



Urinalysis Control (Negative)

【Name】 Urinalysis Control

【Volume】 8ml/bottle, 4ml/bottle

【Intended Use】

Urinalysis control(referred to as Control) is used for quality control of urinalysis strips and analyzers. It can conduct quality control for 13 items of strips, such as Glucose, Bilirubin,Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leucocytes, Microalbumin, Creatinine and Ca.

【Test Principle】

Chemistry reagent contained in the Control reacts with the ingredients within the urinalysis strips, thus, strips color changed.

【Main Composition】

Positive: phosphate buffer 0.2%w/w, glucose 1.0%w/w, sodium chloride 0.5%w/w, hemoglobin 0.1%w/w, albumin 0.7%w/w, ethyl acetoacetate 0.9%w/w, sodium nitrite 0.3%w/w, esterase 0.5%w/w, urea 2%w/w, creatinine 0.2%w/w, Ca 0.1%w/w, bilirubin substitute 0.1%w/w, urobilinogen substitute 0.1%w/w, other non-reactive substances and stabilizers 93.3%w/w.

Negative: urea 2%w/w, sodium chloride 0.5%w/w, phosphate buffer 0.2%w/w, other non-reactive substances and stabilizers 97.3%w/w.

【Storage Conditions & Shelf Life】

Stored at 2°C~8°C, sealed and protected from sunlight. Refer to the label for the shelf life. Its shelf life is 1 month when stored at 2°C~8°C, sealed and protected from sunlight after the first use.

【Applied Analyzer】 Urine Analyzer, Urinalysis Hybrid and Urinalysis System.

【Test Method】

1. Place the Control at room temperature(18°C-25°C) for certain time until it returns to normal temperature. And mix the Control evenly through bottom up and down slightly.

2.Using method on semi-automatic urine analyzer: Adjust the analyzer to QC status;

drip the Control on the strip, the strip side with Control should be placed upward; remove the extra Control with absorbent paper, the absorbent paper can not touch the strip pads(avoid cross-contamination); place the strip on the waiting place of analyzer.

3.Using method on automatic urine analyzer: Adjust the analyzer to QC status; pour the Control into a clean tube; place the tube into corresponding position of the analyzer.

【Result Explanation】

All QC results within the target range indicates qualified, otherwise, the result is unqualified.

【Limits】

Bilirubin and Urobilinogen used for the Control are replaced by chemical substances. Therefore, there is a trace difference in color between the result of Control and the result of urine.

【Matters Needing Attention】

1. The Control follows outside of the control bottle can not be collected back to avoid cross-contamination.

2. Control-skin contact should be avoided. Rinse the contact part with plenty of water if accidental skin contact occurs.

3.Tighten the cap immediately after use, and store it at 2°C- 8°C.

【Reference】

Refer to the supplied control target list.

The supplied reference is obtained through repeat tests. For the same lab, the results might be different when testing on different dates. The difference might be caused by environment, instrument, reagent or test method difference. Even so, the test results should be within the supplied reference range.

【Documents】 ZL01 1 28009.3 Urinalysis Control and Preparation

【Instruction Approved and Modified Date】 04/2023

【Symbols】



Store at



Please read package insert



Expiry Date



Batch code



In Vitro Diagnostic Use



Manufactured by



Authorised Representative



European In Vitro Diagnostic Medical Device Directive 98/79/EC(IVDD)



Catalogue number



Urinalysis Control (Negative)

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Negative: urea 2%w/w, sodium chloride 0.5%w/w, phosphate buffer 0.2%w/w, other non-reactive substances and stabilizers 97.3%w/w.

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【Applied Analyzer】 Urine Analyzer, Urinalysis Hybrid and Urinalysis System.

【Test Method】

1. Place the Control at room temperature(18°C-25°C) for certain time until it returns to normal temperature. And mix the Control evenly through bottom up and down slightly.

