL 555

Clear dark blue solution

REF. 361650-0500 1 X 500 mL

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

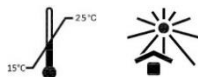
Storage and use conditions

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: 2 months, refer to expiry date on the label and if the "period after opening" symbol is present take it into account.



Active components

FIX-RAL 555

Methanol - CAS 67-56-1: >80%

EOSIN-RAL 555

Eosin Y- CAS 17372-87-1: <0.1%

BLUE-RAL 555

Methylene blue - CAS 61-73-4: < 1%

Hazard classification and safety information

FIX-RAL 555

Danger:



H225 - Highly flammable liquid and vapour.

H301+H311+H331 - Toxic if swallowed, in contact with skin or if inhaled.

H370 - Causes damage to organs.

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

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.

P264 - Wash hands thoroughly after handling.

P280 - Wear protective gloves, protective clothing, eye protection, face protection.

P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor.

P308+P311 - IF exposed or concerned: Call a POISON CENTER or doctor.

| | |
|------|-------|
| CONT | CH3OH |
|------|-------|

EOSIN-RAL 555

Warning:

H317-May cause an allergic skin reaction.

H412 - Harmful to aquatic life with long lasting effects.

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 - Wear protective clothing, protective gloves, eye protection.

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 - Take off contaminated clothing and wash it before reuse.



CONT 5-chloro-2-methyl-2H-isothiazol-3-one/2-methyl-2H-isothiazol-3-one

BLUE-RAL 555

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 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, absolute ethanol, 90° ethanol and isopropanol.

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 treat in accordance with procedures available in the laboratory and promulgated by national authorities.

Manual blood smear: Mix the tube by slow inversion and install a smearing droplet device. Invert the tube and lightly press the drop depositor onto a slide to deposit a small drop of blood (Fig. 1- slide A at step 1).

Using another slide tilted at 45° (Fig. 1- slide B at step 1), spread the blood by capillarity on the short edge (Fig. 1- steps 2 & 3) using a pushing motion (Fig. 1- step 4). A good quality smear does not reach the end of the slide and has a gradual decrease in thickness until the end is feathered. Allow the smear to air dry before fixing or staining.

NB: if you do not have a smearing droplet device, open the tube, and use a pipette to deposit a blood drop.

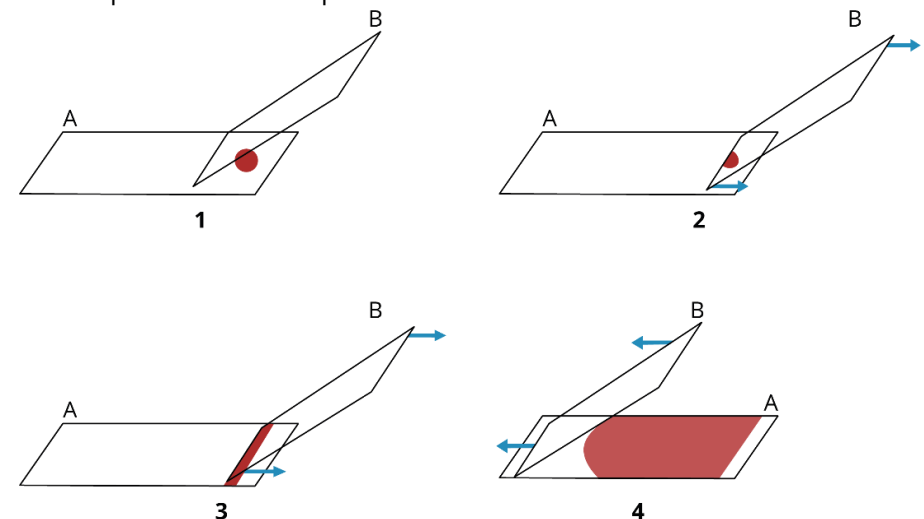


Figure 1. Schematic representation of performing a blood smear
A & B: slides, 1 – 4: steps 1 to 4

Manual bone marrow smear by crushing method: using a pipette deposit, a small amount of the sample on a microscope slide. Blot up blood excess to keep only shiny lumps. Cover the first slide with a slide. Squeeze and thin the sample by sliding and stretching to the end of the slide. A good quality smear does not reach the end of the slide. Discard the slide used for smearing. Allow the smear to air dry before fixing or staining.

