














DIALAB Produktion und Vertrieb von chemisch-technischen Produkten
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Instruction for Use

ACTI-DIFF®


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) |

Introduction

This document provides the information necessary for the use of ACTI-DIFF® with the automatic hematology analyzer meters type MS4 and MS9 manufactured by MELET SCHLOESING Laboratories.

This document is provided in electronic format (e-ifu), using the following URL:
<https://www.dialab.at/en/news/info/> or <http://www.mslabos.com/infos>

 **WARNING** This user manual contains important information regarding the safe use of the ACTI-DIFF®. 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 |
| ACTI-DIFF® | | 3MSR0212 RMSACDF500 RMSACDF250 |

| |
|---|
| Description |
| ACTI-DIFF® is a lysing agent suitable only for automatic blood cell analyzers of the brand MELET SCHLOESING Laboratories. This reagent allows the destruction (Haemolysis) of the Red Blood Cells, the stabilization of the Hemoglobin and the nucleation of the White Globules with a view to their differentiation Lympho, Mono and Granulos. |
| Kit Contents |
| ACTI-DIFF® is combined in different capacities: a) A carton containing a 1.2 liter bottle b) One 500 ml bottle for pack 250 c) One 250 ml bottle for pack 125 |
| Indication for Use |
| ACTI-DIFF® is an in vitro diagnostic device, intended for use by healthcare professionals and only in combination with the conductimetric hematology devices of the MS4 and MS9 range manufactured by MELET SCHLOESING Laboratoires. |
| Intended Use |
| The ACTI-DIFF® reagent is a lysing agent designed to perform the count of white blood cells, hemoglobin, and diff 3 (3 populations) or even 5 diff (5 populations) leukocyte count associated with EODIFF. |
| Composition |
| The ACTI-DIFF® consists of the following elements: <ul style="list-style-type: none"> • Quaternary Ammonium (<3%) • Potassium cyanide (<0.5%) • Preservative |
| Storage conditions - Shelf life - Stability |
| ACTI-DIFF® must never be subjected to temperatures below 15°C and above 25°C. ACTI-DIFF® can be stored for 120 days (16 weeks) after opening. ACTI-DIFF® can be stored for 3 years (see expiration date on the product label) since its date of manufacture. |
| Installation |
| ACTI-DIFF® 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 ACTI-DIFF® with the meter-analyzers of MS4 and MS9 type from the company MELET SCHLOESING LABORATORIES makes it possible to perform a white blood cell count and a reduced hemoglobin photometric measurement.

The measurement is based on the principle of impedancemetry. A current field is changed during the passage of a particle. Conductivity variations are detected and recorded.

ACTI-DIFF® breaks the cytoplasmic membrane of red blood cells, which has the effect of eliminating the erythrocyte population, leaving only the leucocyte population. ACTI-DIFF® also contains a nucleating agent allowing volumetric separation of white blood cells in 3 sub-populations; Lymphocyte, Monocytic, Granulocytic.

ACTI-DIFF® with a potent hemoglobin reducer (Potassium Cyanide) hemoglobin measurement follows the DRABKIN method with a reading at 540 nm. The integration of the transmitted light intensity is evaluated according to the BEER-LAMBERT formula.

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. Ensure that the operating temperature conditions are reached.

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.)

Performances change

The following substances are likely to interfere with the results of the analysis:

- High lactose serums.
- Hemolyzed serums