

Haematology Reagents

(en) English

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 + CARD FOR 1000 CYCLES HUM DLB3	DLB3
H19150	- 1x 1.2 L Diadiff + CARD FOR 1000 CYCLES HUM DLB5	DLB5
H19160	- 1x 5 L Dialys-EO	DLB5
H19148	- 1 x 1.2 L Diadiff	For third party devices

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) - CARD FOR PACK 125 HUM DLB3 (MS-CARD-DLB3-125H)	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 H191612) - CARD FOR PACK 125 HUM DLB5 (MS-CARD-DLB5-125H)	DLB3 / DLB5

For professional in vitro diagnostic use only.

INTENDED USE

- Dialuent (H19120):** Dialuent is an isotonic diluting agent that must be used in combination with DLB3 or DLB5 haematology analysers as accessory solution for professional in vitro diagnostic use. Dialuent is intended for the mechanical separation of the red cells/platelets from the white cells.
- Diatergent (H19130):** Diatergent is a cleaning solution that must be used in combination with DLB3 or DLB5 haematology analysers as accessory solution for professional in vitro diagnostic use. Diatergent is intended for the active and passive cleaning of the tanks and counting holes of the DLB3/DLB5 analysers.
- Diadiff (H19148):** Diadiff is a lysing agent that must be used in combination with open system haematology analysers as accessory solution for professional in vitro diagnostic use. Diadiff is intended for the haemolysis of red blood cells, stabilisation of haemoglobin, and nucleation of white blood cells.
- Diadiff (H19149):** Diadiff is a lysing agent that must be used in combination with DLB3 haematology analyser as accessory solution for professional in vitro diagnostic use. Diadiff is intended for the haemolysis of red blood cells, stabilisation of haemoglobin, and nucleation of white blood cells, with a view to their differentiation of lymphocytes, monocytes and granulocytes.
- Diadiff (H19150):** Diadiff is a lysing agent that must be used in combination with DLB5 haematology analyser as accessory solution for professional in vitro diagnostic use. Diadiff is intended for the haemolysis of red blood cells, stabilisation of haemoglobin, and nucleation of white blood cells, with a view to their differentiation of lymphocytes, monocytes and granulocytes.
- Dialys-EO (H19160):** Dialys-EO is a lysing agent that must be used in combination with DLB5 haematology analyser as accessory solution for professional in vitro diagnostic use. Dialys-EO is intended for the destruction of all blood cells except eosinophilic leukocytes. It allows the counting of the white blood cell eosinophils.
- DLB3 Pack 125H (H19261):** DLB3 Pack 125H is a ready for use system pack and is intended as accessory of DLB3 haematology analyser. The system pack consists of the following reagents:
 - Dialuent is an isotonic diluting agent for the mechanical separation of the red cells/platelets from the white cells.
 - Diatergent is a cleaning agent that cleans the analyser in two modes: as a detergent and as a proteolytic enzyme.
 - Diadiff is a lysing agent intended for the haemolysis of red blood cells, stabilisation of haemoglobin, and nucleation of white blood cells, with a view to their differentiation of lymphocytes, monocytes and granulocytes.
 - Rinse is a rinsing solution and desalinates the parts of the analyser in the stand-by mode that are in contact with a salt reactant.

The system pack is intended for professional in vitro diagnostic use.

- DLB5 Pack 125H (H19262):** DLB5 Pack 125H is a ready for use system pack and is intended as accessory of DLB5 haematology analyser. The system pack consists of the following reagents:
 - Dialuent is an isotonic diluting agent for the mechanical separation of the red cells/platelets from the white cells.
 - Diatergent is a cleaning agent that cleans the analyser in two modes: as a detergent and as a proteolytic enzyme.
 - Diadiff is a lysing agent intended for the haemolysis of red blood cells, stabilisation of haemoglobin, and nucleation of white blood cells, with a view to their differentiation of lymphocytes, monocytes and granulocytes.
 - Rinse is a rinsing solution and desalinates the parts of the analyser in the stand-by mode that are in contact with a salt reactant.
 - Dialys-EO allows the destruction of all blood cells except eosinophilic leukocytes. It allows the counting of the white blood cell eosinophils.

The system pack is intended for professional in vitro diagnostic use.

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 haematology solutions allow cell-by-cell counting for each blood population, i.e. red blood, white blood and platelet populations in combination with haematology analysers. 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, it also includes 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 analysers. It operates in two modes: as detergent and as 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
Non-ionic detergent	< 5 %
Preservative	
Anorganic salts, buffer	

RINSE	CONCENTRATION
Antimicrobial preservative	<0.02 %
Biocide	<0.01 %
Sodium azide	<0.1 %

MATERIAL REQUIRED BUT NOT PROVIDED

Haematology analyser.

REAGENT PREPARATION

The 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.
- Only for laboratory professional use, or for healthcare professionals.
- 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.
- In the event of an incident related to the device, report it to the manufacturer and your competent authority as required

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.
- The stability of the various blood components is different:

Stability in blood at room temperature (4)	
- Differential leucocyte count	2 h-7 d
- Band neutrophiles	2-12 h
- Segmented neutrophiles	3-12 h
- Eosinophiles	12 h-6 d
- Basophiles	2 h-2 d
- Monocytes	2-12 h
- Lymphocytes	3 h-7 d

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

A detailed description is available in the user manual of the relevant analyser.

