# Urine Formed Element Calibrator Traceability Document

DIRUI Industrial Co., Ltd.

# Urine Formed Element Calibrator Traceability Report

Named: Urine formed element calibrator

## Ⅰ.Traceability Specifications

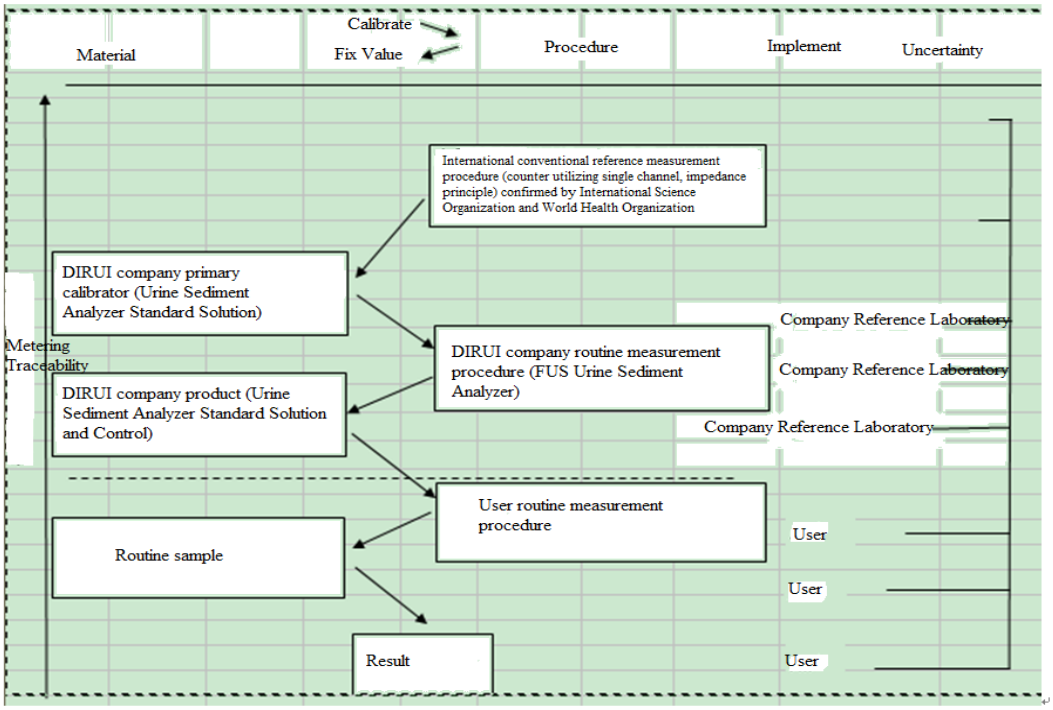
In accordance with the provisions of International Committee for Hematological Standardization of ISO17511 and ICSH, RBC quantity value of calibrator is traceable with international conventional reference procedure: single channel electronic counter, electrical impedance (Z2 cell counter). Traceability details are as follows:

| | |
|---|---|
| Reference of test procedure | International standard procedure for reference range |
| DIRUI test procedure | Z2 Particle Size Analyzer(Target value of transfer program provided by the company) |
| Calibrator | Calibrator liquid for formed element |
| User test procedure | Procedure in user manual(DIRUI offers the parameters) |
| Normal sample | The result of the sample |

## Ⅱ.Quantity Value Traceability Program

In accordance with the provisions of the ISO 17511:2003, RBC quantity value of calibrator liquid for formed elements is traceable with international conventional reference procedure: single channel electronic counter, electrical impedance (Z2 cell counter).

Urine Formed Element Calibrator Traceability Diagram




## Ⅲ.Report

### 1. Experimental information:

1.1 Instrument: Z2 Particle Size Analyzer; FUS-1000 Urinalysis Hybrid

1.2 Materials:

Reagent: Z2 diluent (Lot Number: Z803129A)

Sheath Ⅱ for urinalysis hybrid (Lot Number: 20180702)

Calibrator: FE Calibrator Ⅱ (Lot Number: 20180827)

Quality control: FE Control Ⅱ Positive Control Level 3 (Lot Number: 20180907)

### 2. Experimental procedure：

### 2.1 Evaluation

2.1.1 Urine formed element calibrator evaluation

Take Z2 diluent to clean the small hole pipe for 20 times and then take the result of Z2 diluent as blank value, the blank value needs to comply with the request：＜ 100 particles. Take 1ml urine formed element calibrator, add 19ml z2 diluent, mix them, mixture will be counted by particle size meter, repeat the operation three times, five consecutive bottles, a total of 15 times, the average value of the measured value is converted, and the final average value after conversion is the value of the calibrator.

2.1.2 Data conversion formula: Value= Z2 (show value)×Dilution multiple /1000

**2.2 Accuracy verification of value**

After evaluation use urine formed element calibrator to calibrate FUS-1000, deviation of urine formed element calibrator should <2.5%, deviation of urine formed element control should <2.5%, result should be in the reference of target value.

