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Haematology products

for human blood analysis

Single reagents

REF	Content	Instrument
3MSR0212	- 1x 1.2 L Acti-diff+ MS Card	MS9 / MS4 series
3MSR0216B	- 1x 1 L EO-diff	MS9 / MS4 series
3MSR0216	- 1x 5 L EO-diff	MS9 / MS4 series
3MSR0227	- 1x 5 L Transflux	MS9 / MS4 series

System packs

REF	Product name	Content	Instrument
3MSR0920	MSPACK 125 HUM MS4 3 DIFF	- 1x 2.5 L Isoflux (Ref RMSIFLX2L5) - 1x 500 mL Transflux (RMSTFLX500) - 1x 250 mL Acti-diff (RMSACDF250) - 1x 500 mL Rinse (RMSRINC500) - MS Card	MS4 series
3MSR0970	MSPACK 125 HUM MS4 5 DIFF	- 1x 2.5 L Isoflux (Ref RMSIFLX2L5) - 1x 500 mL Transflux (RMSTFLX500) - 1x 250 mL Acti-diff (RMSACDF250) - 1x 2 L Rinse (RMSRINC2L0) - 1x 500 ml EO-diff (RMSEODF500) - MS Card	MS4 series
3MSR0925	MSPACK 250 HUM MS4 3 DIFF	- 1x 5 L Isoflux (Ref RMSIFLX5L0) - 1x 1 L Transflux (RMSTFLX1L0) - 1x 500 mL Acti-diff (RMSACDF500) - 1x 2 L Rinse (RMSRINC2L0) - MS Card	MS4 series
3MSR0980	MSPACK 250 HUM MS4 5 DIFF	- 1x 5 L Isoflux (Ref RMSIFLX5L0) - 1x 1 L Transflux (RMSTFLX1L0) - 1x 500 mL Acti-diff (RMSACDF500) - 1x 2 L Rinse (RMSRINC2L0) - 1x 1 L EO-diff (RMSEODFH1L) - MS Card	MS4 series
3MSR0910	MSPACK 250 HUM MS9 3 DIFF	- 1x 5 L Isoflux (Ref RMSIFLX5L0) - 1x 1 L Transflux (RMSTFLX1L0) - 1x 500 mL Acti-diff (RMSACDF500) - 1x 2 L Hemoref (RMSHMRF2L0) - MS Card	MS9
3MSR0915	MSPACK 250 HUM MS9 5 DIFF	- 1x 5 L Isoflux (Ref RMSIFLX5L0) - 1x 1 L Transflux (RMSTFLX1L0) - 1x 500 mL Acti-diff (RMSACDF500) - 1x 2 L Hemoref (RMSHMRF2L0) - 1x 1 L EO-diff (RMSEODFH1L) - MS Card	MS9

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 125/250 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:

- **Isoflux:** Isotonic diluting agent for the mechanical separation of the red cells/platelets from the white cells.
- **Transflux:** Cleaning agent for the MS9 and MS4 series.
- **Acti-diff:** 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:** The solution rinses and desalinates the parts of the MS4 series that are in contact with a salt reactant such as the Isoflux, to keep the device clean.

Or:
System packs needed for the 3-diff analysis:

- **MSPACK 125 HUM MS4 3 DIFF:** ready to use pack for 125 cycles with all needed reagents for 3-diff measurements on MS4 series.
- **MSPACK 250 HUM MS4 3 DIFF:** ready to use pack for 250 cycles with all needed reagents for 3-diff measurements on MS4 series.
- **MSPACK 250 HUM MS9 3 DIFF:** ready to use pack for 250 cycles with all needed reagents for 3-diff measurements on MS9 analyser.

Reagents needed for the 5-diff analysis:

- **The mentioned reagents for 3-diff analysis**
- **EO-diff:** Lysing agent for the counting of eosinophilic leukocytes. It allows the counting of the white blood cell eosinophils.

Or:
System packs needed for the 5-diff analysis:

- **MSPACK 125 HUM MS4 5 DIFF:** 125 cycles ready to use pack with all needed reagents for 5-diff measurements on MS4 series.
- **MSPACK 250 HUM MS4 5 DIFF:** 250 cycles ready to use pack with all needed reagents for 5-diff measurements on MS4 series.
- **MSPACK 250 HUM MS9 5 DIFF:** 250 cycles ready to use pack with all needed reagents for 5-diff measurements on MS9 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 MS9/MS4 series 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. An electrical field is changed when a particle passes. Changes in conductivity are detected and recorded. Acti-diff 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 by a powerful haemoglobin reducer (Potassium Cyanide) with a reading at 540 nm.
Isoflux 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). Transflux is an active and passive cleaning agent that cleans the parts of the tanks and counting holes of the MS4/MS9 analysers. It operates in two modes: as detergent and as proteolytic enzyme.
EO-diff 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

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

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

ACTI-DIFF	**CONCENTRATION**
Quaternary ammonium	< 3 %
Potassium cyanide	< 0.5 %
Preservative	

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

RINSE
Distilled water
Preservative

HEMOREF	**CONCENTRATION**
Detergent	< 0.6 %
Preservative	< 1 %

MATERIAL REQUIRED BUT NOT PROVIDED

Haematology analyser (MS9/MS4 series).

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 (please see expiration date on label)
Stability after opening: 16 weeks

WARNINGS AND PRECAUTIONS

For Acti-diff 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. 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.
- It is recommended to carry out the analysis no earlier than 30 minutes and no later than 8 hours after collection.

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 available, please see the manual of the used analyser.

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

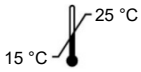
Please refer to local legal requirements.

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

ADDITIONALLY AVAILABLE PRODUCTS

REF	Content	Instrument
3MSR0223	- 1x 0.25 L Hemoref concentré	MS9
3MSR0213	- 1x 0.25 L Cleaning solution	MS9 / MS4 series