DIAGON° (E

INSTRUCTION FOR USE



Dialyse ERMA CF

WHOLE BLOOD LYSING REAGENT

Cat. No.: h30109 0,50 L bottle PRODUCT NAME

Dialyse ERMA CF

INTENDED USE

(For In Vitro Diagnostic Use Only)

Dialyse ERMA CF is used by the ERMA PCE-210, PCE-170N, PCE-170, PCE-90, PCE-80 hematological analyzer red blood cell 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 Erma Diluent. A portion of this first dilution is further diluted with Diaton Erma 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 ERMA CF 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

lauryltrimethylammonium < 20 % chloride glyoxaline < 5 %

PRECAUTIONS

- Avoid contact with the reagent, 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.
- Do not use reagent beyond the expiration date printed on the label.
- Avoid microbial contamination of the reagents or erroneous results may occur.

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handling these reagents.

Use Good Laboratory Practices (GLP) when

INSTRUCTION FOR USE

- 1. Person installing the reagent must be a trained laboratory professional.
- 2. Leave the Dialyse ERMA CF at room temperature for 24 hours.
- 3. Loosen and remove the cap on the Dialyse ERMA CF cubitainer/bottle. Attach the lyse dispenser assembly to the lyse cubitainer/bottle. Tighten the cap.
- 4. Connect the other reagents to the instrument similarly. (see below **'MATERIALS** REOUIRED BUT NOT PROVIDED').
- 5. 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.
- 6. Recalibrate the instrument with CALIBRATOR or CONTROL BLOOD as specified in your Operator's Manual.

STORAGE AND STABILITY

The Dialyse ERMA CF 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 expiration date. Dialyse ERMA CF 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.

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. Erroneous results may be obtained if the reagent is mixed with third party reagents.

Diagon reagents can be only used with other





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MATERIALS REQUIRED BUT NOT **PROVIDED**

Cell Counter (ERMA PCE-210, PCE-170N, PCE-170, PCE-90, PCE-80)

Diaton Erma Diluent

Cat. No.: h30101 20 L

Dialyse Erma

Cat. No.: h30103 0,5 L

Diaclenz Erma

5 L Cat. No.: h30104

SPECIMEN REQUIREMENTS

Dialyse ERMA CF is intended for use with blood specimens collected by vein puncture in EDTA anticoagulant. Specimens for hematological analysis may be stored for up to 8 hours at 16- $30^{0}\mathrm{C}$ or up to 24 hours after collection when refrigerated (2-8 $^{0}\mathrm{C}$).

MANUFACTURER

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