

INSTRUCTION FOR USE

BioLyse M22

WBC-5-diff lysing reagent for automated hematology analysis

Product code: **OM-20611** 1 L
 OM-20615 0.5 L

For *in vitro* diagnostic use only

INTENDED USE

BioLyse M22 WBC-5-diff reagent is a stabilized and micro-filtered lysing agent for quantitative determination of leukocytes (WBC) and leukocyte 5-part differentiation (LYM, MONO, NEU, EO, BA) measurement in whole blood sample on Orphée Mythic-22 hematology analyzers.

BioLyse M22 WBC-5-diff lysing reagent should be used with only BioXol reagents. Erroneous results may be obtained if the reagent is applied with third party reagents.

Please refer to the instrument's User Manual for further information.

INGREDIENTS

Surfactants..... < 2.0 %
Buffers < 1.8 %
Stabilizers < 1.2 %
Preservatives < 0.8 %
in ion-free water

HANDLING PRECAUTIONS

- BioLyse M22 WBC-5-diff reagent is environmental friendly reagent.
- Avoid contact with eyes, skin and clothing.
- In case of eye or skin contact flush eyes with copious amounts of water for several minutes or wash skin area with water.
- Keep the reagent container closed when not in use.
- Wear laboratory gloves when handling the reagent.
- All body fluid samples should be considered potentially infectious materials. Treat all blood and other potentially infectious materials with appropriate precautions. Use gloves, masks and gowns if blood exposure is anticipated.
- Please refer to the MSDS associated with the reagent.
- Use Good Laboratory Practices (GLP) when handling the reagents.

SPECIMEN COLLECTION AND PREPARATION

BioLyse M22 reagent 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 15-30°C or up to 24 hours after collection when refrigerated (2-8°C).

REAGENT PREPARATION

- This reagent is ready for use and can be applied straight from the container; no special reagent preparation is necessary.
- Leave the reagent to reach the room temperature.

REAGENT REPLACEMENT

- Person installing the reagent must be a trained laboratory professional.
- Remove the inlet cap from the reagent container to be replaced. Connect the reagent inlet to the new reagent container.
- Be sure that the colour on each tube, reagent container label and connector in the back of the instrument match.
- Avoid any dust or microbial contamination of the tubing and reagents. Do not pour and mix the remains of a reagent from a container into other one.
- Prime thoroughly the new reagent and measure backgrounds according to the instrument's User Manual.
- When installing a new lot of reagent, recalibrate the instrument as specified in your User Manual.

REAGENT STORAGE, STABILITY AND DISPOSAL

- Store BioLyse M22 WBC-5-diff reagent between +2 and +35°C.
- The shelf life of the BioLyse M22 is 2 years from the date of manufacture, if stored at the prescribed temperature range.
- Do not use reagent beyond the expiration date printed on the container label.
- The open container stability of the reagent is 6 months.
- Dispose of waste product, unused product and contaminated packaging in compliance with local regulations.

MANUFACTURER

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version 2.0

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