Thick blood smear: take 2 μL of blood out of an EDTA tube and place them in the center of a slide. Spread the drop in a circle with the corner of another slide. Allow it to dry for 20 minutes in the open air or for 5 minutes in an incubator or for 2 minutes under a hair dryer. Cover the drop with very little tap water to hemolyze it. Once the hemoglobin has spread, get rid of the red water just inclining the slide. Rinse the drop very gently with tap water. The drop gets a whitish appearance.

Manual bacterial smear: made a thin film of bacteria sample and leave the slide to dry at room temperature. Then bacterial smear can be fixed with mild heat source (Bunsen burner or hot plate) or chemically fixed with chemical fixative (methanol, ethanol, acetic acid, or formalin...)

NB: Never pass through the flame a smear that is not entirely dry, this could cause cracklings and dissemination of bacteria (creation of aerosols).

If necessary, the two fixations can be combined.

Histological sections: dewax and et hydrate tissues sections in appropriate reagents before staining.

Spermocytograms: to avoid any detachment of the smear, make a smear that would be neither too fine, nor too thick and allow the smear to dry well: during several hours in air or on a hot plate.

Reagents and instruments preparation

No preparation needed. The solutions are ready to use. Transfer the solutions into staining baths as indicated in the protocols below.

The rinsing liquid for staining can be distilled, demineralized, or tap water.

Protocols

The staining steps of the protocols indicated below consist of a successive covering of the slides with the different staining reagents or dipping of the slides in the different staining baths. Please refer to the title to know which case you are in. For the covering method, place slide on a stand with fixed smear on top. The processing time only considers the dipping time in the reagents.

Drain excess solution on filter paper at each solution change as shown on the schema (Fig.2).

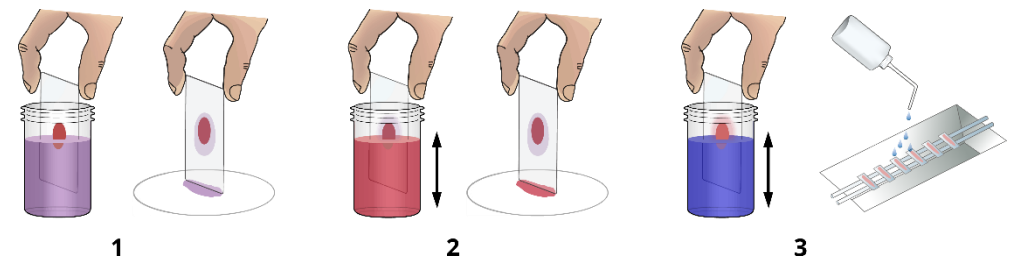


Figure 2. Schematic representation of performing 555 staining

1 – 3: steps 1 to 3

1. Dip slide in the FIX-RAL 555 according to the protocol and drain the excess solution on filter paper.
2. Dip slide in the EOSIN-RAL 555 according to the protocol and drain the excess solution on filter paper.
3. Dip slide in the BLUE-RAL 555 according to the protocol and rinse with distilled water.

Protocol for blood smear staining - Manual bath staining method - Manual microscopic analysis

Processing time [hh: mm: ss]: 00: 00: 15

| Steps | Reagent | Time [mm: ss] | Indications |
|-------|----------------|---------------|------------------|
| Fix | FIX-RAL 555 | 00: 05 | Dip 5 X 1 second |
| Stain | EOSIN-RAL 555 | 00: 05 | Dip 5 X 1 second |
| Stain | BLUE-RAL 555 | 00: 05 | Dip 5 X 1 second |
| Rinse | Rinsing liquid | NA | Quickly |
| Dry | NA | ≥03: 00 | NA |

Protocol for medullary smear staining - Manual bath staining method - Manual microscopic analysis

Processing time [hh: mm: ss]: 00: 03: 00

| Steps | Reagent | Time [mm: ss] | Indications |
|-------|----------------|---------------|-------------|
| Fix | FIX-RAL 555 | 01: 00 | NA |
| Stain | EOSIN-RAL 555 | 01: 00 | |
| Stain | BLUE-RAL 555 | 01: 00 | |
| Rinse | Rinsing liquid | NA | Quickly |
| Dry | NA | ≥03: 00 | NA |

