

Erba Lyse-Diff



EN

Lysing reagent for automated analyzers

IVD

Name	Cat. No.	Package volume
Erba Lyse-Diff	HEM00007 (opened)	1 L
Erba Lyse-Diff	HEM00008 (closed)	1 L

For *in vitro* diagnostic use only

INTENDED USE

Erba Lyse-Diff lysing reagent is a stabilized and micro-filtered lysing agent for stromatolysis of erythrocytes (RBC), for quantitative determination of leukocytes (WBC), leukocyte three-part differentiation (LYM, MID, GRAN) and hemoglobin (HGB) concentration measurement in human blood on hematology analyzer.

Erba Lyse-Diff lysing reagent should be used with only Erba Lachema 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	< 3.5 %
Buffers	< 1.0 %
Preservative	< 0.5 %
Stabilizers	< 0.5 %

in ion-free water

HANDLING PRECAUTIONS

- Erba Lyse-Diff lysing reagent is environmental friendly, cyanide-free and azide-free reagent; does not contain harmful ingredients.
- 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.
- Use Good Laboratory Practices (GLP) when handling the reagents.

SPECIMEN COLLECTION AND PREPARATION

- Erba Lyse-Diff lysing 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 to +30) °C or up to 24 hours after collection when refrigerated (+2 to +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 at room temperature for at least 12 hours.

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 Erba Lyse-Diff lysing reagent between 15 and 30°C.
- The shelf life of the Erba Lyse-Diff lysing agent is 48 months from date of manufacture, if stored at the prescribed temperature range.
- Do not use reagent beyond the expiration date printed on the container label.
- Discard opened container after 120 days.
- Do not use reagent once frozen.
- Dispose of waste product, unused product and contaminated packaging in compliance with local regulations.

USED SYMBOLS



Catalogue Number



Manufacturer



See Instruction for Use



Lot Number



Storage Temperature



Expiry date



In vitro Diagnostics



Content



CE Mark -
Device comply with
the Directive 98/79/EC

50003764
50004171



Erba Lachema s.r.o., Karásek 2219/1d, 621 00 Brno, CZ
e-mail: diagnostics@erbamannheim.com, www.erbalachema.com

HEMA/PI/09/17/B
HEMA/PI/08/17/B

Date of revision: 25. 7. 2017