



Mythic 22 Reagents

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| REF: | HM22-001-1 | Cleaner for Mythic 22 | 1L |
| | HM22-002-1 | OnlyOne | 0.5L |
| | HM22-003-10 | Diluent for Mythic 22 | 10L |

IVD

SUMMARY

The blood counters use the impedance technology to measure the number of cells in a diluted blood sample which pass through an aperture located between two electrodes where a constant electrical current is applied.

The dilution is done with an isotonic solution which is a conductor and does not lyse the blood cells.

The conductivity of the isotonic diluent allows the passage of the electrical current between the two electrodes. When a particle is aspirated through the micro-orifice, it moves its own volume of electrolyte. This applies a modification of the resistance between both electrodes and generates an electrical pulse. The amplitude is directly proportional to the volume of the particle.

Leukoprotective agents prevent leukocytes from lysis and exert a specific discriminatory action on WBC sub-populations. Leucocytes are therefore cytochemically analyzed by measuring the FSC (forward scatter – the diffraction of light by small angles giving information about cell size) and ALL (Axial Light Loss – losses of light intensity in the axis expressing the intercellular complexity). WBC are also analyzed resistively to give a global WBC count.

In the same time, haemoglobin is released from ruptured red blood cells in the medium and stabilized into a single chromophoric complex. Haemoglobin concentration is then determined by a spectrophotometric measurement.

Two dilutions are prepared for WBC/HGB and for RBC/PLT.

COLLECTION AND STORAGE

MYTHIC 22 is a fully automated analyzer performing haematological analysis on whole blood collected on EDTA K3 tubes. The ratio between EDTA and whole blood must be between 1 to 2 mg per ml of blood.

The samples should be used at room temperature no longer than 4 hours after collection. If the analysis can not be done in the time, the samples should be stored at 4°C.

UTILISATION

Before running the analysis, the sample should be gently mixed. Open the tube, place it in the sampling port and press the start key.


CONSERVATION AND SHELF LIFE

Cleaner and diluent must be stored between 8°C and 30°C. OnlyOne lytic reagent must be stored between 18°C and 25°C. The reagents must be used before the expiry date indicated on the label.

REFERENCE

Refer to the Mythic 22 Operator's manual.

NAME AND ADDRESS OF THE MANUFACTURER

 ORPHEE S.A.
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| UTILISATION (For In Vitro Diagnostic use) | | |
| DILUENT: Isotonic solution use for the differentiation of the white blood cells. The diluent is used to dilute the cells, to measure the haemoglobin blank, and with the lyse, allows to count the different populations of leucocytes. | | |
| ENZYMATIC CLEANER: Cleaning solution. This solution is used to clean the system. The presence of an enzyme reduces the formation of proteins deposit. | | |
| LYTIC REAGENT OnlyOne: Lysing agent to obtain the measurement of the haemoglobin, counting and differentiation of the white blood cells. Use in combination with the diluent, this reagent lyses the red blood cells and protects the state of the leukocytes to permit the differentiation in subpopulations. | | |
| ACTIVE COMPONENTS | | |
| ONLYONE | DILUENT | CLEANER |
| <ul style="list-style-type: none"> – alkaline salts – buffer system – mixture of ionic (quaternary ammoniums) and non-ionic detergents – haemoglobin chelating agent – preservatives and leukoprotective agents | Solid content (0.9%) Other components: – Buffer – Preservatives | Proteolytic enzyme Propylene glycol (2.5-10%) Violet dye |
| WASTE TREATMENT | | |
| Chemical residues, in general, are included into special waste. Disposing of the latter is regulated by appropriate laws and ordinances. We recommend contacting the appropriate authorities, or waste disposal enterprises that will advise you on how to dispose of special waste. | | |
| PRECAUTIONS | | |
| ONLYONE | DILUENT | CLEANER |
| For <i>In vitro</i> diagnostic use. For professional use only. Wear protective equipment. Avoid release to sewerage system or to environment. For further information please refer to Material Safety Data Sheet. | | |

