Urine Sediment Control

Product

Urine Sediment Control

Package Specifications

Table 1 Package Specifications

Concentration	Specification	REF
Level Ⅰ	10mL×6	105-043950-00
Level Ⅱ	10mL×6	105-043949-00
Level Ⅲ	10mL×6	105-043948-00
Level Ⅳ	10mL×6	105-043951-00

Intended Use

Urine Sediment Control is used for quality control of the applicable instruments to monitor and assess the precision of the measurement results.

Test Principle

The Urine Sediment Control contains particles that simulate RBCs and WBCs in human urine, thus it can be used to monitor and evaluate the precision of applicable analyzers for urine sediment analysis.

Major Components

Urine Sediment Control should be a colorless fluid with cell precipitates. This product is a suspension of simulated white blood cells (fixed animal white blood cells) and stabilized human RBCs in a medium containing buffer reagent (sodium citrate dihydrate, ≤1%), preservatives (sodium azide, ≤0.01%) and N, N-dimethylacetamide (≤2.5%).

* The target value and content concentration slightly vary from lot to lot.
* For the reference values, refer to the Target Sheets.

Storage and Stability

Stability	
Unopened	The product can be used up to the expiry date indicated on the label if stored unopened at 2-8℃
After opened	30 days (when the product is put back to refrigerator of 2-8℃ immediately after use)

* Do not freeze!
* For production date and expiry date, see the package or the label.

Applicable Instruments

For appliable instruments, see Target Sheet.

Sample Requirements

Not applicable.

Sample Collection and Preparation

Not applicable.

Test Procedure

1. Take the control out of the refrigerator. Restore the control to room temperature by leaving it still at room temperature of 15-30℃ for 15-20 minutes.
2. For the first-time mixing, roll the vial between the palms for about 20-30 seconds uprightly with cap upward, and during the process gently invert the vial for several times to mix it well. During use, invert the vial for 8-10 times before each test. When the product has been kept unused for a long time, re-mix the control before testing it.
3. Ensure the product is well-mixed. If the product is not properly mixed (for example, there is sediment at the vial bottom), repeat step 2. It is a normal phenomenon that a small amount of floccule appears after mixing.
4. Refer to the requirements of QC section in the Operator's Manual of the applicable instruments for QC test.
5. After use, cap the vial immediately and put it back to refrigerator. The control should be put back in the refrigerator within 40 minutes after it is taken out.

Reference Intervals

Not applicable.

Result Elaboration

- The reference values are determined on a well-maintained and properly-calibrated analyzer, using matched reagent specified by manufacturer. The reagent differences, analyzer status, operation techniques and calibration status may cause test results to vary. To ensure product performance, use the matched reagents specified by manufacturer only.
- For higher control sensitivity, each laboratory should establish its own mean and acceptable range and periodically re-evaluate the mean. The laboratory range may include the values outside of the reference range.
- You may establish assay values not listed on the Target Sheet, if the control is suitable for the method.
- Reference values of a new lot of control should be confirmed before the new lot is put into routine use. Test the new lot when the analyzer is in good working order and QC results on the old lot are acceptable. The laboratory's mean of repeated tests should be within the reference range.

Limitations

Not applicable.

Material Required but Not Provided

The following materials are required but not provided with the product: Mindray-manufactured urinalysis analyzers and general laboratory devices.

Reagent Preparation

The product is a ready-to-use control.

Product Performance

- Appearance: colorless to light yellow.
- Between-vial homogeneity(Level Ⅰ): the detection rate shall be more than or equal to 90% and the tested values of RBCs and WBCs should be ≤ 25 cells/ μL.
- Within-vial homogeneity shall meet the requirements of the following table:

CE 0123

Table 2 Within-vial Homogeneity Requirements of Controls

Concentration level	Requirements for CVs of RBC and WBC
Level Ⅱ	≤25%
Level Ⅲ	≤15%
Level Ⅳ	≤15%

- The statistical result of between-vial homogeneity $F_{(test\ value)}$ should be less than or equal to $F_{(0.05, v1, v2)}$, and the CVs of WBC and RBC shall meet the requirements in the following table:

Table 3 Between-vial Homogeneity Requirements of Controls

Concentration levels	Requirements for CVs of RBC and WBC
Level Ⅱ	≤25%
Level Ⅲ	≤15%
Level Ⅳ	≤15%

- The allowed deviation of control tests should meet the requirements in the table 4.

