



Diaton-ERMA

WHOLE BLOOD DILUTING REAGENT

Cat. No.: h30101 20 L cubitainer

PRODUCT NAME

Diaton-ERMA

INTENDED USE

(For In Vitro Diagnostic Use Only)

Diaton-ERMA is used by ERMA PCE-210, PCE-170N, PCE-170, PCE-90, PCE-80 hematological analyzer as a whole blood sample DILUTING reagent.

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. A portion of this first dilution is further diluted with Diaton-ERMA. 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 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 INGRIDIENTS

sodium chloride< 0.5 %sodium sulphate< 1.2 %buffer< 1.2 %stabiliser< 0.02 %

PRECAUTIONS

- This product contains no harmful components and is non-hazardous. In case of skin or eye contact rinse with water.
- 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.
- Use Good Laboratory Practices (GLP) when handling these reagents.

INSTRUCTION FOR USE

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

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.

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.

Issue: PI-30101.en/06.01.2006. Version: 1

Printed: 2010.02.16.









MATERIALS REQUIRED BUT NOT **PROVIDED**

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

• Dialyse-Erma Diff (for PCE-210 only) Cat. No.: h30103 0.5 L

• Diaclenz-Erma

Cat. No.: h30104 5 L

• Diaclean-Erma

Cat. No.: h30105 5 L

• Diaquicklyse-Erma (excl. PCE-210)

Cat. No.: h30102

2.9999999999999E-2 L

SPECIMEN REQUIREMENTS

Diaton-ERMA 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°C or up to 24 hours after collection when refrigerated (2-8°C).

MANUFACTURER

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Issue: PI-30101.en/06.01.2006.

Version: 1 Printed: 2010.02.16. 2/2