Urine Sediment Calibrator

Product

Urine Sediment Calibrator

Package Specifications

Table 1 Package Specifications

Name	Specifications	REF
Urine Sediment Calibrator	10mL×6	105-043513-00

Intended Use

Urine Sediment Calibrator is used for calibrating the applicable instruments to ensure the accuracy of measurement.

Test Principle

The Urine Sediment Calibrator contains particles that simulate RBCs and WBCs in human urine, thus can be used to establish the metrological traceability of the measurement results for applicable instruments.

Major Components

Urine Sediment Calibrator 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.
* This product is traceable to China national standard reference material: *Reference Material for Red Blood Cell and White Blood Cell of Urine Sediment NIM-RM 2028*

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 applicable instruments, see Target Sheet.

Sample Requirements

Not applicable.

Sample Collection and Preparation

Not applicable.

Test Procedure

1. Take the calibrator out of the refrigerator. Restore the calibrator to room temperature by leaving it still at room temperature (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 calibrator 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 calibration section in the Operator's Manual of the applicable instruments for calibration test.
5. After the first calibration, confirm the process by repeating another 5 tests with the calibrator. After calibration completes, the mean values in count screen should be within allowed deviation.
6. After use, wipe the threads on the mouth of the vial and that inside the cap with soft tissue to clean the residues. Then cap the vial immediately and put it back to the refrigerator. The calibrator 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 the matched reagents specified by manufacturer. To ensure product performance, use the matched reagents specified by manufacturer only.

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 calibrator.

Product Performance

- Appearance: colorless to light yellow.
- Within-vial homogeneity shall meet the requirements of the following table:

Table 2 Within-vial Homogeneity Requirements of Calibrator

Parameter	Requirements (CVs)
WBC	≤15%
RBC	≤15%

- The statistical result $F_{\text{calibrated value}}$ of between-vial homogeneity 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 Calibrator

Parameter	Requirements (CVs)
WBC	≤15%
RBC	≤15%

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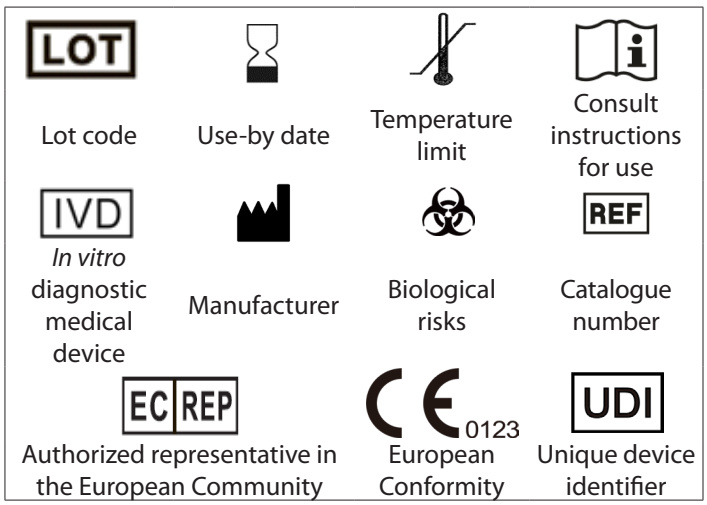
Precautions and Warnings

- For ***in-vitro diagnostic use*** only. The calibrator 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.
- 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 calibrator is well-mixed based on the requirements of the instruction for use. Improper mixing may cause the used and remaining product invalid.
- 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.
- The Material Safety Data Sheet (MSDS) is available upon request.
- 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.
- 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

Manufacturer	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Address	Mindray Building, Keji 12th Road South, High-tech Industrial Park, Nanshan, Shenzhen, 518057, P.R. China.
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Approval Date of the Instruction for Use

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