**3. Result：**

**3.1 Evaluation result of urine formed element calibrator**

| Show value in Z2 Particle Size Analyzer | | | | | | |
|---|---|---|---|---|---|---|
| Diluent Lot Number | Bottle / Time | NO.1 | NO.2 | NO.3 | NO.4 | NO.5 |
| Z803129A | 1 | 55157 | 55391 | 55136 | 55437 | 54900 |
| | 2 | 54637 | 55742 | 55648 | 55060 | 54847 |
| | 3 | 54876 | 55145 | 55246 | 54190 | 55342 |
| | Average | 54890 | 55426 | 55343 | 54896 | 55030 |
| | Conversion (particle /μL) | 1098 | 1109 | 1107 | 1098 | 1101 |
| | Total average(particle /μL) | 1102 | | | | |

The value of urine formed element calibrator is 1102 particles/μL, the degree of uncertainty is 10 particles /μL (Spreading Coefficient, K=2)

**3.2 Value Accuracy Verification**

3.2.1 The result of urine formed element calibrator

| Urine formed element calibrator (20180827) | Value | | | | |
|---|---|---|---|---|---|
| | 1112 | 1140 | 1093 | 1062 | 1111 |
| | 1152 | 1100 | 1070 | 1101 | 1142 |
| Average | 1108 | | | | |
| Target Value | 1102 | | | | |
| Deviation | 0.55% | | | | |

3.2.2 The result of urine formed element control

| Urine formed element control (20180907) | Value | | | | |
|---|---|---|---|---|---|
| | 1037 | 1057 | 1034 | 1034 | 1063 |
| | 1044 | 1068 | 1065 | 1059 | 1038 |
| Average | 1050 | | | | |
| Target Value | 1034 | | | | |
| Deviation | 1.5% | | | | |

**4. Conclusion：**

After the standard of evaluation, the result of DIRUI FE Calibrator Ⅱ

(20180823) is 1102±10 particles /μL，K=2.

**Attachment: Urine formed element calibrator uncertainty evaluation:**

According to the 《Uncertainty of chemical analysis and measurement JJF1135-2005》, the uncertainty of the experiment is analyzed, and the uncertainty produced in the measuring instruments, testing equipment and the testing process is analyzed. As below：

The ambient temperature of our laboratory is controlled between 18 ℃ and 25 ℃, so the influence of temperature on uncertainty is not considered.

**1. Relative Deviation of urine formed element calibrator（$CV_w$）**

The urine formed element calibrator should be determined 15 times. The average value is 1102 particles /μL.

Calculate Arithmetic mean

$$\bar{x} = \frac{\sum_{i=1}^{n} x_i}{n} = 1102 \text{cells/μL}$$

$\bar{x}$ represents the arithmetic mean results of the nth measurement

$$S = \sqrt{\frac{\sum_{i=1}^{n} (x_i - \bar{x})^2}{n-1}} = 5.048$$

S represents the same measure will be tested in 10 times as the dispersion value of results

$x_i$ represents the result of NO.i test

$\bar{x}$ represents the arithmetic mean of test time(n)

$$CV_w = \frac{S}{\bar{x}} = \frac{5.048}{1102} = 0.458 \times 10^{-2}$$

**2. The uncertainty caused by measuring instrument（$CV_{sys}$）**

The measuring instrument used in this experiment is a micro liquid shifter. Uncertainty is given on the metrological verification certificate (U2) 44μl

Conversion of the uncertainty of the micropipettor to the standard uncertainty:

$$S = \frac{U}{k} = \frac{2.44}{2} = 1.22$$

Relative standard uncertainty of micro liquid shifters:

$$CV_{sys} = \frac{S}{\bar{x}} = \frac{1.22}{1000} = 0.122 \times 10^{-2}$$

**3. The uncertainty caused by measuring equipment（$CV_{oth}$）**

The measuring equipment used in this experiment is Z2 Particle Size Analyzer Z2. The standard tube is used in the process of metrological verification. The uncertainty caused by aperture is 0.35μm.

Convert uncertainty to standard deviation $S = \frac{U}{k} = \frac{0.35}{2} = 0.175$

Relative standard deviation ($CV_{sys}$)= $\frac{S}{\bar{x}} = \frac{0.175}{540} = 0.032 \times 10^{-2}$

U represents uncertainty of standard tube aperture

S represents the standard deviation of aperture of standard tube

$\bar{x}$ represents standard tube aperture

**4. Relative extended uncertainty**

Calculated using the following formula and inclusion factor 2 (95% confidence level)

$$U = (\sqrt{CV^2_w + CV^2_{sys} + CV^2_{oth}}) \times 2$$

$$= (\sqrt{(0.458 \times 10^{-2})^2 + (0.122 \times 10^{-2})^2 + (0.032 \times 10^{-2})^2}) \times 2$$

$=0.95\times10^{-2}$

**5. Expanded uncertainty**

Expanded uncertainty=Test value× Relative extended uncertainty

$=1143 \times 1.42 \times 10^{-2}$=16 particles /μL

Conclusion: Test results and uncertainty representation: （1102±10）(cells/μL), K=2