



TRI-LEVEL HOMOCYSTEINE CONTROL SET

INTENDED USE:

Catch Inc. Tri-level Homocysteine Control Set, unassayed, is a ready-to-use and can be used to monitor the accuracy and precision of assays designed to quantitate homocysteine.

SUMMARY AND PRINCIPLE:

Use of controls that mimic actual patient specimens by each laboratory enables the laboratory to reliably monitor the day-to-day performance of analytical methods. Monitoring control results aid in the detection of analytical errors caused by faulty technique, reagent deterioration, or instrument problems.

Catch Inc. Tri-level Homocysteine Control Set is designed to be used exactly as real patient specimens. Results can be compared to the target values listed here and with control ranges established by the laboratory. Homocysteine levels provided are in low, medium and high ranges.

REAGENTS:

Catch Inc. Tri-level Homocysteine Control Set is prepared from human serum, which has either been modified by dilution with homocysteine-free serum or to which purified synthetic homocysteine (in the form of homocystine) has been added to obtain elevated concentrations as necessary. Sodium azide (< 0.1%) is used as a preservative. These controls are liquid ready-to-use and may be stored refrigerated and shipped cooled with ice packs. Stability is as listed on the product label. The controls are stable until the expiration date.

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 that products derived from human blood will not transmit infectious agents, this product 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. Tri-level Homocysteine Controls 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 Tri-level Control is provided in a kit as listed below.

Product Number	Product Description	Product Packaging
C-103	Tri-Level Homocysteine Control	2 x 5 mL each levels A,B,C

The Catch Inc. Tri-level Homocysteine Controls are provided ready-to-use. Bottle caps are color-coded as follows: Level A, green; Level B, yellow; Level C, red. The color code is also stated on the label. 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 the controls to the refrigerator.

TARGET VALUES:

Target values based on repetitive analyses using Catch Inc.'s 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 these controls. QC testing should be performed in accordance with local, state, and/or federal regulations or accreditation requirements.

Target Values

Level	Homocysteine $\mu\text{mol/L}$
A	7.5
B	12.0
C	29.0

LIMITATIONS:

If the controls are frozen, thaw and thoroughly, but gently, mix before using.

Manufactured for Catch Incorporated
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