

IVD

REF 991-91791

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BX002

NEFA Standard

[Intended purpose]

The NEFA Standard is designed to be used with NEFA-HR(2) for the quantitative determination of Non-esterified fatty acid (NEFA) in serum. The usage and application of this standard is reserved for professional use only.

[Reagents and Contents]

NEFA Standard: 2 × 10 mL

Contains oleic acid (NEFA 1 mEq/L).

[Determination of assigned values]

Assigned values: See bottle labels.

Determination:

The concentration of NEFA is determined by measuring a standard with the manufacturer's standing measurement procedure and the manufacturer's internal standard.

The concentration of NEFA of the manufacturer's internal standard was determined by dissolving the weighed oleic acid in the buffer.

[Reagent preparation]

Use as supplied.

[Warnings and precautions]

- For *in vitro* diagnostic use.
- The usage and application of this standard is reserved for professional use only. Please refer to respective national and local regulations and legislation.
- Not to be used internally in humans or animals.
- Do not use the standards for any other purpose than described herein. Refer to the instructions for use of NEFA-HR(2).
- Do not use the bottles and other materials in the package for any purposes other than those described herein.
- If the standards come in contact with mouth, eyes or skin, wash off immediately with a large amount of water. Consult a physician if necessary.
- All devices including standards and standard bottles that come in contact with specimen should be considered potentially infectious.
- Store the standards under the specified conditions. Do not use the standards past the expiration date stated on each bottle label.
- After opening the standards, it is recommended to use them immediately. When the opened standards are stored, cap the bottles and keep them under the specified conditions.
- Do not use the standards that were frozen in error. Such standards may give false results.
- Do not mix the standards, which have different lot numbers.
- When discarding the standards, dispose of them according to local or national regulations.
- The standards contain 0.05% sodium azide as a preservative. Sodium azide may react with lead or copper plumbing to form explosive compounds. Even though the standards contain minute quantities of sodium azide, drains should be flushed well with a large amount of water, when discarding the standards.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

[Storage and shelf life]

Product	Storage condition	Shelf life
NEFA Standard	2 – 10°C	12 months

Check the expiration date on the label before use.

[Information]

Catalogue number	Product	Contents
994-91801	NEFA-HR(2) R1 Set	(R1a) Color Reagent A 4 × for 50 mL (R1b) Solvent A 4 × 50 mL
990-91901	NEFA-HR(2) R2 Set	(R2a) Color Reagent B 4 × for 25 mL (R2b) Solvent B 4 × 25 mL
991-91791	NEFA Standard	NEFA Standard 2 × 10 mL

[Symbols]

	In vitro diagnostic medical device
	Unique Device Identifier
	Contents of the kit
	Consult instructions for use or consult electronic instructions for use
	Temperature limit
	Batch code
	Use-by date (last day of the month)
	Manufacturer
	Importer
	Authorized representative in the European Community/ European Union
	Catalogue number

<https://diagnostic-wako.fujifilm.com/cemarkingproducts/index.html>



FUJIFILM Wako Chemicals Europe GmbH

Fuggerstr. 12, 41468 Neuss, Germany

Telephone : +49 2131 311 272

Fax : +49 2131 311 110

URL : wako-chemicals.de



FUJIFILM Wako Pure Chemical Corporation

1-2, Doshomachi 3-Chome, Chuo-ku Osaka 540-8605, Japan

Telephone : +81 6 6203 3749

Fax : +81 6 6203 1917

URL : fujifilm.com/ffwk/en

Wako

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