














Melet Schloesing Pharmaceuticals | Rue du Collège 90 | CH-2300 La-Chaux-de-Fonds | Suisse

Instruction for Use

HEMOREF[®]

Explanation of symbols

| | |
|---|---|
|  | Reference Catalog |
|  | Expiration date |
|  | Lot number |
|  | Manufacturer |
|  | Consult the instructions for use |
|  | Compliance with European Directive 98/79 / EC |
|  | When followed by "WARNING", this symbol means "Attention! Failure to do so may lead to erroneous examination results and / or degradation of the device." |
|  | In vitro diagnostic medical device |
|  | Protect from the sun |
|  | Keep away from moisture |
|  | Temperature limits (lower and upper) |




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Introduction

This document provides the information necessary for the use of HEMOREF® with automatic MS9-type hematology analyzers manufactured by MELET SCHLOESING Laboratoires.

This document is provided in electronic format (e-ifu), using the following URL: <http://www.mslabos.com/infos>

 **AVERTISSEMENT** WARNING This user manual contains important information on the safe use of HEMOREF®. Please read this document as a whole before using the product

Identification of the legal manufacturer



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| | | |
|----------------------------|-------------------------|--------------------------|
| Product designation | CE IVD | product reference |
| HEMOREF® | | RMSHMRF2L0 |

| |
|--|
| Description |
| HEMOREF® is a rinsing agent suitable only for MS9 automatic blood cell analyzers of the brand MELET SCHLOESING Laboratories. This reagent allows the cleaning / rinsing of the device. |
| Kit Contents |
| HEMOREF® is available as a 2-liter bottle. . |
| Indication for Use |
| HEMOREF® is an in vitro diagnostic device intended for use by healthcare professionals and only in combination with the conductimetric hematology devices of the MS9 range manufactured by MELET SCHLOESING Laboratories. |
| Intended Use |
| HEMOREF ® Reagent is a cleaning / rinsing agent intended to keep certain parts of the appliance clean. |
| Composition |
| HEMOREF® is composed of the following elements: <ul style="list-style-type: none">• Detergent (<0.6%)• Conservative (<1%) |
| Storage conditions - Shelf life - Stability |
| HEMOREF® must never be subjected to temperatures below 15 ° C and above 25 ° C. HEMOREF® can be stored for 120 days (16 weeks) after opening. HEMOREF® can be stored for 3 years (see expiration date on the product label) since the date of manufacture. |
| Installation |
| HEMOREF® is ready to use and requires no preparation. A detailed description of the reagent installation / replacement is available in the relevant analyzer user guide. |



Collection and preparation of the sample

When collecting the blood sample, avoid any violent aspiration to avoid the phenomenon of hemolysis that could influence the results of the hematological analysis. Also be sure to limit the sampling time to avoid micro-coagulation problems.

The blood sample to be analyzed should be collected in a collection tube containing EDTA K3 anticoagulant. The use of the sampling tube must be carried out according to the instructions of the supplier.

Conservation of samples:

Whole blood samples are stable for about 4 hours at room temperature and 24 hours at 2-6 ° C.

Gentle and prolonged homogenization of the blood / anticoagulant mixture is essential before any analysis, refer to the supplier's instructions.

It is recommended to carry out the analysis no earlier than 30 minutes and no later than 8 hours after collection.

Test principle

The combination of the HEMOREF ® reagent with the MS9 meter-analyzers from MELET SCHLOESING LABORATOIRES makes it possible to clean / rinse parts of the device.

Disposal of the product

Respect the protocol applied by your laboratory for the neutralization and elimination of waste

Warnings and precautions

Precautions:

- Use only for in vitro diagnostics.
- Please read the Safety Data Sheet (MSDS) before use.
- Please follow all pre-analytical steps in the laboratory.
- Handle reagents with care to prevent the formation of bubbles.
- Do not use directly after transport or directly after handling. Wait a few minutes.

Warnings:

- Reagents can cause irritation of the eyes, skin and mucous membranes.
- In case of contact, rinse with plenty of water and seek immediate medical attention. In case of accidental ingestion, call a doctor immediately!
- Avoid particles or bacteria coming into contact with the reagent.
- Do not use reagents beyond the expiry date or beyond the open bottle time.
- Place the reagents at the main unit of the device.
- Do not transfer / mix reagents whether they are of the same type or batch.
- Do not reuse an empty container as this may distort the results or damage the machine.
- Do not use the product in case of deterioration of the protective packaging.
- If a reagent has been accidentally spilled, wipe it off immediately with a damp cloth.
- Do not use the product if there is any sign of deterioration (turbidity, color change, etc.)