Protocol for spermcytograms staining - Manual bath staining method - Manual microscopic analysis

Processing time [hh: mm: ss]: 00: 01 :20

| Steps | Reagent | Time [mm: ss] | Indications |
|-------|----------------|---------------|-------------------|
| Fix | FIX-RAL 555 | 01: 00 | NA |
| Stain | EOSIN-RAL 555 | 00: 10 | Dip 10 X 1 second |
| Stain | BLUE-RAL 555 | 00: 10 | Dip 10 X 1 second |
| Rinse | Rinsing liquid | NA | Quickly |
| Dry | NA | ≥03: 00 | NA |

Protocol for histo-cytology samples staining - Manual bath staining method - Manual microscopic analysis

Processing time [hh: mm: ss]: 00: 00: 15

| Steps | Reagent | Time [mm: ss] | Indications |
|-------|----------------|---------------|-------------|
| Fix | FIX-RAL 555 | 00: 05 | NA |
| Stain | EOSIN-RAL 555 | 00: 05 | |
| Stain | BLUE-RAL 555 | 00: 05 | |
| Rinse | Rinsing liquid | NA | Quickly |
| Dry | NA | ≥03: 00 | NA |

Protocol for cyto-bacteriology of fluids, urines and cytopunctures - Manual bath staining method - Manual microscopic analysis

Processing time [hh: mm: ss]: 00: 00 :15

| Steps | Reagent | Time [mm: ss] | Indications |
|-------|----------------|---------------|-------------|
| Fix | FIX-RAL 555 | 00: 05 | |
| Stain | EOSIN-RAL 555 | 00: 05 | NA |
| Stain | BLUE-RAL 555 | 00: 05 | |
| Rinse | Rinsing liquid | NA | Quickly |
| Dry | NA | ≥03: 00 | NA |

Protocol for cyto-bacteriology of cerebrospinal fluid (CSF) samples staining - Manual bath staining method - Manual microscopic analysis

Processing time [hh: mm: ss]: 00: 01: 04

| Steps | Reagent | Time [mm: ss] | Indications |
|-------|----------------|---------------|------------------|
| Fix | FIX-RAL 555 | 01: 00 | NA |
| Stain | EOSIN-RAL 555 | 00: 02 | Dip 2 X 1 second |
| Stain | BLUE-RAL 555 | 00: 02 | Dip 2 X 1 second |
| Rinse | Rinsing liquid | NA | Quickly |
| Dry | NA | ≥03: 00 | NA |

Protocol for fixed and paraffined tissues sections staining - Manual bath staining method - Manual microscopic analysis

Processing time [hh: mm: ss]: 00: 00 :23

| Steps | Reagent | Time [mm: ss] | Indications |
|----------------------|-----------------|---------------|--|
| Stain | EOSIN-RAL 555 | 00: 05 | |
| Stain | BLUE-RAL 555 | 00: 07 | NA |
| Rinse | Rinsing liquid | NA | Briefly |
| Differentiate | 90° ethanol | 00: 01* | Shake in the bath until the slide gets the wished tint |
| Stop differentiation | Isopropanol | 00: 10 | NA |
| Mount | Mounting medium | ≥03: 00 | |

* The differentiation step in ethanol 90° can be extended to 2 seconds.

Dewax and et hydrate tissues sections in appropriate reagents before staining. Do not dip slides in the FIX-RAL 555 solution.

Protocol for cytology of punctions (breast and deep organs), effusion liquids of the serous membrane (pleura, peritoneum ...) staining - Manual bath staining method - Manual microscopic analysis

Processing time [hh: mm: ss]: 00: 00: 15

| Steps | Reagent | Time [mm: ss] | Indications |
|-------|----------------|---------------|-------------|
| Fix | FIX-RAL 555 | 00: 05 | |
| Stain | EOSIN-RAL 555 | 00: 05 | NA |
| Stain | BLUE-RAL 555 | 00: 05 | |
| Rinse | Rinsing liquid | NA | Quickly |
| Dry | NA | ≥03: 00 | NA |

Protocol for Plasmodium research in thick blood smear - Manual bath staining method - Manual microscopic analysis

