PDM签审页

PDM版本：

PDM编码：

产品名称	出口_尿液干化学分析质控物(阳性)_说明书_英文		
库存编码	1017235	版本号	20230424
成品尺寸	180×130mm	单位	mm
印刷色	单色	允差	±2mm
材质	胶版纸，双面印刷		
备注			
设计			
审核			
批准			

DIRUI®

Urinalysis Control (Positive)

【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, urobilinagen 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℃~8℃, sealed and protected from sunlight. Refer to the label for the shelf life. Its shelf life is 1 month when stored at 2℃~8℃, 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℃-25℃) 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℃- 8℃.
【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 LOT Batch code IVD In Vitro Diagnostic Use  Manufactured by

EC REP Authorised Representative CE European In Vitro Diagnostic Medical Device Directive 98/79/EC(IVDD) REF Catalogue number

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DIRUI® Urinalysis Control Reference

Attachment

Strips / Item	Dirui E10	Roche Combur10	Dirui M10	ARKRAY 10EA	Dirui H-800	Dirui H Series	Dirui FUS-2000	Dirui FUS-1000 FUS-1000Plus FUS-3000Plus	Dirui H-1600 MUS-3600 MUS-9600	SIEMENS 10SG	Dirui A10
Glucose	3+~4+	3+~4+	1+~4+	2+~4+	2+~4+	2+~4+	2+~4+	1+~3+	1+~3+	1+~3+	1+~3+
Bilirubin	1+~3+	1+~3+	2+~4+	2+~4+	1+~3+	1+~3+	1+~3+	1+~3+	1+~3+	2+~3+	2+~3+
Ketone	2+~4+	2+~4+	2+~4+	2+~4+	1+~3+	1+~3+	1+~3+	1+~4+	1+~4+	1+~4+	1+~4+
Blood	3+~5+	3+~5+	1+~3+	1+~3+	1+~3+	1+~3+	1+~3+	1+~3+	1+~3+	1+~3+	1+~3+
Protein	2+~4+	2+~4+	2+~4+	2+~4+	1+~3+	1+~3+	1+~3+	1+~4+	1+~4+	1+~3+	1+~3+
Urobilinogen	2+~4+	2+~4+	1+~4+	1+~4+	1+~3+	1+~3+	1+~3+	1+~3+	1+~3+	1+~3+	1+~3+
Leukocytes	1+~3+	1+~3+	1+~4+	1+~4+	1+~3+	1+~3+	1+~3+	1+~3+	1+~3+	±~2+	±~3+
Specific Gravity	1.010~1.025	1.010~1.025	1.010~1.025	1.010~1.025	1.015~1.030	1.015~1.030	1.015~1.030	1.015~1.030	1.015~1.030	1.015~1.030	1.015~1.030
pH	5.5~7.5	5.5~7.5	5.5~7.5	5.5~7.5	6.0~8.0	5.5~7.5	6.0~8.0	5.5~7.5	5.5~7.5	6.0~8.0	6.0~8.0
Microalbumin*1	/	/	/	/	>0.15	>0.15	>0.15	>0.15	≥0.15	/	/
Microalbumin*2	/	/	/	/	80~150	80~150	80~150	80~150	80~150	/	/
Creatinine	/	/	/	/	8.8~26.5mmol/L 100~300mg/dL	8.8~26.5mmol/L 100~300mg/dL	8.8~26.5mmol/L 100~300mg/dL	8.8~26.5mmol/L 100~300mg/dL	8.8~26.5mmol/L 100~300mg/dL	/	/
Ca	/	/	/	/	5.0~10mmol/L 20~40mg/dL	5.0~10mmol/L 20~40mg/dL	5.0~10mmol/L 20~40mg/dL	5.0~10mmol/L 20~40mg/dL	5.0~10mmol/L 20~40mg/dL	/	/
Nitrite	Positive							1+~2+	1+~2+	Positive	

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

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04/2023

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Glucose	3+~4+	3+~4+	1+~4+	2+~4+	2+~4+	2+~4+	2+~4+	1+~3+	1+~3+	1+~3+	1+~3+
Bilirubin	1+~3+	1+~3+	2+~4+	2+~4+	1+~3+	1+~3+	1+~3+	1+~3+	1+~3+	2+~3+	2+~3+
Ketone	2+~4+	2+~4+	2+~4+	2+~4+	1+~3+	1+~3+	1+~3+	1+~4+	1+~4+	1+~4+	1+~4+
Blood	3+~5+	3+~5+	1+~3+	1+~3+	1+~3+	1+~3+	1+~3+	1+~3+	1+~3+	1+~3+	1+~3+
Protein	2+~4+	2+~4+	2+~4+	2+~4+	1+~3+	1+~3+	1+~3+	1+~4+	1+~4+	1+~3+	1+~3+
Urobilinogen	2+~4+	2+~4+	1+~4+	1+~4+	1+~3+	1+~3+	1+~3+	1+~3+	1+~3+	1+~3+	1+~3+
Leukocytes	1+~3+	1+~3+	1+~4+	1+~4+	1+~3+	1+~3+	1+~3+	1+~3+	1+~3+	±~2+	±~3+
Specific Gravity	1.010~1.025	1.010~1.025	1.010~1.025	1.010~1.025	1.015~1.030	1.015~1.030	1.015~1.030	1.015~1.030	1.015~1.030	1.015~1.030	1.015~1.030
pH	5.5~7.5	5.5~7.5	5.5~7.5	5.5~7.5	6.0~8.0	5.5~7.5	6.0~8.0	5.5~7.5	5.5~7.5	6.0~8.0	6.0~8.0
Microalbumin*1	/	/	/	/	>0.15	>0.15	>0.15	>0.15	≥0.15	/	/
Microalbumin*2	/	/	/	/	80~150	80~150	80~150	80~150	80~150	/	/
Creatinine	/	/	/	/	8.8~26.5mmol/L 100~300mg/dL	8.8~26.5mmol/L 100~300mg/dL	8.8~26.5mmol/L 100~300mg/dL	8.8~26.5mmol/L 100~300mg/dL	8.8~26.5mmol/L 100~300mg/dL	/	/
Ca	/	/	/	/	5.0~10mmol/L 20~40mg/dL	5.0~10mmol/L 20~40mg/dL	5.0~10mmol/L 20~40mg/dL	5.0~10mmol/L 20~40mg/dL	5.0~10mmol/L 20~40mg/dL	/	/
Nitrite	Positive							1+~2+	1+~2+	Positive	

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
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