

## Kit Copro-Duo 2x24

REF. 362350-0000

Staining for parasitic coprology



IFU097B

Changes tracking ..... 7

Legal representatives ..... 7

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](http://my.ral-diagnostics.fr).

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### Intended use

Kit Copro-Duo is intended to be used for parasitic coprology concentration and staining 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 Copro-Duo allows concentration technique so called biphasic: parasitic concentration is achieved by two non-miscible phases, one is aqueous (M.F. solution or Aceto-Acetic buffer pH=5.0 according to Bailenger) and the other is organic (Organic Phase Ethyl Acetate based). Both phases permit the partition coefficient of each faecal particle to be assessed and the concentration of the parasitic elements at the bottom. The concentration technique according to Blagg and coll. (MIF) allows the staining and preservation of parasitic elements. It is particularly recommended for the detection of the most fragile parasites (trophozoites), cysts and eggs (Schistosoma eggs and non-fertilized Ascaris eggs).

## Kit description

<b>Wooden sampling spatula</b>	<b>x24</b>
<b>Tubes holders</b>	<b>x24</b>
<b>Sedimentation tubes</b>	<b>24 X 30mL</b>
<b>Centrifugations tubes</b>	<b>24 X 10mL</b>
<b>Merthiolate-Formalin (M.F. solution)</b>	
Clear orange red solution	
REF. 365020-0400	1 X 400 mL
<b>Organic phase ethyl acetate based</b>	
Clear colorless solution	
REF. 335350-0400	1 X 400 mL
<b>Lugol Coprology</b>	
Clear dark brown solution	
REF. 367240-0003	2 X 3 mL
<b>Aceto-acetic buffer pH=5.0 according to Bailenger</b>	
Clear colorless solution	
REF. 366220-0400	1 X 400 mL

For a specific batch, refer to the analysis certificate of the batch available at [my.ral-diagnostics.fr](http://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

### Merthiolate-Formalin (M.F. solution for Kit MIF)

Danger:

H226 - Flammable liquid and vapour.

H315 - Causes skin irritation.

H317 - May cause an allergic skin reaction.

H319 - Causes serious eye irritation.

H335 - May cause respiratory irritation.

H341 - Suspected of causing genetic defects.

H350 - May cause cancer.

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.

P308+P313 - IF exposed or concerned: Get medical advice/attention.

<b>CONT</b>	HCHO 24%
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**Organic phase ethyl acetate based**

Danger:

H225 - Highly flammable liquid and vapour.

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.

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

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

P312 - Call a POISON CENTRE or doctor if you feel unwell.

P337+P313 - If eye irritation persists: Get medical advice/attention.

**CONT** CH3COOC2H5**Lugol Coprology**

Warning:

H373 - May cause damage to organs (thyroid gland) through prolonged or repeated exposure (if swallowed).

P314 - Get medical advice/attention if you feel unwell.

**CONT** KI**Aceto-acetic buffer pH=5.0 according to Bailenger**

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](http://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 physiological water, Pasteur pipette centrifuges with suspension for centrifugation tubes (10 mL, Ø 16 mm).

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**

For concentration according to Blagg and Coll. (MIF)

In a 30 ml sedimentation tube prepare extemporaneously the mixture in the following order:

4 drops of Lugol Coprology and 15 ml of Merthiolate-Formalin (M.F. solution).

For concentration according to Bailenger

For staining: Mix extemporaneously one drop of Lugol Coprology with 2 ml of Merthiolate-Formalin Solution (M.F Solution) in the order described here.

