OPERATOR'S MANUAL

Hemolynac•310

MK-310W

NIHON KOHDEN

General

Intended Purpose

For in vitro diagnostic use only.

Hemolynac•310 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 the Nihon Kohden hematology analyzers to measure hemoglobin concentration.

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-1301, MEK-1302, MEK-1303, MEK-1305, MEK-9100, MEK-9200

Analyte or Marker

Hemoglobin concentration 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 this lysing reagent. The descriptions of each symbol are given in the table below.

Symbol	Description
	Use by
LOT	Lot number
REF	Catalogue number
	Fragile
	Keep away from sunlight

Symbol	Description
	Temperature limits
	This way up
	Keep away from rain
	Stacking limit by number ("n" is the limiting number)
	Caution

Symbol	Description
	Operator's manual; operating instructions
IVD	In vitro diagnostic medical device
UDI	Unique Device Identifier

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

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.

Hazards Identification

Signal Word

Warning (Not classified in CLP)

Hazard Statement

- H316 Causes mild skin irritation
- H401 Toxic to aquatic life
- EUH210
  Safety data sheet available on request

Precautionary Statement Prevention

- P273 Avoid release to the environment.

Precautionary Statement Response

- P332+P313
  If skin irritation occurs: Get medical advice/attention.

Precautionary Statement Disposal

- P501 Dispose of contents/container in accordance with local and national regulations.

0614-907955
Printed:

Dodecyltrimethylammonium chloride: < 3.0%

Cetrimonium chloride: < 0.1%

Citric acid monohydrate: < 2.0%

Using the Lysing Reagent

Measurement Principles

Hemolynac•310 is a hemolytic reagent for hemoglobin measurement. Hemolynac•310 lyses the red blood cells to elute hemoglobin in the diluted blood sample so that the hemoglobin concentration can be measured. The eluted hemoglobin reacts with the quaternary ammonium salt in the reagent and changes to a hemoglobin compound.

The hemoglobin compound is measured by absorbance (520 nm) by the Nihon Kohden hematology analyzers. The absorbance of the hemoglobin compound is proportional to the hemoglobin concentration. This hemolytic reagent does not contain cyanide.

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 30ºC (59 to 86ºF). Otherwise the measurement data may be inaccurate.
- Gently invert the lysing reagent before connecting the 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

Quaternary ammonium salts: 2.7%

Interfering Substances or Limitations

The following interfering substances have been confirmed to have no effect on hemoglobin measurement below the listed concentrations.

Substance	Max. Serum Concentration
Bilirubin C	25.0 mg/dL
Bilirubin F	17.9 mg/dL
Hemolyzed hemoglobin:	0.18 g/dL
Chyle	1,031 FTU
Total protein	1.02 g/dL

Environment Conditions

Storage and Transport Environment Temperature

1 to 30ºC (34 to 86ºF)
(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 30ºC (59 to 86ºF)

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 90 days of opening.

Package and Catalog Number

Model	Qty	Catalog Number
MK-310W	250 mL × 1 container	T493D

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	01 Sep 2015	Initial issue	0654-905318
3rd Edition	07 Mar 2022	IVDR compliance	0614-907955

NOTE
- The code number of this manual was changed from 0654-905318A to 0614-907955 when the manual was updated from 2nd Edition to 3rd 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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