2.Using method on semi-automatic urine analyzer: Adjust the analyzer to QC status;

drip the Control on the strip, the strip side with Control should be placed upward; remove the extra Control with absorbent paper, the absorbent paper can not touch the strip pads(avoid cross-contamination); place the strip on the waiting place of analyzer.

3.Using method on automatic urine analyzer: Adjust the analyzer to QC status; pour the Control into a clean tube; place the tube into corresponding position of the analyzer.

【Result Explanation】

All QC results within the target range indicates qualified, otherwise, the result is unqualified.

【Limits】

Bilirubin and Urobilinogen used for the Control are replaced by chemical substances. Therefore, there is a trace difference in color between the result of Control and the result of urine.

【Matters Needing Attention】

1. The Control follows outside of the control bottle can not be collected back to avoid cross-contamination.

2. Control-skin contact should be avoided. Rinse the contact part with plenty of water if accidental skin contact occurs.

3.Tighten the cap immediately after use, and store it at 2°C- 8°C.

【Reference】

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【Documents】 ZL01 1 28009.3 Urinalysis Control and Preparation

【Instruction Approved and Modified Date】 04/2023

【Symbols】



Store at



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Expiry Date



Batch code



In Vitro Diagnostic Use



Manufactured by



Authorised Representative



European In Vitro Diagnostic Medical Device Directive 98/79/EC(IVDD)



Catalogue number

Strips	Dirui	Roche	Dirui	ARKRAY	Dirui	Dirui	Dirui	Dirui	Dirui	SIEMENS	Dirui
Item	E10	Combur10	M10	10EA	H-800	H Series	FUS-2000	FUS-1000 FUS-1000Plus FUS-3000Plus	H-1600 MUS-3600 MUS-9600	10SG	A10
Glucose	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Bilirubin	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Ketone	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Blood	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Protein	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Urobilinogen	Normal	Normal	Normal	Normal	Normal 3.4~17μmol/L	Normal 3.4~17μmol/L	Normal 3.4~17μmol/L	Normal 3.4~17μmol/L	Normal 3.4~17μmol/L	3.2~16μmol/L	3.2~16μmol/L
Leukocytes	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Specific Gravity	1.010~1.020	1.000~1.015	1.005~1.020	1.005~1.020	1.015~1.025	1.015~1.025	1.015~1.025	1.010~1.025	1.010~1.025	1.015~1.025	1.015~1.025
pH	6.0~7.0	6.0~7.0	6.0~7.0	6.0~7.0	5.5~7.5	5.5~7.5	5.5~7.5	5.5~7.5	5.5~7.5	6.0~7.5	6.0~7.0
Microalbumin ^{*1}	/	/	/	/	Negative	Negative	Negative	Negative	Negative	/	/
Microalbumin ^{*2}	/	/	/	/	10~30	10~30	10~30	10~30	10~30	/	/
Creatinine	/	/	/	/	0.9~4.4mmol/L 10~50mg/dL	0.9~4.4mmol/L 10~50mg/dL	0.9~4.4mmol/L 10~50mg/dL	0.9~4.4mmol/L 10~50mg/dL	0.9~4.4mmol/L 10~50mg/dL	/	/
Ca	/	/	/	/	1.0~2.5mmol/L 4~10mg/dL	1.0~2.5mmol/L 4~10mg/dL	1.0~2.5mmol/L 4~10mg/dL	1.0~2.5mmol/L 4~10mg/dL	1.0~2.5mmol/L 4~10mg/dL	/	/
Nitrite	Negative										

Note: Microalbumin^{*1} is the microalbumin item of H11-MA, H11-MA(N), H12-MA, H11-800MA, H12-800MA, FUS-11MA, FUS-12MA, FUS-11MA II, FUS-12MA II reagent strips.

