BIO-RAD

Liquichek™ Urinalysis Levels 1 and 2

REF	**435**	Bilevel	12 x 12 mL (6 per level)
	436	Level 1	12 x 12 mL
	437	Level 2	12 x 12 mL
	435X	Bilevel MiniPak	2 x 12 mL (1 per level)

CE IV

ENGLISH

INTENDED USE

Liquichek Urinalysis Control is intended for use as an assayed quality control urine to monitor the precision of urinalysis test procedures for the analytes listed in this package insert.

SUMMARY AND PRINCIPLE

The use of quality control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices. Two levels of control are available to allow performance monitoring within the clinical range.

REAGENT

This product is prepared from human urine with added human erythrocytes, simulated leukocytes, constituents of animal origin, chemicals, preservatives and stabilizers. The control is provided in liquid form for convenience.

STORAGE AND STABILITY

This product will be stable until the expiration date when stored unopened at 2 to 8°C. Once the control is opened and stored tightly capped, all analytes will be stable for 30 days at 2 to 25°C. This product should never be frozen.

This product is shipped under refrigerated conditions.

PROCEDURE

This product should be treated the same as patient specimens and run in accordance with the instructions accompanying the instrument, kit, or reagent being used.

Before sampling, allow the control to reach room temperature (18 to 25°C) and invert the vial several times to ensure homogeneity. After each use, promptly replace the stopper or dispenser tip closure and return to 2 to 25°C storage.

Dispose of any discarded materials in accordance with the requirements of your local waste management authorities. In the event of damage to packaging, contact the local Bio-Rad Laboratories Sales Office or Bio-Rad Laboratories Technical Services.

DISPENSER TIP INSTRUCTIONS

1. Carefully remove the vial screw cap and stopper.
2. Securely attach the dispenser tip to the top of the vial by tightening the original vial screw cap over the dispenser tip.
3. Invert the vial several times to ensure homogeneity.
4. Remove the dispenser tip closure.
5. While holding the urine test strip, gently depress the sides of the dispenser tip. Draw the control sample across all the reagent pads, thoroughly saturating each pad. Do not aspirate control back into the vial.
6. Wipe off dispenser tip and recap with closure being sure not to cross contaminate the level 1 by using level 2 closure.
7. Return vial to 2 to 25°C.
8. A new dispenser tip should be used with each new control vial.

LIMITATIONS

1. This product should not be used past the expiration date.
2. If there is evidence of microbial contamination or excessive turbidity in the product discard the vial.
3. This product is not intended for use as a standard.
4. This product contains gentamicin. Follow the instructions provided by manufacturers of the reagent and/or test system for samples containing gentamicin.

ASSIGNMENT OF VALUES

The results printed in this insert were derived from replicate analyses and are specific for this lot of product. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications. Each laboratory should use the results provided only as a reference and establish its own parameters of precision.

Refer to *www.qcnet.com* for insert update information.

SPECIFIC PERFORMANCE CHARACTERISTICS

This product is a stabilized liquid product manufactured under rigid quality control standards. To obtain consistent vial-to-vial assay values, the control requires proper storage and handling as described.

Optional Supplies

Item No. 987000 – Dispenser Tips for Screw Caps (100/package)

REF	CE	IVD	EXP	LOT
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