

# Reticulonac MK-110W

## General

### Intended Purpose

*For in vitro diagnostic use only.*

Reticulonac is for in vitro diagnostic use as a stain for fluorescent detection of whole blood cells for analysis by Nihon Kohden hematology analyzers to measure reticulocyte counts and 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.

### Device Intended for Use in Combination with

MEK-9200

### Analyte or Marker

Reticulocyte 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 stain. The descriptions of each symbol are given in the table below.

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

0614-907977

Printed:

Symbol	Description
	Manufacturer
	European representative

Symbol	Description
	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 stain.
- Do not swallow the stain. If swallowed, rinse the mouth immediately. Do not force vomiting. See a physician.
- If the stain contacts the eyes or mouth, wash immediately with plenty of water and see a physician.
- If the stain contacts the skin, wash with plenty of water.

## Hazards Identification

### Hazard Statement

- EUH210 Safety data sheet available on request

## Using the Stain

### Measurement Principle

Reticulonac contains fluorescent dye of acridine dye. Acridine dye stains whole blood cells which contain the nucleic acids so that stained cells can be detected by the different fluorescence. The reticulocytes can be measured by distinguishing reticulocytes from other blood cells by the scattered light and fluorescence detection using the flow cytometry method.

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

### Procedure

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

- NOTE
- Use the stain without diluting or sterilizing it.
  - Use the stain at a liquid temperature of 15 to 30°C (59 to 86°F). Otherwise the measurement data may be inaccurate.

- Gently invert the stain before connecting the reagent container to the hematology analyzer.
- Be careful of splashing liquid when replacing the stain.
- Do not refill the stain.
- When using the stain, be careful that no dust, bacteria or other contaminants enter the container.

## Technical Information

### Composition

Active ingredients:

Acridine dye: 0.001%

### Interfering Substances or Limitations

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

Substance	Max. Serum Concentration
Bilirubin C	21.1 mg/dL
Bilirubin F	21.1 mg/dL
Hemolysis hemoglobin	0.51 g/dL
Chyle	1490 FTU
Total protein	3.99 g/dL

## Environmental Conditions

### Storage Environment

Temperature: 2 to 8°C (36 to 46°F) (Do not freeze and keep away from sunlight.)

### Transport Environment

Temperature: 1 to 30°C (34 to 86°F)

The stain can be transported at 1 to 30°C within 4 weeks. (Do not freeze and keep away from sunlight.)

NOTE: Do not freeze the stain. If the stain is frozen, the measurement data may be inaccurate due to precipitation of stain 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 stain within 60 days of opening.

## Package and Catalog Number

Model	Qty	Catalog Number
MK-110W	250 mL × 1 container	MK-110W-1M

## Disposal

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

NOTE: Dispose of the stain 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	19 Mar 2020	Initial issue	0604-913283
4th Edition	28 Feb 2022	IVDR compliance	0614-907977

- NOTE
- The code number of this manual was changed from 0604-913283B to 0614-907977 when the manual was updated from 3rd Edition to 4th 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.

### Copyright Notice

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1st Edition: 19 Mar 2020  
4th Edition: 28 Feb 2022

