



Install Kit – NTproBNP (L1 – L5)

ORDER NO.: C-1001ro

INTENDED USE

Install Kits are unassayed controls intended for use during assay installations for the following analyte: N-Terminal pro hormone B-type Natriuretic Peptide (NTproBNP).

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 | 39 - 61 | pg/mL |
| 2 | 124 - 178 | pg/mL |
| 3 | 10119 - 14041 | pg/mL |
| 4 | 21381 - 28901 | pg/mL |
| 5 | 29153 - 37085 | pg/mL |

DILUTION

If needed, the reagent manufacturer's recommended diluent can be used to make dilutions of Level 5 to obtain a result within the analytical measuring range. Samples diluted 1:2 can have deviations of up to 18% per reagent manufacturer.

If Level 5 is above the analytical measuring range:

Determine the theoretical recovery of Level 5. Perform a 1:2 dilution of the high level using the manufacturer's recommended diluent. The results must be multiplied by the dilution factor (DF) and account for deviations of 18% (0.18) from the theoretical.

Theoretical recovery = (1:2 recovery) x 2 (DF) / (1 - 0.18)

For example: 1:2 mean recovery = 15,000 pg/mL

Theoretical recovery = 15,000 pg/mL x 2 / (1 - 0.18) = 36,585 pg/mL

LIMITATIONS

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

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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1-207-892-1300

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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**

| Issue Date | Modification |
|-------------|--|
| Apr 8, 2025 | Summary section updated to include language that this product is manufactured using individual levels. |