

Human haematology solutions

Haematology solutions for human blood analysis

Single reagents

REF	Content	Instrument
H19120	- 1x 20 L Dialuent	DLB3 / DLB5
H19130	- 1x 5 L Diatergent	DLB3 / DLB5
H19149	- 1x 1.2 L Diadiff + MS Card	DLB3
H19150	- 1x 1.2 L Diadiff + MS Card	DLB5
H19160	- 1x 5 L Dialys-EO	DLB5
H19140C	- 1x 0.25 L Rinse concentrate	DLB3 / DLB5

System packs

REF	Product name	Content	Instrument
H19261	DLB3 Pack 125H	- 1 x 2.5 L Dialuent (Ref H19121) - 1 x 500 mL Diatergent (Ref H19131) - 1 x 250 mL Diadiff (Ref H19151) - 1 x 500 mL Rinse (Ref H19142) - MS Card	DLB3
H19262	DLB5 Pack 125H	- 1 x 2.5 L Dialuent (Ref H19121) - 1 x 500 mL Diatergent (Ref H19131) - 1 x 250 mL Diadiff (Ref H19151) - 1 x 2 L Rinse (Ref H19141) - 1 x 500 ml Dialys-EO (Ref H19161) - MS Card	DLB3 / DLB5

For professional in vitro diagnostic use only.

GENERAL INFORMATION

Method	Impedancemetry
Shelf life	3 years from date of production
Storage	+15-25 °C
No. of cycles	1000 for the single reagents and 125 for the packs

INTENDED USE

The solutions are dedicated for the 3-diff and 5-diff analysis of the human blood.

Reagents needed for the 3-diff analysis:

- **Dialuent:** Isotonic diluting agent for the mechanical separation of the red cells/platelets from the white cells.
- **Diatergent:** Cleaning agent for the instruments DLB3 and DLB5.
- **Diadiff:** Lysing agent for the haemolysis of red blood cells, the stabilisation of haemoglobin, and the nucleation of white blood cells with a view to their differentiation (lymphos, monos, granulos) in human blood.
- **Rinse concentrate:** The solution rinses and desalinates the parts of the analyser that are in contact with a salt reactant such as the Dialuent, to keep the device clean.
- **Or: DLB3 Pack 125H:** ready to use pack with all above mentioned components for 3-diff measurements on DLB3 analyser.

Reagents needed to the 5-diff analysis:

- **All the mentioned reagents above**
- **Dialys-EO:** Lysing agent for the counting of eosinophilic leukocytes. It allows the counting of the white blood cell eosinophils.
- **Or: DLB5 Pack 125H:** ready to use pack with all above mentioned components for 5-diff and 3-diff measurements on DLB3 or DLB5 analyser.

DIAGNOSTIC SIGNIFICANCE

Haematology analysis can assess several health conditions involving blood and its components. Professional users can discover numerous diseases with the help of haematology measurements, like inflammation, anaemia, infection, haemophilia, blood-clotting disorders and leukaemia.

TEST PRINCIPLE

The combination of the haematology solutions with the DLB3/DLB5 analysers allows cell-by-cell counting for each blood population, i.e. red blood, white blood and platelet populations.

The measurement is based on the principle of impedancemetry combined with cytochemistry (1). An electrical field is changed when a particle passes. Changes in conductivity are detected and recorded. Diadiff breaks the cytoplasmic membrane of red blood cells with the effect of eliminating the erythrocyte population, leaving only the leucocyte population. It also contains a nucleating agent allowing the volumetric separation of white blood cells in 3 sub-populations: lymphocytes, monocytes, and granulocytes.

Diadiff also contains a haemoglobin stabilizer. The haemoglobin measurement follows the Drabkin method (2) by a powerful haemoglobin reducer (Potassium Cyanide) with a reading at 540 nm.

Dialuent as the diluting agent makes it possible to perform two sequential dilutions performing a mechanical partition of the red cells/platelets and white cells. This mechanical separation is necessary in view of the too different number of white and red cells (platelets). Diatergent is an active and passive cleaning agent that cleans the parts of the tanks and counting holes of the DLB3/DLB5 analysers. It operates in two modes: as a detergent and as a proteolytic enzyme.

Dialys-EO breaks the cytoplasmic membrane of red blood cells and some white blood cells to leave only eosinophilic white blood cells for the 5-diff analysis.

