





Dialyse-Erma Diff

WHOLE BLOOD LYSING REAGENT

Cat. No.: h30103 0.5 L bottle

PRODUCT NAME

Dialyse-Erma Diff

INTENDED USE

(For In Vitro Diagnostic Use Only)

Dialyse-Erma Diff is used by the ERMA PCE-210 hematological analyzer as an hemolysing reagent for the assay of , 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 Diff) 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 azide	< 0,01 %
potassium cyanide	< 0,33 %
aliphatic alcohol	< 18,5 %
detergent	< 16,5 %

PRECAUTIONS

- 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.

Issue: PI-30103.en/06.01.2006.

Version: 1

- Cyanide in waste and unused reagent has to be neautralised before disposal according to Evironmental 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.

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. Connect the other reagents to the instrument similarly (see 'MATERIALS REQUIRED BUT NOT PROVIDED' below).
- 4. Prime the reagents through the instrument thouroughly to wash out third party reagents, traces of which may cause erroneous results. Refer to the instrument Operator's Manual for further information.
- 5. Attach the lyse dispenser assembly to the cubitainer/bottle. Tighten the cap.
- 6. 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 expiration 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

Printed: 2010.02.16.







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 (ERMA PCE-210)
- Diaton-Erma

20 L Cat. No.: h30101

• Diaclenz-Erma

5 L Cat. No.: h30104

• Diaclean-Erma

Cat. No.: h30105 5 L

• CYANIDE NEUTRALISING KIT (Provided FREE OF CHARGE upon request)

SOLUTION A

Cat. No.: 27101 1L bottle

SOLUTION B

Cat. No.: 27102 1L bottle

SPECIMEN REQUIREMENTS

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

MANUFACTURER

DIAGON LTD.

Baross u. 52, 1047 Budapest, Hungary

Web: www.diagon.com

Tel.: +36 1 3696500, Fax.: +36 1 3696301 E-mail: diagon@diagon.com

Issue: PI-30103.en/06.01.2006.

Version: 1 Printed: 2010.02.16. 1/2