Install Kit – FT4 (L1 – L5)

ORDER NO.: C-1002ro

INTENDED USE
Install Kits are unassayed controls intended for use during assay installations for the following analyte: free thyroxine (FT4).

Install Kits are non-automated and intended for Roche install technician use only.

Each Install kit consists of one bottle each of Levels 1 through 5 unassayed controls. Each bottle contains 2.5 milliliters.

SUMMARY
This Install kit contains five levels of individually manufactured unassayed controls to be used for assay installations. Please see APPROXIMATE VALUES section for more information as this product is not manufactured in the same manner as VALIDATE (equal-delta).

REAGENTS
Reactive Ingredients:
Purified chemicals and constituents of human and/or animal source in human serum.

Nonreactive Ingredients:
Preservatives and stabilizers.

Precautions and Warnings:
For In Vitro Diagnostic Use
Disposal of all waste material should be in accordance with local guidelines.

WARNING: Potentially Biohazardous
Human source material is considered potentially biohazardous. Use the Centers for Disease Control (CDC) recommended universal precautions for handling VALIDATE products.

STORAGE AND STABILITY
Install Kits are stored at -10° to -25°C. ***Do NOT store in a frost-free freezer.*** Install kits are stable until the expiration date printed on the bottle and storage container when handled according to instructions. ***A maximum of two (2) freeze-thaw cycles are recommended per assay installation, please discard after that time.***

PREPARATION
Prior to use, remove the bottle(s) from storage and allow to come to room temperature (18° to 25°C). Invert gently several times before dispensing.

To maximize stability, it is recommended that exposure to room temperature be minimized. Tightly cap opened bottles and return to -10° to -25°C immediately after dispensing or discard as stated above.

Discard any solutions that appear to have gross bacterial contamination.

APPROXIMATE VALUES
The values listed are approximate and provided only for reference. Actual observed values will vary depending on the lot number, temperature, reagent and/or calibrator.

Level	Range	Units
1	0.12 – 0.28	ng/dL
2	1.11 – 1.94	ng/dL
3	2.18 – 3.95	ng/dL
4	4.14 – 6.38	ng/dL
5	5.70 – 8.43	ng/dL

LIMITATIONS
Install Kit solutions are not intended for use as routine quality control materials or as calibration materials.

The following symbols may be used where applicable in labeling for LGC Clinical Diagnostics products:



Lot Number


Expiration Date


Manufacturer


Storage Temperature



In Vitro Diagnostic Medical Device



Catalog Number


Insert


Biological Risk


Do Not Reuse

Any serious incident occurring in relation to the use of this device shall be reported to the Manufacturer as well as the Competent Authority of the member state in which the user/patient is established.

CONTACT INFORMATION

For technical assistance, please call:

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Issue Date	Modification
Apr 16, 2025	Summary section updated to include language that this product is manufactured using individual levels.