MCDh 4 concentrate

REF. 313610-1000

Differential staining of cellular structures

CE IVD

IFU004D

For professional use only.
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

MCDh 4 concentrate is intended to be used in combination with Kit RAL Stainer MCDh and RAL Stainer instrument for the differential staining of 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

The MCDh panoptic staining allows to perform blood cell counting, realized by using successively four reagents: MCDh 1, MCDh 2, MCDh 3 and MCDh 4.
MCDh 1, formulated with ethylic alcohol, is a mixture of neutral stains. It allows a smear fixation and prepares the staining, especially the one of hydrosoluble elements such as basophilic granules. Those stains are inactive in alcoholic medium, and only react selectively when released in MCDh 2 solution. This releasing generates the precipitation of neutral stains, leading to erythrocytes, cytoplasm of neutrophilic granulocytes as well as eosinophilic granules staining.
MCDh 3 is an aqueous solution which stains cytoplasm of monocytes and lymphocytes. MCDh 3 also eases the metachromasia process as it colors azurophilic granules red. Eventually, MCDh 4 removes excess of stain and participates to differentiation of cellular elements thanks to action of specially selected rinsing agents.
The successive action of MCDh 1, MCDh 2, MCDh 3 and MCDh 4 brings the violet color (typical Romanowsky-Giemsa effect), particularly visible in chromatin, platelets and neutrophilic granules.

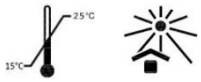
Device description

MCDh 4 concentrate
Clear colourless solution
REF. 313610-1000 1 X 1 L

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



Active components

MCDh 4
Potassic mono phosphate - CAS 7778-77-0: 0.3%
Anhydrous disodic phosphate - CAS 7558-79-4: 0.3%

Hazard classification and safety information

MCDh 4 concentrate
Warning:

H226 - Flammable liquid and vapour.
H317 - May cause an allergic skin reaction.
H319 - Causes serious eye irritation.
H336 - May cause drowsiness or dizziness.
H411 - Toxic to aquatic life with long lasting effects.
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 doctor, a POISON CENTER if you feel unwell.
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P391 - Collect spillage.

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

CONT	Isopropylic alcohol

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 and these following CellaVision RAL Diagnostics devices:
Kit RAL Stainer MCDh REF. 360200-0000
RAL Stainer REF. 405000

This equipment may vary depending on the protocol. 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.

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.

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

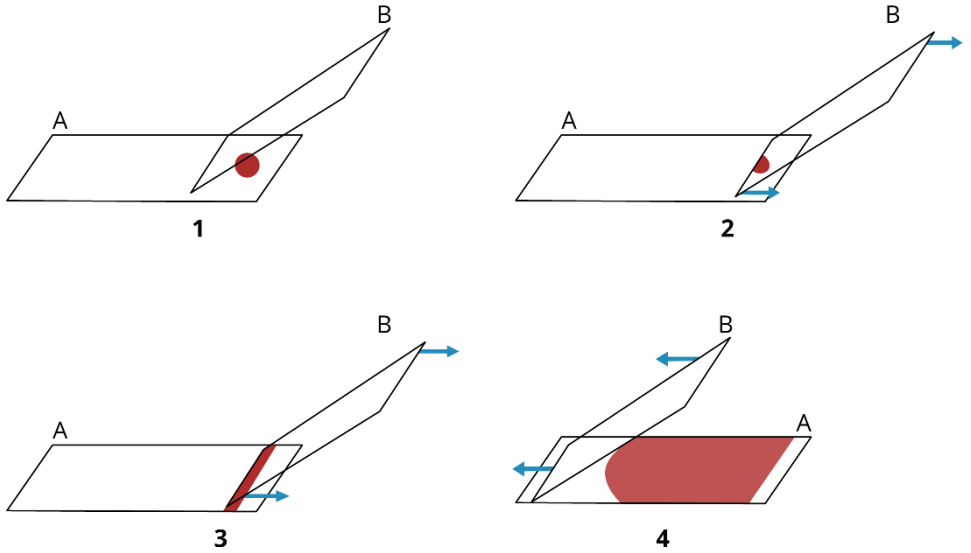


Figure 1. Schematic representation of performing a blood smear.
A & B: slides, 1 – 4: steps 1 to 4

Reagents and instruments preparation
Prepare the rinsing solution in the rising tank by diluting the MCDh 4, concentrate content to 8L of distilled or demineralized water. Then connect the rinsing tank to RAL Stainer. This rinsing liquid has a shelf life of 2 months after dilution.

