Kit Myeloperoxidase

REF. 361610-0000

Fixation and differential staining of cellular structures

CE IVD

IFU091A-RAL

For professional use only.
Please read all information carefully before using this device.

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Intended use

Kit Myeloperoxidase is intended to be used for fixation and differential staining of cellular structures.

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

Cytochemical detection of myeloperoxidase activity is usually performed for acute leukemia diagnosis. The test positivity is a strong marker for myeloid differentiation.
Peroxidase granulations form an insoluble bright red compound with Pyronin in presence of Alpha-Naphtol and Hydrogen Peroxide. The nuclei of leukocytes stain blue with Mayer Haematoxylin.

Kit description

Formalin / Ethanol solution
Clear colorless solution
REF. 310850-0125 1 X 125 mL

Alphanaphtol solution
Clear colorless to ambre solution
REF. 320750-0030 1 X 30 mL

Pyronin, 0,2% in aqueous solution
Clear red solution
REF. 361800-0125 1 X 125 mL

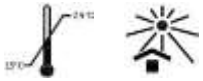
Hydrogen peroxide 3%
Clear colorless solution
REF. 300980-0010 1 X 10 mL

Mayer haematoxylin
Clear red violet solution
REF. 361620-0125 1 X 125 mL

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.



Hazard classification and safety information

Formalin / Ethanol solution

Danger: H225 - Highly flammable liquid and vapour. H315 - Causes skin irritation. H317 - May cause an allergic skin reaction. H319 - Causes serious eye irritation. H331 - Toxic if inhaled. 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.

CONT	HCHO 24%

Alphanaphtol solution

Danger: H225 - Highly flammable liquid and vapour. H319 - Causes serious eye irritation.
P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P280 - Wear protective gloves, protective clothing, eye protection. P337+P313 - If eye irritation persists: Get medical advice/attention.

Pyronin, 0,2% in aqueous solution

Danger: H350 - May cause cancer.
P280 - Wear protective gloves, protective clothing, eye protection, face protection. P308+P313 - IF exposed or concerned: Get medical advice/attention.
EUH 208 – Contains Formol 24%. May produce an allergic reaction.

CONT	HCHO 24%

Hydrogen peroxide 3%

No labelling applicable

Mayer haematoxylin

Warning: H302 - Harmful if swallowed.
P301+P312 - IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell.

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

Microscope slides.

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

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.

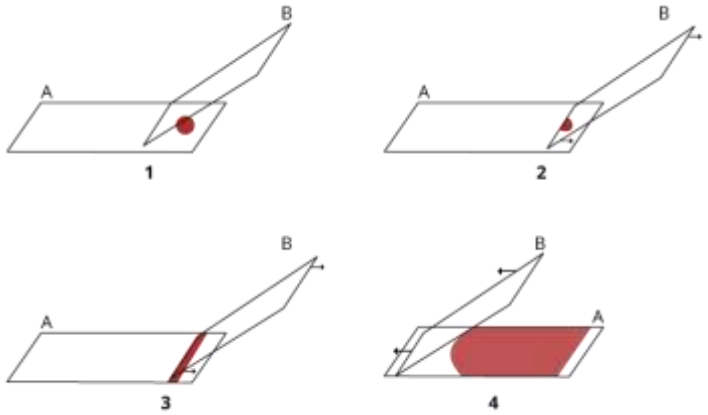


Figure 1. Schematic representation of performing a blood smear
A & B: slides, 1 – 4: steps 1 to 4

Reagents and instruments preparation

Formalin / Ethanol solution and Mayer haematoxylin solution are ready to use.
Prepare the peroxidase stain in the mixing bottle labelled 5: Put 1 ml of Alpha-naphtol solution, add 4 ml of Pyronin solution and then 1 drop of Hydrogen peroxide.

Protocols

The staining steps of the protocols indicated below consist of a successive covering of the slides with the different staining reagents.
For the staining steps, place slide on a stand with fixed smear on top.

RAL Diagnostics recommend performing staining with a blood smear with a normal WBC count and no known abnormal pathology as reference.

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

Processing time: 10 min

Steps	Reagent	Time [mm: ss]	Indications
Fix	Formalin / Ethanol solution	01:00	No
Rinse	Tap water	No	No
Dry	No	No	Air dry
Stain	peroxidase stain	03:00	Get rid of reagent then rinse
Rinse	Tap water	No	No
Dry	No	No	Air dry
Stain	Mayer haematoxylin	03:00	Quickly rinse
Rinse	Tap water	03:00	No
Dry	No	No	Air dry

Expected results

Peroxidase granules: bright red
Nuclei of leukocytes: blue
Erythrocytes: light beige

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.

RAL Diagnostics recommend using a positive smear and a negative smear from different patient samples at reagents renewal and for the first staining cycle of 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).

Staining results for each cell type 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 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.

RAL Diagnostics recommend performing staining with a blood smear with a normal WBC count and no known abnormal pathology as reference.

This method is very advantageous because it does NOT use benzidine base.
A study made on 101 Acute Leukemia (AL) cases by Latger-Cannard et al. demonstrated both the 96% specificity and the 99% sensitivity of the method, with a threshold for positive staining of 3 %. When using the Alpha-naphtol/pyronine–based staining, the mean number of positive blast cells is statistically lower than that obtained using benzidine, but without incidence on AL classification.

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. Staining conducted according to these recommendations will remain stable for several days.

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
LOT	Batch code
SN	Serial number
REF	Catalogue reference
	Date of manufacture
	Use up to
UDI	Unique device identifier
	Manufacturer
	Importer
	Entity distributing the medical advice in the region concerned
CE	CE marking device
IVD	In vitro diagnostic medical device
	Authorised Representative in the European Community
	Authorised Representative in Switzerland
UK CA	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
2	Do not reuse
	Do not resterilize
	Contents sufficient for n tests
	Hazardous material contained
	Consult instructions for use
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

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Change tracking

Date	Version	Changes
05/2022	IFU091A-RAL	IVDR (EU) 2017/746 compliance

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