

Linearity FD Neurofilament Light Chain (NfL)

For Research Use Only. Not for use in diagnostic procedures.

REF K744M-5

5 x 1 mL

LOT 07178



Aalto Scientific Ltd
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USA



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INTENDED USE

The Audit® MicroControls™ Linearity FD Neurofilament Light Chain (NfL) is intended for Research Use Only. Not for use in diagnostic procedures.

This product is not intended for use in investigations subject to 21 CFR 812.

WARNINGS AND PRECAUTIONS

Because this product is of human origin, it should be handled as though capable of transmitting infectious diseases. Each serum, plasma or whole blood donor unit used in the preparation of this material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV and nonreactive for HBsAg. Because no test method can offer complete assurance that HIV, hepatitis B virus, and hepatitis C virus or other infectious agents are absent, this material should be handled as though capable of transmitting infectious diseases. This product may also contain other human source material for which there is no approved test. The FDA recommends such samples be handled at the Centers for Disease Control's Biosafety Level 2.

Linearity FD Neurofilament Light Chain (NfL) is intended solely for Research Use Only. Not for use in diagnostic procedures. AUDIT® MicroControls™, Inc. will not be liable for any unclaimed damages arising from any other usage.

MATERIALS PROVIDED

The Linearity FD Neurofilament Light Chain (NfL) consists of 5 levels of freeze dried material and additives in human serum.

Linearity FD Neurofilament Light Chain (NfL), 5 x 1 mL

Each set of Linearity FD Neurofilament Light Chain (NfL) is prepared in a manner such that an equal distance exists between each consecutive level.

STORAGE AND STABILITY

Linearity FD Neurofilament Light Chain (NfL) is stored at 2-8°C and will remain stable in the unopened bottle until the expiration date. Do not store in a frost-free freezer. After reconstituting, the contents should be used according to the instrument manufacturer's instructions and stored at 2-8°C for 24 hours.

INSTRUCTIONS FOR USE

1. Remove a vial from the package.
2. Using a pipette, reconstitute the product with 1 mL of deionized water.
3. Allow the vial to sit at room temperature for 5 minutes.
4. Occasionally swirl for 15 minutes, or until all visible material is dissolved. Do not shake. Do not mix mechanically. Avoid getting any undissolved material on the sides of the vial or the stopper.
5. When all visible solid material is dissolved, invert several times to dissolve any material on the stopper.
6. Swirl occasionally for at least 5 minutes.
7. Use immediately or return to 2-8°C.
8. The vial should remain stored at 2-8°C at all times. If additional sampling is necessary, the time outside of 2-8°C storage should be minimized.

LIMITATIONS OF THE PROCEDURE

This product is not intended for use in clinical or diagnostic settings.

If the contents of any of the vials become frozen, discard all vials and request a replacement set, as the results will not be valid.

The Linearity FD Neurofilament Light Chain (NfL) must not be used for calibration or standardization of assays.

Target values and ranges are intended only as guidelines.

Dispose of any discarded materials in accordance with the requirements of your local waste management authorities.

EXPECTED VALUES

Each lot of product is manufactured such that a linear relationship exists among levels. Actual results obtained may vary depending on instrumentation, methodology and assay temperature. Results may also be dependent on the accuracy of the instrument/reagent system calibration. The material and information presented here in no manner constitutes an overruling of any federal, state or other regulatory body's regulations and/or guidelines.

ORDERING INFORMATION

PRODUCT NUMBER	PRODUCT DESCRIPTION	PRODUCT PACKAGING
K744M-5	Linearity FD Neurofilament Light Chain (NfL)	5 x 1 mL

Distributed by AUDIT® MicroControls™, Inc. - U.S. customers only please call (866) 252-8348 or www.auditmicro.com

	Instrument	Units	A	B	C	D	E
NfL	Siemens Atellica	pg/mL	4.64	58.2	114	159	227



Catalog Number



Use By
(YYYY-MM-DD)



Lot Number



Caution



www.auditmicro.com/inserts



2 ~ 8°C
Temperature Limit



Manufactured By