Processing time [hh: mm: ss]: 00: 00: 07

| Steps | Reagent | Time [mm: ss] | Indications |
|-------|----------------|---------------|------------------|
| Fix | FIX-RAL 555 | 00: 01 | NA |
| Stain | EOSIN-RAL 555 | 00: 03 | Dip 3 X 1 second |
| Stain | BLUE-RAL 555 | 00: 03 | Dip 3 X 1 second |
| Rinse | Rinsing liquid | NA | Very gently |
| Dry | NA | ≥03: 00 | NA |

Protocol for blood film for Plasmodium research - Manual bath staining method - Manual microscopic analysis

Processing time [hh: mm: ss]: 00: 01: 04

| Steps | Reagent | Time [mm: ss] | Indications |
|-------|----------------|---------------|------------------|
| Fix | FIX-RAL 555 | 01: 00 | NA |
| Stain | EOSIN-RAL 555 | 00: 02 | Dip 2 X 1 second |
| Stain | BLUE-RAL 555 | 00: 02 | Dip 2 X 1 second |
| Rinse | Rinsing liquid | NA | Quickly |
| Dry | NA | ≥03: 00 | NA |

Protocol for staining of tissular Protozoa (Leishmania, Toxoplasma, Microsporidiosis), Cryptosporidium, Pneumocystis carinii, fungi contributing to deep Mycosis - Manual bath staining method - Manual microscopic analysis

Processing time [hh: mm: ss]: 00: 02: 05

| Steps | Reagent | Time [mm: ss] | Indications |
|-------|----------------|---------------|-------------|
| Fix | FIX-RAL 555 | 01: 00 | NA |
| Stain | EOSIN-RAL 555 | 00: 25 | |
| Stain | BLUE-RAL 555 | 00: 40 | |
| Rinse | Rinsing liquid | NA | Quickly |
| Dry | NA | ≥03:00 | NA |

Protocol for veterinary parasitology (Piroplasmosis, M.pachydermatis)- Manual bath staining method - Manual microscopic analysis

Processing time [hh: mm: ss]: 00: 00: 15

| Steps | Reagent | Time [mm: ss] | Indications |
|-------|----------------|---------------|------------------|
| Fix | FIX-RAL 555 | 00: 05 | Dip 5 X 1 second |
| Stain | EOSIN-RAL 555 | 00: 05 | Dip 5 X 1 second |
| Stain | BLUE-RAL 555 | 00: 05 | Dip 5 X 1 second |
| Rinse | Rinsing liquid | NA | Quickly |
| Dry | NA | ≥03: 00 | NA |

Protocol for *Trichomonas* research - Manual bath staining method - Manual microscopic analysis

Processing time [hh: mm: ss]: 00: 02: 15

| Steps | Reagent | Time [mm: ss] | Indications |
|-------|----------------|---------------|-------------|
| Fix | FIX-RAL 555 | 00: 15 | |
| Stain | EOSIN-RAL 555 | 01: 00 | NA |
| Stain | BLUE-RAL 555 | 01: 00 | |
| Rinse | Rinsing liquid | NA | Quickly |
| Dry | NA | ≥03:00 | NA |

Protocol for *Microfilaria* research - Manual bath staining method - Manual microscopic analysis

Processing time [hh: mm: ss]: 00: 00: 30

| Steps | Reagent | Time [mm: ss] | Indications |
|-------|----------------|---------------|-------------------|
| Fix | FIX-RAL 555 | 00: 10 | Dip 10 X 1 second |
| Stain | EOSIN-RAL 555 | 00: 10 | Dip 10 X 1 second |
| Stain | BLUE-RAL 555 | 00: 10* | Dip 10 X 1 second |
| Rinse | Rinsing liquid | NA | Quickly |
| Dry | NA | ≥03:00 | NA |

*The staining step in BLUE-RAL 555 can be extended to 20 seconds (20 x 1 second dips).

Protocol for *Helicobacter pylori* research - Manual bath staining method - Manual microscopic analysis

Processing time [hh: mm: ss]: 00: 00: 22

| Steps | Reagent | Time[mm: ss] | Indications |
|----------------------|------------------|--------------|------------------------|
| Stain | EOSIN-RAL 555 | 00: 07 | NA |
| Stain | BLUE-RAL 555 | 00: 05 | |
| Rinse | Rinsing liquid | NA | Dry on to filter paper |
| Differentiate | 90° ethanol | 00: 10 | Dip and shake |
| Stop differentiation | Absolute ethanol | NA | NA |
| Dehydrate | Mounting medium | NA | 2 baths |

Dewax and et hydrate tissues sections in appropriate reagents before staining. Do not dip slides in the FIX-RAL solution.