Protocols
The staining steps of the protocols indicated below consist of a successive dipping of the slides in the different staining baths.
The processing time only considers the dipping time in the reagents.

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

Processing time [hh: mm: ss]: 00: 11: 10

Steps	Reagent	Time [mm: ss]	Indications
Fix and pre-stain	MCDh1	07:00	Without agitation
Stain	MCDh2	03:00	With agitation
Stain	MCDh2	00:30	
Stain	MCDh3	00:30	
Rinse	Reconstituted MCDh 4	00:10	
Dry	NA	03:00	NA

***Note**: In case of refringence/water artefact phenomena, pre-fix the slides 2min in a bath of absolute ethanol before staining. Directly start the staining after pre-fixation step without drying the slides.*

Expected results

Nuclei / chromatin: +/- dense purple
Granulocytes cytoplasm: light purplish-pink
Granulocytes eosinophilic granules: orangey
Granulocytes basophilic granules: dark blue
Granulocytes neutrophilic granules: +/- deep purple
Lymphocytes cytoplasm with RNA: pure blue
Lymphocytes cytoplasm without RNA: light blue
Lymphocytes azurophilic granules: red
Monocytes cytoplasm: cloudy blue
Erythrocytes: pinkish-beige
Platelets chromomere: purplish-red
Platelets hyalomere: bluish
Blood parasites nucleus: red
Blood parasites cytoplasm: blue

If observed results vary from those expected, contact CellaVision RAL Diagnostics technical service through your usual supplier for assistance.

Performance

The performance of the MCDh 4 concentrate was evaluated in combination with the other components of the Kit RAL Stainer MCDh in a hospital laboratory with 473 clinical samples (blood and bone marrow).
The sensitivity of the Kit RAL Stainer MCDh reagents was evaluated in comparison with the routine laboratory's reference technique: MCDh bath staining method in Slide Maker Stainer (SMS) automaton.
All tests were performed in parallel under the same conditions.
The results obtained in this study show that the efficiency of the Kit RAL Stainer MCDh is equivalent to the MCDh routine method.
The MCDh 4 concentrate in combination with Kit RAL Stainer MCDh and RAL Stainer instrument enable cell structure staining and microscopic analysis.

As they do not allow the detection of analytes, analytical performance is not applicable to this reagent.
This medical device is based on scientific validity (scientific peer-reviewed literature) and demonstration of clinical performance through experience gained from routine diagnostic testing, and the regular evaluation of these performances under Post Market Performance Follow-up (PMPF), to ensure that they continue to meet the expected performance and safety standards.

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 blood smear with a normal WBC count and no known abnormal pathology at reagent renewal and for the first staining 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 precipitates).
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.

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

MCDh 4 concentrate solution may have a yellow tint without altering the quality of staining. It must be diluted Q.S 8 L in the RAL Stainer rinsing tank of 10 L capacity. Pour the 1L of MCDh 4 concentrate bottle and complete to 8 L with distilled or demineralized water. This rinsing solution has a shelf life of 2 months after dilution.
Different batches of reconstituted products can be mixed in the rinsing tank of RAL Stainer.

In case of refringence/water artefact phenomena, pre-fix the slides 2min in a bath of absolute ethanol before staining.

The first staining cycle may appear slightly lighter than the final color shade. If necessary, you can prime staining with bare slides or with a smear without analyze them.

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. Staining conducted according to these recommendations 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
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
EC REP	Authorised Representative in the European Community
CH REP	Authorised Representative in Switzerland
UK REP	Authorised Representative in United Kingdom
UK CA	Complies with UK guidelines
	Do not use if packaging is damaged
	Keep away from light Keep away form heat
	Temperature limit: 15-25°
	Temperature limit: 15-30°
	Keep dry
	Box: handling upwards
	Fragile
STERILE R	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
CONT	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

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Changes tracking

Date	Version	Changes
03/2025	IFU004D	Update in the following paragraph: Performance and Expected results. Removal of the GMED logo.
07/2024	IFU004C	Update in the following paragraphs: User quality control and Table of symbols and abbreviations. Add of CH-REP and UK-REP symbols.
05/2023	IFU004B	Update in header and the following paragraphs: Storage and use conditions, active components, operating procedure, Expected results, Recommendations, notes and troubleshooting. Add of legal representatives and GMED logo
05/2022	IFU004A	Update according to IVDR (EU) 2017/746

Legal representatives

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