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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# Urinalysis Control Reference

Attachment

| Item \ Strips | Dirui | Roche | Dirui | ARKRAY | Dirui | Dirui | Dirui | Dirui | Dirui | SIEMENS | Dirui |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | E10 | Combur10 | M10 | 10EA | H-800 | H Series | FUS-2000 | FUS-1000<br>FUS-1000Plus<br>FUS-3000Plus | H-1600<br>MUS-3600<br>MUS-9600 | 10SG | 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<br>100~300mg/dL | 8.8~26.5mmol/L<br>100~300mg/dL | 8.8~26.5mmol/L<br>100~300mg/dL | 8.8~26.5mmol/L<br>100~300mg/dL | 8.8~26.5mmol/L<br>100~300mg/dL | / | / |
| Ca | / | / | / | / | 5.0~10mmol/L<br>20~40mg/dL | 5.0~10mmol/L<br>20~40mg/dL | 5.0~10mmol/L<br>20~40mg/dL | 5.0~10mmol/L<br>20~40mg/dL | 5.0~10mmol/L<br>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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