## 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.

### Protocol for concentration according to Blagg and Coll. (MIF) - Manual microscopic analysis

Processing time [hh :mm :ss]: NA

Steps	Reagent	Time [mm: ss]	Indications
Add sample	Lugol- MF solution	NA	2 to 3 g of stools or 2 to 3 mL if liquid
Triturate	NA	NA	Until completely homogenized
Sediment	NA	NA	allow to sediment for a maximum of 2 minutes (no longer).
Emulsify	Organic phase ethyl acetate based	NA	Pour 5 ml of supernatant in a 10 mL centrifugation tube, add 4 to 5 mL of Organic Phase Ethyl Acetate based. Emulsify by shaking vigorously either manually or with a vortex, then degas.
Centrifuge	NA	02: 00	Centrifuge at 1600 rpm*
Remove supernatant	NA	NA	Get rid of the supernatant by turning the tube upside down. If traces of the ring remain, clean the tube with cotton.
Suspend pellet	Physiological water	NA	Suspend pellet with some drops of physiological water sediment with a Pasteur pipette for examination

*\*If the ring appearing between both aqueous and organic phases is thick, scrape it from the wall of the tube with a Pasteur pipette or a loopful.*

### Protocol for concentration according to Bailenger - Manual microscopic analysis

Processing time [hh :mm :ss]: NA

Steps	Reagent	Time [mm: ss]	Indications
Sample	Aceto-acetic buffer pH=5.0 according to Bailenger	NA	In a 30 mL sedimentation tube, mix 3 to 4 g of stools (or 2 to 3 mL if liquid) with 15 mL of Aceto-Acetic buffer pH=5.0 according to Bailenger.
Triturate	NA	NA	Until completely homogenized
Sediment	NA	NA	allow to sediment for a maximum of 2 minutes (no longer).
Emulsify	Organic phase ethyl acetate based	NA	Pour 5 ml of supernatant in a 10 mL centrifugation tube, add 4 to 5 mL of Organic Phase Ethyl Acetate based. Emulsify by shaking vigorously either manually or with a vortex, then degas.
Centrifuge	NA	02: 00	Centrifuge at 1600 rpm*
Remove supernatant	NA	NA	Get rid of the supernatant by turning the tube upside down. If traces of the ring remain, clean the tube with cotton.
Suspend pellet	Physiological water	NA	Suspend pellet with some drops of physiological water sediment with a Pasteur pipette for examination
Stain (optional)	Lugol- MF solution	NA	Add one drop of this mixture obtained at the previous step to 2 mL of Lugol- MF solution. Examine a drop.

*\*If the ring appearing between both aqueous and organic phases is thick, scrape it from the wall of the tube with a Pasteur pipette or a loopful.*

## Expected results

### *Without staining*

parasites are observed by their refringency.

### *With staining*

**Cysts, eggs and parasites:** yellowish green or +/- dark-brown

After some hours, initial staining by **Lugol Coprology** is replaced by a tint caused by Eosin.

**Cytoplasm:** red.

**Nuclear membrane:** dark red to black

**Chromatin:** appears only by refringence

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.

CellaVision RAL Diagnostics recommends staining a freshly made sample at reagent renewal and for the first staining each day. Samples stained for quality control purposes should be checked to ensure that they are satisfactory for intended test (properly stained and free of precipitate).

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.

Kit Copro-Duo 2x24 allows to process up to 24 tests.

Do not exceed the sedimentation time, as some larger parasite's eggs could sediment and cause a false-negative result.

Stools direct examination complements the concentration methods and must be carried out on stools at +37°C to avoid damaging the vegetative forms. After direct examination, the stools can be kept for 24 hours at + 4°C.

### **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**

Staining quality and reproducibility depend on the correct use of the products.

### **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

## Bibliography

**BAILENGER J.**, *Coprologie parasitaire et fonctionnelle*, Imp. E. Drouillard, 3ème éd., 1973, p. 280-281

**BOUREE P.**, *Aide-mémoire de parasitologie et de pathologie tropicale*, Flammarion, Médecine-Sciences, 2ème éd., 1994, p. 280-281

## Changes tracking

Date	Version	Changes
06/2023	IFU097B	Update in header and the following paragraphs: storage and use conditions, hazard classification and safety information, operating procedure and Recommendations, notes and troubleshooting. Adjunction of legal representatives and GMED logo.
05/2022	IFU097A	Update according to IVDR (EU) 2017/746

## Legal representatives

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

