

INSTRUCTION FOR USE

Dialyse-Diff-LMG

IVD

WHOLE BLOOD LYING REAGENT

Cat. No.: h20212

5 L cubitainer

PRODUCT NAME

Dialyse-Diff-LMG

INTENDED USE

(For In Vitro Diagnostic Use Only)

Dialyse-Diff-LMG is used by the ABX/Roche Cobas Minos STL, STEL, STX, STEX, Micros (18 param.), Helios, Argos hematological analyzer as a hemolysing reagent for the assay of hemoglobin, white blood cell count, lymphocytes count, mid cell, granulocyte count.

SUMMARY AND PRINCIPLE

A sample volume of a whole blood specimen is aspirated into the analyzer where a portion of it is automatically diluted with Diaton Diff. LMG Diluent. A portion of this first dilution is further diluted with Diaton Diff. LMG Diluent. This second dilution of the sample is then introduced into impedance particle analyzer where the red blood cell count (RBC) and the thrombocyte count (PLT) is measured. To the remainder of the first dilution a lysing reagent (Dialyse-Diff-LMG) is added for the measurement of hemoglobin (HGB), white blood cell count (WBC), lymphocytes count (LYM), mid cell (MID), granulocyte count (GRAN). Consult your specific instrument Operator's Manual for additional information with respect to procedures and principles for whole blood hematological analysis.

ACTIVE INGREDIENTS

lauryltrimethyl-ammonium chloride	< 20 %
inorganic salt	< 3,1 %
potassium cyanide	< 0,1 %



PRECAUTIONS

- Hazardous category, risk and safety phrases, by latest CLP regulation:



Xn, Harmful

R32: Contact with acids liberates very toxic gas.
 S60: This material and its container must be disposed of as hazardous waste.

- The reagent contains CYANIDE. Avoid contact with skin and eyes, as cyanide is poisonous if swallowed.

- Store separate from acidic chemicals, acidification of solution will generate poisonous hydrogen cyanide gas.
- Avoid contact with skin and eyes as quaternary ammonium salts may cause irreversible effects to these tissues. Wear appropriate safety equipment such as gloves and a lab coat. In case of skin contact, rinse immediately with plenty of water. If swallowed, induce vomiting and seek medical advice.
- Specimens, samples and all materials coming into contact with them should be handled as if capable of transmitting infection and disposed of with proper precautions.
- Cyanide in waste and unused reagent has to be neutralised before disposal according to Environmental Regulations. A CYANIDE NEUTRALISING KIT is provided by Diagon upon request.
- Do not use reagent beyond the expiration date printed on the label.
- Avoid microbial contamination of the reagents or erroneous results may occur.
- Use Good Laboratory Practices (GLP) when handling these reagents.



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- Person installing the reagent must be a trained laboratory professional.
- Leave the reagent at room temperature for at least 24 hours.
- Connect the other reagents to the instrument similarly (see 'MATERIALS REQUIRED BUT NOT PROVIDED' below).
- Prime the reagents through the instrument thoroughly to wash out third party reagents, traces of which may cause erroneous results. Refer to the instrument Operator's Manual for further information.
- Attach the lyse aspiration assembly to the cubitainer/bottle. Tighten the cap.
- Recalibrate the instrument with CALIBRATOR or CONTROL BLOOD as specified in your Operator's Manual.

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STORAGE AND STABILITY

The reagent has an unopened stability of 18 months from date of manufacture when stored at 15–35°C in a dark place. See package label for expiry date. Reagent displaying any signs of contamination or instability, as indicated by cloudiness or color change, should be replaced. DO NOT use reagent once frozen.

Once installed on the instrument the reagent is stable for 60 days.

Store separate from acidic chemicals, acidification of solution will generate poisonous HYDROGEN CYANIDE gas.

EXPECTED RESULTS

Performance should be within instrument specifications.

LIMITATIONS

Reagent has to be used within the ambient temperature range of 15–35°C. Measured parameters may be inaccurate due to the influence of abnormal samples. Consult the Operator's Manual for indications of these conditions. Confirm any measured or computed parameter by the reference methods if these conditions are indicated.

Diagon reagents can be only used with other Diagon reagents. Erroneous results may be obtained if the reagent is mixed with third party reagents.

MATERIALS REQUIRED BUT NOT PROVIDED

- Cell Counter (ABX/Roche Cobas Minos STL, STEL, STX, STEX, Micros (18 param.), Helios, Argos)
- Diagon Diff. LMG Diluent
 - Cat. No.: h20201 20 L
 - Cat. No.: h20211 5 L
- Dia-Cleaner
 - Cat. No.: h20205 5 L
 - Cat. No.: h20215 1 L
- Diaclair
 - Cat. No.: h20103 5 L
 - Cat. No.: h20113 1 L
- CYANIDE NEUTRALISING KIT (Provided FREE OF CHARGE upon request)
 - SOLUTION A
 - Cat. No.: h27101 1 L
 - SOLUTION B
 - Cat. No.: h27102 1 L

SPECIMEN REQUIREMENTS

Dialyse-Diff-LMG is intended for use with blood specimens collected by venipuncture in EDTA anticoagulant.



MANUFACTURER

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