QUALITY CONTROL AND CALIBRATION

We recommend using the R&D Systems™ haematology controls. The lot specific values and ranges are available on our website.

PERFORMANCE CHARACTERISTICS

Linearity:

Parameter	Linearity range considered	
WBC	0 to 212 x10 ³ /mm ³	+/- 15%
RBC	0 to 8.9 x10 ⁹ /mm ³	+/- 5.3%
HGB	0 to 2.5 g/dl 2.5 to 24 g/dl	+/- 0.32 g/dl +/- 10%
PLT	0 to 24 x10 ³ /mm ³ 24 to 1400 x10 ³ /mm ³	+/- 6 x10 ³ /mm ³ +/- 11%

Accuracy:

Parameter	R2
WBC 1x dilution	0.9979 (0 to 92x10 ³ /mm ³)
	0.9993 (0 to 90x10 ³ /mm ³)
WBC dilution 1x and 2x (>100 10 ³ /mm ³)	0.9965 (0 to 249x10 ³ /mm ³)
	0.9961 (0 to 249x10 ³ /mm ³)
RBC	0.9999
	0.9995
HGB	0.9999
	0.9997
PLT	0.9997
	0.9999

Reproducibility:

	WBC	RBC	MCV (fl)	HGB	PLT
AVERAGE	7.51	4.68	78.54	13.17	214.8
SD	0.14	0.04	0.27	0.16	11.28
CV	1.92	0.93	0.34	1.24	5.25
AVERAGE	7.48	4.58	80.63	13.25	223.5
SD	0.13	0.06	0.26	0.13	8.58
CV	1.78	1.34	0.33	0.96	3.84
AVERAGE	7.62	4.52	81.55	12.73	219.7
SD	0.16	0.08	0.32	0.28	8.29
CV	2.05	1.84	0.39	2.22	3.77

The clinical performance was a comparative study compared to the Beckman DXH device with the results:

Parameter	Unity	Slope	Intercept	R
Leukocytes	103 /mm ³	1.0466	0.176	0.9802
Lymphocytes	103 /mm ³	1.0079	0.25	0.9799
Monocytes	103 /mm ³	0.485	0.37	0.5022
Neutrophils	103 /mm ³	0.9942	0.027	0.9808

Eosinophils	103 /mm ³	0.8905	0.26	0.7912
Erythrocytes	106/mm ³	0.9386	0.88	0.4151
Hemoglobin	g/dl	0.9116	0.76	0.8759
MCV	fl	0.9145	9.63	0.9239
Hematocrit	%	0.8690	4.8	0.8913
Platelets	103 /mm ³	0.888	19	0.9594

The other performance characteristics (e.g. such as threshold value, diagnostic sensitivity and diagnostic specificity) depend on the instrument, since the measurement is performed by the instrument alone via the counting chamber, and are therefore please see for these information the manual of the used analyzer.

TRACEABILITY

No international standard is available for haematology reagents.

EXPECTED VALUES

Laboratory Test	Normal Range in US Units
Basophils	0-3 % of lymphocytes
Eosinophils	0-8 % of white blood cells
Hematocrit	F 36.0-46.0 % of red blood cells M 37.0-49.0 % of red blood cells
Hemoglobin	F 12.0-16.0 g/dL M 13.0-18.0 g/dL
Leukocytes (WBC)	4.5-11.0 x 10 ³ /mm ³
Lymphocytes	16-46 % of white blood cells
Mean corpuscular hemoglobin (MCH)	25.0-35.0 pg/cell
Mean corpuscular hemoglobin concentration (MCHC)	31.0-37.0 g/dL
Mean corpuscular volume (MCV)	F 78-102 μm ³ M 78-100 μm ³
Monocytes	4-11 % of white blood cells
Neutrophils	45-75 % of white blood cells
Platelets (Thrombocytes)	130-400 x 10 ³ /μL
Red Blood Cell Count (RBC)	F 3.9-5.2 x 10 ⁶ /μL M 4.4-5.8 x 10 ⁶ /μL
WBC (White blood cells, Leukocytes)	4.5-11.0 x 10 ³ /mm ³

Table: normal-laboratory-values (5)

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

- Paterakis, George & LAOUTARIS, N.P. & ALEXIA, S.V. & SIOUROUNIS, P.V. & STAMULAKATOU, A.K. & PREMETIS, E.E. & SAKELLARIOU, Ch & TERZOGLU, G.N. & Papassotiropu, 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
- Al-Naemi, Amjad. (2018). Hemoglobin measurement Cyanmethemoglobin (HiCN) (Drabkin's Method). 10.13140/RG.2.2.36612.83845.
- Goossens W, Van Duppen V, Verwiltghen RL. K2- or K3- EDTA: the anticoagulant of choice in routine haematology? Clin Lab Haematol. 1991;13:291-295.
- Guder et al Recommendations of the Working Group on Preanalytical Quality of the German Society for Clinical chemistry and lab Medicine english_2010 https://www.iapac.org/fact-sheet/normal-laboratory-values/

USED SYMBOLS

	Symbol	Description
		Dispose of the tests and packaging appropriately
		
		
		25°C
		15°C