REAGENT COMPOSITION

DIALUENT	CONCENTRATION
Anorganic salts, buffer	
EDTA	< 1 %
Dimethyl urea	< 1 %
Sodium fluoride	< 1 %
Preservative	

DIATERGENT	CONCENTRATION
Proteolytic enzyme	< 1 %
Nonionic detergent	< 1 %
Denatured alcohol	< 3 %
Dye	
Preservative	

DIADIFF	CONCENTRATION
Quaternary ammonium	< 3 %
Potassium cyanide	< 0.5 %
Preservative	

DIALYS-EO	CONCENTRATION
Phosphate buffer	< 1 %
Non-ionic detergent	< 5 %
Preservative	

RINSE CONCENTRATE

Distilled water
Preservative

MATERIAL REQUIRED BUT NOT PROVIDED

DLB3/DLB5 haematology analyser.

REAGENT PREPARATION

Rinse Concentrate (single reagent):
Dilute 250 mL of the concentrate with distilled water to 10 L (40-fold dilution).
The other single reagents and the system packs are ready to use.

STORAGE AND STABILITY

Temperature: +15-25 °C
Keep away from direct sunlight and moisture.
Stability in unopened containers: 3 years from date of production (see expiration date on label)
Stability after opening: 16 weeks

WARNINGS AND PRECAUTIONS

For Diadiff and system packs:



H411: Toxic to aquatic life with long lasting effects
 P102: Keep out of reach of children
 P273: Avoid release to the environment
 P391: Collect spillage
 P501: Dispose of contents/container in accordance with local/regional/national/international regulations

General for all solutions:

- For in-vitro diagnostic use only.
- Please refer to the safety data sheet and take the necessary precautions for the use of laboratory reagents.
- Please consider the reagent infectious and treat it according to current procedures.
- Follow all pre-analytical steps in the laboratory.
- Handle the reagents carefully to avoid bubbles.
- Do not use directly after transport or directly after handling.
- Reagents may cause irritation to eyes, skin and mucous membranes.
- In case of contact, rinse thoroughly with water and seek medical attention immediately.
- In case of accidental ingestion, call a doctor immediately!
- Prevent contamination of the reagent with particles or microorganisms.
- Do not use the reagent beyond the expiry date or beyond the open bottle time.
- Place the reagents next to the main unit of the device.
- Do not mix reagents of the same nature or batch.
- Do not reuse an empty container for risk distorting the results or damaging the machine.
- Do not use the product when the protective packaging is damaged.
- Do not use the product if there is any sign of deterioration (turbidity, colour change, etc.)
- For diagnostic purposes, the results should always be assessed together with the patient's medical history, clinical examinations and other findings.

SPECIMEN COLLECTION AND STORAGE

- Avoid any intensive aspiration when collecting the blood sample to avoid haemolysis, which can influence the results of the haematology analyser. Also reduce the sample collection time to avoid microcoagulation problems.
- The blood sample to be analysed should be collected in a collection tube containing EDTA K3 anticoagulant (3). The use of the sampling tube must be carried out according to the instructions of the supplier.
- A gentle and prolonged homogenization of the blood/anticoagulant mixture is essential before any analysis, according to the instructions of the supplier.

TEST PROCEDURE

A detailed description of the installation/replacement of the reagents is available in the user manual of the relevant analyser.

INTERPRETATION OF RESULTS

For further information please see the manual of the used analyser.

QUALITY CONTROL AND CALIBRATION

We recommend to use the ©R&D haematology controls. The lot specific values and ranges are available on our website.

LIMITATIONS

Several substances can interfere with the results:

- Analgesic derivatives of procaine ester
- Medication with anticoagulant actions: Oral anticoagulants (antivitamin K, Antithrombin III and IV)
- High volume cortisone treatment
- High lactose serum
- Lipemic or haemolytic serum can also affect results

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Paterakis, George & LAOUTARIS, N.P. & ALEXIA, S.V. & SIOUROUNIS, P.V. & STAMULAKATOU, A.K. & PREMETIS, E.E. & SAKELLARIOU, Ch & TERZOGLOU, G.N. & Papassotiriou, Ioannis & Loukopoulos, Dimitris. (1994). The effect of red cell shape on the measurement of red cell volume. A proposed method for the comparative assessment of this effect among various haematology analysers. Clinical & Laboratory Haematology. 16. 235 - 245. 10.1111/j.1365-2257.1994.tb00416.x.
2. Al- Naemi, Amjad. (2018). Hemoglobin measurement Cyanmethemoglobin (HiCN) (Drabkin's Method). 10.13140/RG.2.2.36612.83845.
3. Goossens W, Van Duppen V, Verwilghen RL. K2- or K3- EDTA: the anticoagulant of choice in routine haematology? Clin Lab Haematol. 1991;13:291-295.

USED SYMBOLS

Symbol	Description
	Keep out of sunlight
	Keep dry
	Dispose of the tests and packaging appropriately
	Warning

