

Dia-Lyse-Diff D-CF**IVD** **WHOLE BLOOD LYISING REAGENT**

Cat. No.: h31102

0,5 L bottle

PRODUCT NAME

Dia-Lyse-Diff D-CF

INTENDED USE**(For In Vitro Diagnostic Use Only)**

Dia-Lyse-Diff D-CF is used by the DIAGON D-Cell 60, Mindray BC 2800, 3000, 3000plus, 3200 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 Dia-Diluent-D. A portion of this first dilution is further diluted with Dia-Diluent-D. 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 (Dia-Lyse-Diff D-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 chloride	< 20 %
organic buffer	< 1,1 %
glyoxaline	< 0,5 %

**PRECAUTIONS**

- This product contains no harmful components and is non-hazardous. Avoid contact with skin and eyes as detergents 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.
- 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 24 hours.
3. Loosen and remove the cap on the reagent cubitainer/bottle. Attach the LYSE aspiration 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 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 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.

MATERIALS REQUIRED BUT NOT PROVIDED

- Cell Counter (DIAGON D-Cell 60, Mindray BC 2800, 3000, 3000plus, 3200)
- Dia-Diluent-D
Cat. No.: h31101 20 L
- Dia-Rinse-DB
Cat. No.: h31103 20 L
Cat. No.: h31113 5 L
- Dia-EZ-Cleaner-D
Cat. No.: h31104 0,1 L
Cat. No.: h31114 0,05 L
- Dia-Probe-Cleaner-D
Cat. No.: h31105 0,05 L
Cat. No.: h31115 0,02 L

SPECIMEN REQUIREMENTS

Dia-Lyse-Diff D-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 16-30⁰C or up to 24 hours after collection when refrigerated (2-8⁰C).

**MANUFACTURER**

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