



HOMOCYSTEINE LINEARITY SET

INTENDED USE:

Catch Inc. unassayed Homocysteine Linearity Set is ready-to-use and can be used to monitor the linearity of assays designed to quantitate homocysteine.

SUMMARY AND PRINCIPLE:

Use of the linearity set that mimics actual patient specimens, enables the laboratory to reliably monitor the linearity performance of an analytical method. Monitoring the linearity results can allow the detection of analytical errors caused by faulty technique, reagent deterioration, or instrument problems.

Run the five levels of Catch Inc. Homocysteine Linearity Set exactly as real patient specimens. Results can be compared to the target values listed here and with appropriate ranges established by the laboratory. Homocysteine levels provided are in low, medium and multiple high ranges.

REAGENTS:

Catch Inc. Homocysteine Linearity Set is prepared from human serum, which has either been modified by dilution with homocysteine-free serum or to which homocysteine (as the purified chemical L-homocysteine form) has been added to obtain elevated concentrations as necessary. Sodium azide (< 0.1%) is used as a preservative. This linearity set is comprised of five liquid ready-to-use levels and may be stored refrigerated and shipped with ice packs. Stability is as listed on the product label.

WARNINGS AND PRECAUTIONS:

Human serum was used in the manufacture of this product. Each donor unit was tested using FDA cleared reagents and found to be negative or non-reactive for HIV-1, HIV-2, HIV-AG, HCV, HbsAg, and RPR. Because no test method can offer complete assurance, products derived from human blood should be handled with the same precautions used for patient specimens.

Warning: This reagent is for *in vitro* diagnostic use only. **DO NOT INGEST.** Avoid contact with skin and eyes. Contains sodium azide which may react with lead or copper plumbing to form explosive compounds. Flush drains with copious amounts of water when disposing of this reagent. Additional safety information concerning storage and handling of this product is provided within the Material Safety Data Sheet for this product. To obtain an MSDS, please call our customer service department at:+

1 (866) 719-6099

STABILITY AND STORAGE:

Store the Catch Inc. linearity set at 2-8°C until the expiration date stated on the label. Once opened the controls may be used for up to 30 days if promptly returned to the refrigerator when not in use.

PROCEDURE:

Materials provided: The Catch Inc. Homocysteine Linearity Set is provided in kits as listed below.

Product Number	Product Description	Product Packaging
L-105	Homocysteine Linearity Set	5 x 5 mL each levels A, B, C, D, E

Catch Inc. Homocysteine Linearity Set is provided ready-to-use. Bottle caps are color-coded as follows: Level A, green; Level B, yellow; Level C, red; Level D, blue and Level E, white. Remove from the refrigerator and swirl gently. (Note: vigorous swirling will create unwanted bubbles). Transfer aliquots of the required size to appropriate sample cups for the instrument being used. Cap and return to the refrigerator.

Run each level 2 or 3 times to ensure reliable results. Average results for each of the five levels and plot each average result versus the Target value shown below on linear graph paper. A linear relationship should be obtained. If desired, make intermediate levels by mixing two levels appropriately. A

homocysteine level below the lowest provided level (A) may be obtained by dilution using the zero standard provided by the Homocysteine Reagent manufacturer.

TARGET VALUES:

Target values based on repetitive analyses using the Catch Inc. reagent for homocysteine quantitation on several instruments are shown below. Values obtained may vary slightly based on the method and instrument used. Each laboratory must establish its own mean and range for each level of this homocysteine linearity set. QC testing should be performed in accordance with local, state, and/or federal regulations or accreditation requirements

Target Values

Level	Homocysteine μmol/L
A	7.4
B	12.7
C	27.4
D	45.5
E	85.8

LIMITATIONS:

If the linearity materials are frozen, thaw and then thoroughly, but gently, mix before use.

Manufactured for Catch Incorporated
11822 Northcreek Parkway North,
Suite 107
Bothell, WA 98011
1-866-719-6099

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