

## Kit MIF-Color

REF. 361410-0000

Staining for parasitic coprology



IFU094A-RAL

For professional use only.

Please read all information carefully before using this device.

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### Intended Use

Kit MIF-Color is intended to be used for parasitic coprology concentration and staining prior microscopic examination.

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 parasitic coprology, MIF staining (Merthiolate, Iodine, Formalin) is simultaneously used as a concentration, staining and preservation technique for parasitic elements.

Two staining techniques are practicable: simple MIF technique and diphasic MIF technique.

The variation using the simple MIF staining technique, is recommended especially for the detection of amoebae and other protozoa. It uses the difference of density between the elements of the sample and the parasites: stools are mixed in a solution at a fixed density so that the densest parasites immediately fall to the bottom through a process of sedimentation or centrifugation, while non-digested food particles and bacteria float or remain suspended.

The variation using the diphasic MIF staining technique, is recommended especially for the detection of the most fragile parasites (trophozoites), cysts and eggs (Schistosoma eggs and non-fertilized Ascaris eggs). This is a physico-chemical technique said to be diphasic: parasitic concentration is achieved in two non-miscible phases, one is aqueous and the other is lipophilic. Both phases allow a partition coefficient, which value is influenced, for each fecal particle (parasites and wastes), by its hydrophilic-lipophilic ratio.

## Kit description

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

Clear orange red solution  
REF. 365150-0125 2 X 125 mL

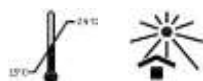
### Lugol, COPROLOGY

Clear dark brown solution  
REF. 367240-0020 1 X 20 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

Storage temperature: 15-25°C away from light.  
Bottle shelf life before and after opening: refer to expiry date on label.



## 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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### Lugol, COPROLOGY

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 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

Microscope slides, stemmed glass, glass stick, ether or ethyl acetate, physiological water – Pasteur pipette – Centrifuges with suspension for centrifugation tubes.

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

### Reagents and instruments preparation

#### For simple MIF staining technique

Prepare extemporaneously 3 drops of Lugol, COPROLOGY to 7 drops of Merthiolate-Formalin (M.F. solution for Kit MIF).

#### For diphasic MIF staining technique

Prepare extemporaneously 3 drops of Lugol, COPROLOGY to 47 drops of Merthiolate-Formalin (M.F. solution for Kit MIF).

## Protocol

### **Protocol for simple MIF staining technique - Manual microscopic analysis**

Processing time: NA

Steps	Reagent	Time [mm: ss]	Indications
Add sample	Lugol-MF solution	NA	add a knob of stools (about 0.25 g)
Triturate	None	NA	Until completely homogenized
Sediment	None	NA	Allow to rest for 20 to 30 min or Allow to rest for 24 hours or Centrifuge for 3 minutes at 1500 rpm.
Sample			sample from the top layer of the sediment with a Pasteur pipette for examination

### **Protocol for diphasic MIF staining technique - Manual microscopic analysis**

Processing time: NA

Steps	Reagent	Time [mm: ss]	Indications
Add sample	Lugol-MF solution	NA	1 volume of stools (2 to 3 g approx.) for 10 volumes of MIF mixture
Triturate	None	NA	Until completely homogenized
Clarify	None	NA	Get rid of the voluminous pieces according to the usual method (sedimentation or sieving).
Emulsify	Ether or Ethyl Acetate	NA	Add an equal volume
Sediment	None	NA	Centrifuge at 1600 rpm

Suspend pellet	None	NA	
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## Expected results

**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 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 use of the medical device.

## User quality Control

Users are responsible for determining the appropriate quality control procedures for their laboratory and complying with applicable laboratory regulations.

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 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

To prevent products degradation, please comply with the storage and handling recommendations specified in this manual.

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. Do not exceed the sedimentation time, as some larger parasite's eggs could sediment and cause a false-negative result. *Dientamoeba fragilis* is not stained by the simple MIF staining. Simple MIF staining technique is recommended regardless of the initial stools consistency. Large amounts of stools can be fixed and stored for several years. The conservation of the stained parasites in the sediment is endless, if the tube is properly closed preventing them from drying. When a preserved sediment must be examined several weeks later, it should first be placed in suspension by agitating the tube, then allowed to rest for some ten minutes before examining. To avoid apparition of thin precipitate which reduces staining of parasite, it's recommended to:

- mix extemporaneously Lugol Coprology and Merthiolate-Formalin.
- respect the introduction order of stains to prepare it (first Lugol Coprology, then Merthiolate-Formalin).

### **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**

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	SYMBOL	INTERPRETATION
	Explosive		Batch code
	Flammable		Serial number
	Oxidizer		Catalogue reference
	Compressed gas		Date of manufacture
	Corrosive		Use up to
	Toxic		Unique device identifier
	Harmful		Manufacturer
	Health Hazard		Importer
	Environmental Hazard		Entity distributing the medical advice in the region concerned
	No labelling applicable		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

**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

## Change tracking

Date	Version	Changes
05/2022	IFU094A-RAL	IVDR (EU) 2017/746 compliance

