Urinalysis Control

PLEASE READ THIS OPERATING INSTRUCTION CAREFULLY BEFORE USE.

Only Use For In Vitro Diagnostic. Only use for professional.

INTENDED USE

Urinalysis Control is intended for urine analyzer and matched urine reagent strips in order to monitor the quality of urinalysis test.

SUMMARY

Urinalysis Control is a ready-to-use liquid preparation that works with urine analyzer and matched urine reagent strips. Urinalysis Control NO.I is Negative control, NO.II is Positive control, NO.III is Positive control for Ascorbic Acid only. Urinalysis Control contains four types. Quality control projects of each type are described in the table 1.

Table 1 Type and Quality control project

Type	Quality control projects
UQ-10	pH, Nitrite, Glucose, Specific Gravity, Blood, Protein, Bilirubin, Urobilinogen, Ketone, Leukocytes(WBC)
UQ-11	pH, Nitrite, Glucose, Specific Gravity, Blood, Protein, Bilirubin, Urobilinogen, Ketone, Leukocytes(WBC), Ascorbic Acid
UQ-13	pH, Nitrite, Glucose, Specific Gravity, Blood, Protein, Bilirubin, Urobilinogen, Ketone, Leukocytes(WBC), Creatinine, Calcium, Micro Albumin
UQ-14	pH, Nitrite, Glucose, Specific Gravity, Blood, Protein, Bilirubin, Urobilinogen, Ketone, Leukocytes(WBC), Ascorbic Acid, Creatinine, Calcium, Micro Albumin

REAGENT

Urinalysis Control is prepared in aqueous base by adding chemicals, constituents of animal origin, preservatives and stabilizers. This product does not contain the substances extracted from urine.

PROCEDURE

This product should be treated the same as patient specimen and run according to the instructions of the instrument, kit, or reagent.

1. Before testing, make operating temperature to reach 18°C to 30°C.
2. Unscrew the cap and draw the liquid in the bottle across all reaction areas of the urine reagent strip, thoroughly saturating each pad. Or you can also pour out the liquid into the test tube and dip the urine reagent strip into it. When using with the test tube, it could supply 6 times tests per tube at most. Don' t mix the used with the unused.

LIMITATIONS

1. This product is not intended for use as a standard.
2. If there is evidence of microbial contamination or excessive turbidity in the product discard the vial.
3. This product should not be used past the expiration date.

CAUTIONS

1. Please replace cap tightly and store it at 2°C to 8°C after each use.
2. If the product is opened too long or the environmental temperature is not at 18°C to 30°C, the testing result maybe low or high.
3. This product should be treated the same as patient specimens. After use, dispose as the medical waste. If the liquid touches the eyes and skin, clean it immediately.

STORAGE AND STABILITY

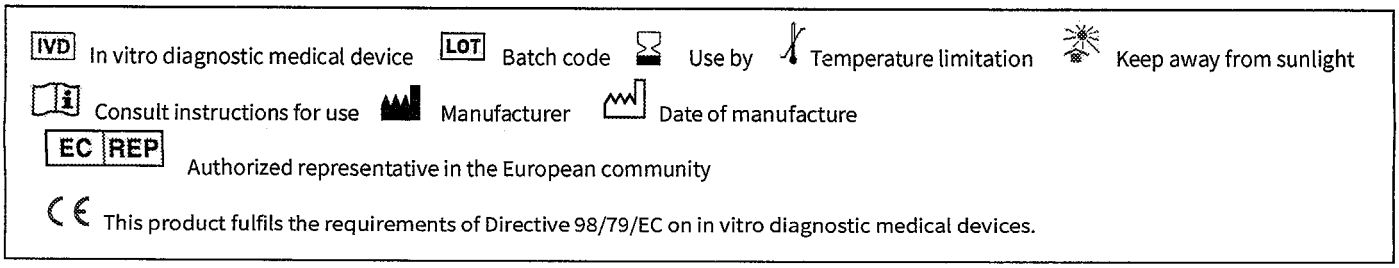
This product will be stable for one year until the expiration date when stored unopened at 2°C to 8°C and out of light. Once the control is opened and stored tightly capped, all analytes will be stable for 15 days at 2°C to 8°C. This product should never be frozen.

ASSIGNMENT OF VALUES

Enclosed quality control results is only the reference of this certain batch. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacture test method modifications. Each laboratory should use the results provided only as a reference and establish its own parameters of precision.

AVAILABILITY **NO.I : 8mL, NO.II : 8mL, NO.III : 8mL.**

EXPLANATIONS FOR SYMBOLS ON THE LABEL



REFERENCES

[1] Cong Yulong, Ma Junlong, Zhang Shimin. Practical Urine Analysis Technology and Clinical. People's Medical Publishing House, September 2013, 1st edition.

