

Hemolynac•5 MEK-910

General

Intended Purpose

For in vitro diagnostic use only.

Hemolynac•5 is for in vitro diagnostic use as a lysing reagent for use in lysing red blood cells in diluted human venous whole blood samples for analysis by Nihon Kohden hematology analyzers to measure the five differential white blood cells.

Read the hematology analyzer operator's manual together with this manual before and during use.

NOTE: Read the SDS (Safety Data Sheet) carefully before use. The SDS is available from your Nihon Kohden representative.

Devices Intended for Use in Combination with

MEK-7222, MEK-7300, MEK-8222

Analyte or Marker

Five differential white blood cells in whole blood

Target Treated Population

The target populations are linked to the Nihon Kohden hematology analyzers. The target patient populations are populations found in clinical laboratories.

Specimen Collection and Preparation

- Use a sample of human whole blood only.
- When using a sampling tube, use EDTA as an anticoagulant.
- For collection and handling of blood samples, refer to the hematology analyzer operator's manual.

Intended Users

For laboratory professional use only, in laboratories with suitable equipment for hematological testing. Qualified personnel, e.g. laboratory technicians trained in hematology analysis techniques, will be able to use according to this operator's manual.

Symbols

The following symbols are used with the lysing reagent. The descriptions of each symbol are given in the table below.

Symbol	Description	Symbol	Description
	Use by		Keep away from rain
	Lot number		Stacking limit by number ("n" is the limiting number)
	Catalogue number		Caution
	Fragile		Operator's manual; operating instructions
	Keep away from sunlight		In vitro diagnostic medical device
	Temperature limits		Unique Device Identifier
	This way up		

0614-907970

Printed:

Symbol	Description	Symbol	Description
	Manufacturer		The CE mark is a protected conformity mark of the European Union.
	European representative		

Safety Information

CAUTION A caution alerts the user to possible injury or problems with the instrument associated with its use or misuse such as instrument malfunction, instrument failure, damage to the instrument, or damage to other property.

Pay attention to all safety information in this operator's manual.

CAUTION

- Wear protective gloves when handling the lysing reagent.
- Do not swallow the lysing reagent. If swallowed, rinse the mouth immediately. Do not force vomiting. See a physician.
- If the lysing reagent contacts the eyes or mouth, wash immediately with plenty of water and see a physician.
- If the lysing reagent contacts the skin, wash with plenty of water.

Using the Lysing Reagent

Measurement Principles

Hemolynac•5 is a hemolytic reagent for the five differential white blood cells measurement. Hemolynac•5 lyses the red blood cells to measure the five differential white blood cells in the diluted blood sample so that Lymphocytes, Monocytes, Neutrophils, Eosinophils and Basophils can be measured.

The five differential white blood cells are measured by the flow cytometry method using a semiconductor laser of hematology analyzers manufactured by Nihon Kohden.

For details, refer to the hematology analyzer operator's manual.

Procedure

Connect the container with the lysing reagent to a Nihon Kohden hematology analyzer. For the connection method, refer to the hematology analyzer operator's manual.

- NOTE
- Use the lysing reagent without diluting or sterilizing it.
 - Use the lysing reagent at a liquid temperature of 15 to 30°C (59 to 86°F). Otherwise the measurement data may be inaccurate.
 - Gently invert the lysing reagent before connecting the lysing reagent container to the hematology analyzer.

- Be careful of splashing liquid when replacing the lysing reagent.
- Do not refill the lysing reagent.
- When using the lysing reagent, be careful that no dust, bacteria or other contaminants enter the container.

Technical Information

Composition

Active ingredients:

Sodium alkyl ether sulphate: 0.11%

Interfering Substances or Limitations

The following interfering substances have been confirmed to have no effect on five differential white blood cells measurement below the listed concentrations.

Substance	Max. Serum Concentration
Bilirubin C	33.1 mg/dL
Bilirubin F	31.6 mg/dL
Chyle	2384 FTU

Environmental Conditions

Storage and Transport Environment

Temperature: 1 to 30°C (34 to 86°F) (Do not freeze and keep away from sunlight.)

NOTE: Do not freeze the lysing reagent. If the lysing reagent is frozen, the measurement data may be inaccurate due to precipitation of reagent ingredients.

Operating Environment

Temperature: 15 to 30°C (59 to 86°F)

Expiration Date

The expiration date is shown on the container label and package.

Shelf Life Date After Opening the Package

Use the lysing reagent within 30 days of opening.

Package and Catalog Number

Model	Qty	Catalog Number
MEK-910	500 mL × 1 container	T499
	500 mL × 3 containers	T496

Disposal

When disposing of the lysing reagent, such as when the expiration date is past, follow the instructions on the SDS of the lysing reagent.

NOTE: Dispose of the lysing reagent according to your local laws and your facility's guidelines for waste disposal (for incineration, melt treatment, sterilization and disinfection). Otherwise, it may affect the environment.

Revision History

Edition	Date	Details	Code Number
1st Edition	10 Apr 1998	Initial issue	0604-010639
6th Edition	22 Feb 2022	IVDR compliance	0614-907970

- NOTE
- The code number of this manual was changed from 0604-010639D to 0614-907970 when the manual was updated from 5th Edition to 6th Edition.
 - Changes made in the most recent edition are indicated by a bar in the left margin of each page.

Note for users in the territory of the EEA and Switzerland:
Any serious incident that has occurred in relation to the device must be reported to the European Representative designated by the manufacturer and the Competent Authority of the Member State of the EEA and Switzerland in which the user and/or patient is established.

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