

TruLab Urine

Assayed quality control material for monitoring assay performance of quantitative in vitro determination of various analytes

Order Information

5 9170 99 10 061	6 x 5 mL	Level 1
5 9170 99 10 062	20 x 5 mL	Level 1
5 9180 99 10 061	6 x 5 mL	Level 2
5 9180 99 10 062	20 x 5 mL	Level 2

Description

TruLab Urine is a liquid-stable human-based control urine. TruLab Urine contains biological material of specified origin: Human salivary amylase, hCG derived from human urine, and human and bovine serum albumin.

The concentration of the biological material does not exceed the maximum, lot specific target value concentration of the analyte.

Storage

The unopened and opened bottles of TruLab Urine controls must be stored at 2 – 8°C.

Stability

Unopened: Until the end of the indicated month of expiry

Opened: At least up to 3 months

Proper storage and handling of this product must be observed. Do not freeze!

Increased turbidity and/or characteristic smell indicate bacterial growth. Discard control if microbial contamination is observed.

Warnings and Precautions

1. Components of TruLab Urine derived from human source material were found to be non-reactive when tested with approved methods for HBsAg, anti-HIV 1+2 and anti-HCV. As there is no possibility to exclude definitely that products derived from human source transmit infectious agents, it is recommended to handle the control with the same precautions used for patient specimens.
2. TruLab Urine contains biological material of specified origin. The controls should be handled as potentially infectious and with the same precautions used for patient specimens.
3. Please refer to the safety data sheets and take the necessary precautions for the use of calibrators and controls.
4. For professional use only!

Preparation

TruLab Urine is liquid and ready to use.

Procedure

Thoroughly mix the contents of the vial before each use by gently inverting for approx. 5 minutes. Open the vial and transfer the required control quantity into a clean sample cup. Replace the cap immediately and store the vial at 2 – 8°C.

Please refer to the reagent package insert for instructions for use.

Assay Values

The assigned target values for these controls are based upon replicate assays of representative samples of the product by participating laboratories. All values have been assigned with instruments and instrument manufacturer's reagents available at the time of assay. Subsequent instrument or reagent modifications may invalidate the assigned values.

Target values may vary slightly with different reagents and/or methodologies used, especially if not mentioned in the table of values. The assay values listed are valid only for the corresponding lot.

Each laboratory should establish corrective action in case of deviations in control recovery.

Control Ranges

Ranges of acceptance were calculated as assigned value \pm the maximum tolerable deviation of a single value according to the Guidelines of the German Federal Medical Council (Rilibäk) from 2003 [3].

For the analytes not listed in the Rilibäk the ranges are given as \pm 20% of the target value.

Literature

1. Röhle G, Siekmann L. Quality assurance of quantitative determination. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 1393-1401.
2. Biosafety in Microbiological and Biomedical Laboratories. U.S. Department of Health and Human Services, Washington 1993 (HHS Publication No. [CDC] 93-8395).
3. Richtlinie der Bundesärztekammer zur Qualitätssicherung quantitativer laboratoriumsmedizinischer Untersuchungen. Deutsches Ärzteblatt 2003;100:A 3335-38.

Waste management

Please refer to local legal requirements.

Manufacturer

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