

# URITROL™ Liquid Urinalysis Control

**REF** Cat no. Product  
 U5-11 URITROL Liquid Level 1 (3 vials x15ml)  
 U5-12 URITROL Liquid Level 2 (3 vials x15ml)  
 U5-13 URITROL Liquid Level 1,2 (1 vial of each Level, 2 vials x15ml)

## Intended use

Professional use

URITROL™ Liquid Urinalysis control, Dropper Style, is intended for use as an assayed quality control urine to monitor and maintain the accuracy and precision of the urine strip and the analyzer.

## Product description

URITROL™ Liquid Urinalysis control is prepared from human urine with added other substances. It also contains preservatives and stabilizers. The control is provided in liquid form for convenience. Two levels of control are available to allow performance monitoring within the clinical range.

## Stability and Storage

- Unopened vial: it will the control is opened and stored at 2°C to 8°C
- Opened vial: once the control is opened and stored tightly capped, all analyses will be stable for one month at 2°C to 8°C

\* Please do not store the control in a room temperature after open.

## Procedure

This product should be used in accordance with the instructions accompanying the instrument, kit or reagent being used. Before sampling, allow the control to come to room temperature. Thoroughly mix the contents of the tube before each use by inverting for several minutes. Replace the cap immediately after use and store in as described in the [Stability and Storage] section. URITROL™ Liquid Urinalysis control should be disposed in accordance with the safety regulation applicable at your facility.

## Instructions for use

### Visual & semi-automated urine chemistry analysers:

- Open the cap, and flow one drop of the control from top to bottom of the strip.  
**Warning: do not touch the surface of the strip pads with the mouth of the bottle to avoid reabsorbing.**
- Remove excessive urine, and read the results by visual or semi-auto urine chemistry analysers.
- Replace the cap immediately after use.

### Fully automated urine chemistry analysers:

- Open the cap, and pure the URITROL liquid into clean tube. The minimum volume is different for each urine chemistry analyser (e.g. URISCAN Super+: 2ml).
- Replace the cap immediately after use.
- Install the tube with control and perform the test in accordance with the instruction of analyzer.

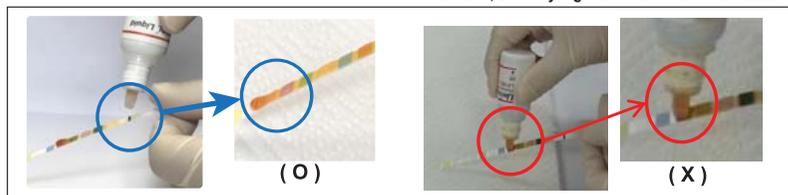
## Expected values

The expected values may vary slightly with different lot numbers and reagent strips, pregnancy test kit. The expected values printed in this insert were derived from replicate analyses of representative samples of the product and by YD Diagnostics. All values have been assigned with manufacturer's reagents available at the time of assay. It is recommended that each laboratory establishes its own expected ranges.

## Limitation of procedures

This product should not be used past the expiration date. This product must be mixed well before use to ensure reproducible results. See manufacturer's product insert for the list of limitations for each test method.

\* Ketones, Leucocyte grades can be affected if inhaled.



## Result table

The expected values for reagent urine strips.

Analyte	YD URISCAN (Visual & Analyzer)		Analyte	Siemens (Visual & Analyzer)		Analyte	Roche (Visual & Analyzer)	
	Analyte Range			Analyte Range			Analyte Range	
	Level 1	Level 2		Level 1	Level 2		Level 1	Level 2
Blood	Negative	50 - 250 RBC/ $\mu$ l (2+ - 3+)	Glucose	Negative	100 - $\geq$ 1000 mg/dL ( $\pm$ - 3+)	Specific Gravity	1.005 - 1.025	1.005 - 1.025
Bilirubin	Negative	1.0 - 3.0 mg/dL (2+ - 3+)	Bilirubin	Negative	Small - Large (1+ - 3+)	Refractometer	1.000 - 1.010	1.010 - 1.025
Urobilinogen	0.1 - 1.0 mg/dL Normal ( $\pm$ )	4 - 12 mg/dL (2+ - 4+)	Ketones	Negative	15 - $\geq$ 160 mg/dL (1+ - 4+)	pH	5.0 - 7.0	5.0 - 8.0
Ketones	Negative	10 - 100 mg/dL (1+ - 3+)	Specific Gravity	1.000 - 1.020	1.010 - $\geq$ 1.030	Leukocyte	Negative	25 - 500 WBC/ $\mu$ l (1+ - 3+)
Protein	Negative	100 - 1,000 mg/dL (2+ - 4+)	Refractometer	1.000 - 1.010	1.010 - 1.025	Nitrite	Negative	Positive
Nitrite	Negative	Positive	Blood	Negative	Small - Large (1+ - 3+)	Protein	Negative	25 - 500mg/dL (1+ - 4+)
Glucose	Negative	100 - 2,000 mg/dL ( $\pm$ - 4+)	pH	5.0 - 7.0	5.0 - 7.0	Glucose	Negative	50 - 1000mg/dL (1+ - 4+)
pH	5.0 - 7.0	5.0 - 7.0	Protein	Negative	30 - $\geq$ 300 mg/dL (1+ - 3+)	Ketones	Negative	5 - 150mg/dL (1+ - 4+)
S.G	$\leq$ 1.005 - 1.025	1.010 - $\geq$ 1.030	Urobilinogen	0.2 - 1.0 EU/dL	2.0 - $\geq$ 8.0 EU/dL	Urobilinogen	Normal	1 - 12mg/dL (1+ - 4+)
Refractometer	1.000 - 1.010	1.010 - 1.025	Nitrite	Negative	Positive	Bilirubin	Negative	1.0 - 6.0mg/dL (1+ - 3+)
Leucocytes	Negative	25 - 500 WBC/ $\mu$ l (1+ - 3+)	Leucocytes	Negative	Small - Large (1+ - 3+)	Blood	Negative	25 - 250 RBC/ $\mu$ l (2+ - 4+)
Ascorbic Acid	10 - 50mg/dL (1+ - 3+)	Negative						
Micro Albumin	Neg - 30 mg/L (Negative - 1+)	80 - 150 mg/L (2+ - 3+)						
Creatinine	10 - 100 mg/dL ( $\pm$ - 2+)	50 - 300 mg/dL (1+ - 4+)						

<b>IVD</b> For in vitro diagnostic use	<b>REF</b> Catalog Number	<b>LOT</b> Lot Number	Use by / Expiry data	Attention, See instructions for use
<b>CE</b> European Conformity	Store at	<b>EC REP</b> Authorized Representative	Manufacturer	

**YD Diagnostics**

**Manufacturer**  
 YD Diagnostics CORP.  
 76, Seori-ro, Idong-eup, Cheoin-gu, Yongin-si,  
 Gyeonggi-do, 17127, Republic of Korea  
 Tel. 82-31-329-2000 / Fax. 82-31-329-2002

**CE**

**EC REP**  
**CARE diagnostica Laborreagenzien GmbH**  
 Weseler Str. 110, 46562 Voerde, Germany  
 TEL : 49-281-94-40-40 / FAX : 49-281-944-04-10