Expected results

Blood or bone marrow smear

Nuclei / chromatin: +/- dense purple

Leukocytes cytoplasm without RNA: light pinkish

Granulocytes eosinophilic granules: orange- brown

Granulocytes basophilic granules: dark purple-blue

Granulocytes neutrophilic granules: +/- deep purple

Lymphocytes cytoplasm without RNA: pure blue

Lymphocytes cytoplasm without RNA: light blue

Lymphocytes azurophilic granules: red

Monocytes cytoplasm: grey-blue

Erythrocytes: light red

Platelets chromomere: purple-red

Platelets Hyalomere: bluish

Blood parasites nucleus (Plasmodium): red

Blood parasites cytoplasm (Plasmodium): blue

Spermocytograms

Head piece -Nucleus: purple

Head piece-Acrosome: pink

Midpiece: purplish pink

Flagellum: light pink

Assess in Percentage:

- abnormalities of the head, midpiece and flagellum
- agglutinates
- leucocytes, erythrocytes and cells

Parasitology and Mycology

Cytoplasm of host, fungic or parasitic eucaryot cells: blue to dark blue, depending on the ribosomal richness.

Nuclei: purple red

Helicobacter pylori on histological sections

Helicobacter pylori: dark blue

Nuclei: blue

Cytoplasm: pink to red

Collagen: very pale pink

Histo-cytology

Nuclei: red violet

Acidophilic cytoplasm: pink

Basophilic cytoplasm: blue

Collagen: pale pink

Erythrocytes: beige

If observed results vary from those expected, please contact CellaVision 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.

The following examples are for hematological and bacterial samples.

Hematological sample: CellaVision RAL Diagnostics recommends staining a freshly made blood smear with a normal WBC count and no known abnormal pathology at reagent renewal and for the first staining cycle 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).

Bacterial sample: CellaVision RAL Diagnostics recommend using a known bacteria sample for reagents quality control at reagents renewal, for each staining cycle or at least for the first staining cycle if a stain is performed multiple times daily.

The result is checked under a microscope, in comparison with the results obtained by the usual technique validated by the laboratory.

Staining results 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 CellaVision 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.

Kit RAL 555 allows to process up to 200 slides.

The FIX-RAL 555 contains methanol which is very hygroscopic, and must be therefore regularly refilled, namely in countries having high humidity). We advise you to put the lids back on the bottles at the end of staining cycles if you notice that FIX-RAL 555 evaporates quickly in your laboratory.

The color of EOSIN-RAL 555 solution may appear more or less dark, but the staining results are not affected either way.

The oxidation level of BLUE-RAL 555 is standardized during manufacture, but this level varies over time and in transferring small quantities of eosin from bottle to bottle. It is essential to remove excess of EOSIN-RAL 555 before dipping the slide into BLUE-RAL 555.

The rinsing liquid for staining can be distilled, demineralized, or tap water.

Products 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

Staining quality and reproducibility depend on the correct use of the products. Staining conducted according to these recommendations will remain stable for several days. If it is necessary to store the stained smears for several months or years, CellaVision RAL Diagnostics recommended mounting them with a coverslip, using a suitable mounting liquid and storing them in a light and dustproof container.

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 |

| SYMBOL | 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 |
|  | Keep away from heat |
|  | Temperature limit: 15-25° |
|  | Temperature limit: 15-30° |
|  | 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 |

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Changes tracking

| Date | Version | Changes |
|---------|---------|--|
| 10/2023 | IFU023B | Update in header and the following paragraphs: Storage and use conditions, Active components, Operating procedure, Expected results and Recommendations, notes and troubleshooting. Adjunction of legal representatives and GMED logo. |
| 05/2022 | IFU023A | IVDR (EU) 2017/746 compliance |

Legal representatives

| Countries | Address |
|-------------------------|---|
| United Kingdom (UK-REP) | QAVIS UK Ltd, company N° SC679796, 56-66 Frederick Street Edinburgh, EH21LS, United Kingdom |
| Switzerland (CH-REP) | MedEnvoy Switzerland, Gotthardstrasse 28, 6302 Zug Switzerland |