DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
IZ NOE-Sued, Hondastrasse, Objekt M55, 2351 Wr. Neudorf, Austria
Phone: +43 (0) 2236 660910-0, Fax: +43 (0) 2236 660910-30, e-mail: office@dialab.at

DIACON URINE Level 2
(Assayed Control Urine)

Liquid universal control urine for the use as control of accuracy and precision of tests for the quantitative in vitro determination of various analytes on photometric systems.

REF	Content		
D08582	12 x 5 mL	Level 2	finished kit
D08582SV	1 x 5 mL	Level 2	single vial
D08582VSV	1 x 5 mL	Level 2	unlabeled single vial (OEM)

For professional in vitro diagnostic use only.

GENERAL INFORMATION

Shelf life 24 months from production date
Storage 2 - 8 °C

INTENDED USE

Liquid universal control urine for the use as control of accuracy and precision of tests for the quantitative in vitro determination of various analytes on photometric systems.

REAGENT COMPOSITION

Diacon Urine Level 2 is a liquid-stable human-based control urine. Diacon Urine Level 2 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.

MATERIAL REQUIRED BUT NOT PROVIDED

- Clinical chemistry analyser.

REAGENT PREPARATION

The controls are liquid and ready to use.

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

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

STORAGE AND STABILITY

Storage:	The unopened and opened bottles of Diacon Urine Level 2 must be stored at 2 – 8 °C.
Stability:	
Unopened	until indicated date of expiration
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 Diacon Urine Level 2 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. Diacon Urine Level 2 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!

TEST PROCEDURE

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

LOT SPECIFIC VALUES AND RANGES

Assigned target values for this control are based upon replicate assays of representative samples of the product by participating laboratories.
The assay values and ranges provided for each analyte listed are derived using DIALAB reagents or reagents from other manufacturers.
The 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.

Ranges of acceptance were calculated as assigned value ± the maximum tolerable deviation of a single value accordinig 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 ± 20% of the target value.

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

Values and Expiry Date are LOT specific.
Please refer to table with LOT specific assay data.

LIMITATIONS

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.

WASTE MANAGEMENT

Please refer to local legal requirements.

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.

CE IVD