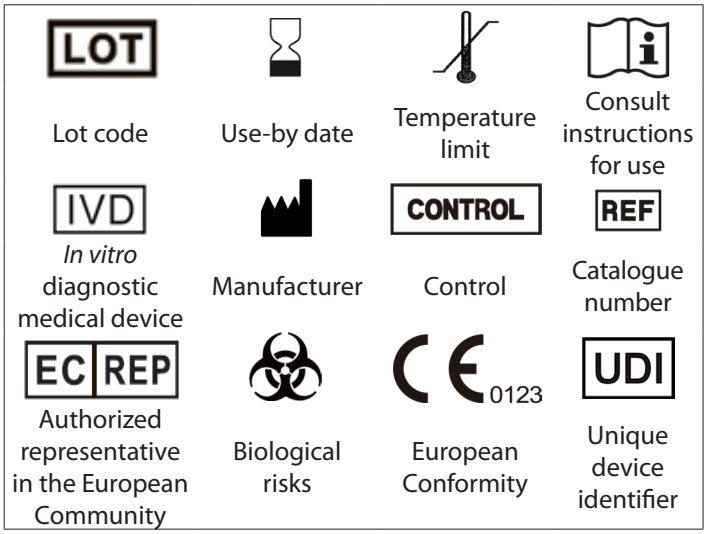
Table 4 Allowed Deviation of Controls

Parameter	WBC	RBC
Unit	cells/μL	cells/μL
Level Ⅱ	±25	±20
Level Ⅲ	±70	±60
Level Ⅳ	±200	±200

Precautions and Warnings

- For ***in-vitro diagnostic use*** only. The control must be handled by laboratory professionals and skilled/ trained medical professionals only.
- Read the package inserts carefully before using this product. The product shall be used before the expiry date and do not use expired products. Confirm that the lot No. on the vial label of the product matches that on the Target Sheet, except for Level Ⅰ.
- Confirm the integrity of the package before use. Do not use the product if the package is damaged. Otherwise, the test results may not be accurate.
- Before use, confirm the control is well-mixed based on requirements of the instruction for use. Improper mixing may cause the used and remaining product invalid.
- If the control test results are not in the allowed deviation range, calibrate the analyzer with a matched calibrator and then perform the control test again.
- The product contains potential biohazardous substances and human and zoonotic origin substances. This product has been tested for antibody to human immunodeficiency virus(HIV), hepatitis B surface antigen (HBsAg), antibody to hepatitis C virus (HCV) and antibody to Treponema pallidum (TP) with a method approved by the national management authority. The results are all negative. However, as no testing method can rule out the potential risk of infection with absolute certainty, this material should be handled as a patient sample to avoid biological risk.
- Wear proper personal protective equipment (e.g. gloves, lab coat, etc.) and follow safe laboratory procedures when handling this product in the laboratory.
- Dispose of any discarded material in accordance with the requirements of your local government regulations.
- All identified risks have been reduced as far as possible by generally acknowledged state of art, and the overall residual risk is acceptable.
- Do not take the product into mouth, If you accidentally take it into your mouth, seek medical treatment immediately.
- Avoid exposure to skin. If you accidentally spill the product on your skin, wash it off with plenty of water immediately.
- Avoid exposure to eyes. If you accidentally spill the product into your eyes, wash it off with plenty of water immediately, and seek medical treatment if necessary.
- The Material Safety Data Sheet (MSDS) is available upon request.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Symbols



References

Not applicable.

Company Contact

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