[2] Shang Hong, Wang Yisan, Shen Ziyu. National Clinical Laboratory Procedures. People's Medical Publishing House, March 2015, 4th edition.

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ASSIGNMENT OF VALUES

The results printed in this accessory sheet are specific for this lot of product. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents or by manufacture test method modifications. Each laboratory should use the results provided only as a reference and establish its own parameters of precision.

Urine Analyzers		URIT-500B	URIT-30/31/50/180/330/500C/560/1530	URIT-330/560/1530	URIT-1500/1550/1560/1600/1610 UC-1800/1810 US-1680/1681 URIT-1600PLUS	SIEMENS	ARKRAY	Roche
Reagent Strips		URIT 10G/11G/13G/14G	URIT 10G/11G/13G/14G	URIT 11F/12F/14F	URIT 11F/12F/14F/11FA/12FA/14FA	Multistix 10SG	Aution Sticks 10EA	Combur Te
NO. I	pH	4.5~6.0	4.5~6.0	5.0~6.0	5.0~6.0	5.0~6.0	5.0~6.0	5.0~6.5
	Nitrite	-	-	-	-	Negative	neg.	neg.
	Glucose	-	-	-	-	Negative	norm.	norm.
	Specific Gravity	1.005~1.010	1.005~1.010	1.005~1.010	1.005~1.010	⩽1.005~1.015	⩽1.000~1.010	⩽1.005~1.0
	Blood	-	-	-	-	Negative	neg.	neg.
	Protein	-	-	-	-	Negative	neg.	neg.
	Bilirubin	-	-	-	-	Negative	neg.	neg.
	Urobilinogen	Normal	Normal	Normal	Normal	3.2μmol/L	norm.	norm.
	Ketone	-	-	-	-	Negative	neg.	neg.
	Leukocytes(WBC)	-	-	-	-	Negative	neg.	neg.
	Creatinine	⩽0.9mmol/L	⩽0.9~4.4mmol/L	⩽0.9~4.4mmol/L	⩽0.9mmol/L			
	Calcium	⩽1.0~2.5mmol/L	⩽1.0~2.5mmol/L	⩽1.0~2.5mmol/L	⩽1.0~2.5mmol/L			
	Micro Albumin	13G:0mg/L;14G: ⩽ 10mg/L	13G:0mg/L;14G: ⩽10mg/L	⩽10mg/L	⩽10mg/L			
	Ascorbic Acid	-	-	-	-			
NO.II	pH	6.0~7.0	6.0~7.0	6.0~7.5	6.0~7.5	6.0~7.5	6.0~7.5	6.0~7.5
	Nitrite	+	+	+	+	Postive	+1~+2	pos.
	Glucose	+2~+4	+2~+4	+2~+4	+2~+4	+1~+3	+1~+4	+1~+4
	Specific Gravity	1.015~1.025	1.015~1.025	1.015~1.025	1.015~1.025	1.010~1.025	1.000~1.020	1.010~1.02
	Blood	+2~+3	+1~+3	+1~+3	+2~+3	+1~+3	+1~+3	+2~+5
	Protein	+1~+3	+1~+3	+1~+3	+1~+3	+2~+3	+2~+4	+2~+4
	Bilirubin	+2~+3	+2~+3	+2~+3	+2~+3	+2~+3	+2~+4	+1~+3
	Urobilinogen	+1~+3	+1~+3	+1~+3	+1~+3	16~66μmol/L	+1~+4	+2~+4
	Ketone	+1~+3	±~+2	±~+2	±~+2	±~+2	+1~+4	+2~+4
	Leukocytes(WBC)	+1~+3	+1~+3	+1~+3	+1~+3	±~+2	75~500(Leu/μL)	+1~+3
	Creatinine	8.8~⩾26.4mmol/L	8.8~⩾26.4mmol/L	17.6~⩾26.4mmol/L	17.6~⩾26.4mmol/L			
	Calcium	2.5~7.5mmol/L	2.5~7.5mmol/L	2.5~7.5mmol/L	2.5~7.5mmol/L			
	Micro Albumin	13G: ⩾100mg/L 14G: ⩾150mg/L	13G: ⩾100mg/L 14G: ⩾150mg/L	⩾150mg/L	⩾150mg/L			
NO.III	Ascorbic Acid	+1~+3	+1~+3	+1~+3	+1~+3			

Note 1: The contents of this page are not part of the manual, these are the calibration of the instrument at about 25 ℃ test results, for reference only. Quality control projects will result different results due to different reaction principles. Note 2: When the test temperature is low, some items such as WBC \ GLU will be low.