Microalbumin^{*2} is the microalbumin item of H2-Cr, H12-Cr, H13-Cr, H13-Ca, H14-Ca, H13-800Cr, H14-800Ca, FUS-13Cr, FUS-14Ca, FUS-13Cr II, FUS-14Ca II reagent strips.

Creatinine mmol/L= mg/dL/11.3

Ca mmol/L= mg/dL/4



DIRUI INDUSTRIAL CO., LTD.
95 Yunhe Street, New & High Tech.
Development Zone
Changchun, Jilin 130012 P.R.China

Tel: +86 (431) 85100409
Fax: +86 (431) 85172581
E-mail: dirui@dirui.com.cn
Http://www.dirui.com.cn



Emergo Europe B.V. Westervoortsedijk 60
6827 AT Arnhem The Netherlands

04/2023

Strips	Dirui	Roche	Dirui	ARKRAY	Dirui	Dirui	Dirui	Dirui	Dirui	SIEMENS	Dirui
Item	E10	Combur10	M10	10EA	H-800	H Series	FUS-2000	FUS-1000 FUS-1000Plus FUS-3000Plus	H-1600 MUS-3600 MUS-9600	10SG	A10
Glucose	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Bilirubin	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Ketone	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Blood	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Protein	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Urobilinogen	Normal	Normal	Normal	Normal	Normal 3.4~17μmol/L	Normal 3.4~17μmol/L	Normal 3.4~17μmol/L	Normal 3.4~17μmol/L	Normal 3.4~17μmol/L	3.2~16μmol/L	3.2~16μmol/L
Leukocytes	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
Specific Gravity	1.010~1.020	1.000~1.015	1.005~1.020	1.005~1.020	1.015~1.025	1.015~1.025	1.015~1.025	1.010~1.025	1.010~1.025	1.015~1.025	1.015~1.025
pH	6.0~7.0	6.0~7.0	6.0~7.0	6.0~7.0	5.5~7.5	5.5~7.5	5.5~7.5	5.5~7.5	5.5~7.5	6.0~7.5	6.0~7.0
Microalbumin ^{*1}	/	/	/	/	Negative	Negative	Negative	Negative	Negative	/	/
Microalbumin ^{*2}	/	/	/	/	10~30	10~30	10~30	10~30	10~30	/	/
Creatinine	/	/	/	/	0.9~4.4mmol/L 10~50mg/dL	0.9~4.4mmol/L 10~50mg/dL	0.9~4.4mmol/L 10~50mg/dL	0.9~4.4mmol/L 10~50mg/dL	0.9~4.4mmol/L 10~50mg/dL	/	/
Ca	/	/	/	/	1.0~2.5mmol/L 4~10mg/dL	1.0~2.5mmol/L 4~10mg/dL	1.0~2.5mmol/L 4~10mg/dL	1.0~2.5mmol/L 4~10mg/dL	1.0~2.5mmol/L 4~10mg/dL	/	/
Nitrite	Negative										

Note: Microalbumin^{*1} is the microalbumin item of H11-MA, H11-MA(N), H12-MA, H11-800MA, H12-800MA, FUS-11MA, FUS-12MA, FUS-11MA II, FUS-12MA II reagent strips.

Microalbumin^{*2} is the microalbumin item of H2-Cr, H12-Cr, H13-Cr, H13-Ca, H14-Ca, H13-800Cr, H14-800Ca, FUS-13Cr, FUS-14Ca, FUS-13Cr II, FUS-14Ca II reagent strips.

Creatinine mmol/L= mg/dL/11.3

Ca mmol/L= mg/dL/4



DIRUI INDUSTRIAL CO., LTD.
95 Yunhe Street, New & High Tech.
Development Zone
Changchun, Jilin 130012 P.R.China

Tel: +86 (431) 85100409
Fax: +86 (431) 85172581
E-mail: dirui@dirui.com.cn
Http://www.dirui.com.cn



Emergo Europe B.V. Westervoortsedijk 60
6827 AT Arnhem The Netherlands

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