DIRUI 迪瑞

Urine Formed Elements Analysis System Traceability Document

Internal Document, No Disclosure

DIRUI Industrial Co., Ltd.

Urine Formed Elements Analysis System Traceability Document

1. Manufacturer

DIRUI Industrial Co., Ltd.

2. Standard Solution and Control for Urine Sediment Analyzer

DIRUI Urine Sediment Analyzer Standard Solution and Control are water base material; used together with urine sediment analyzer reagents; and are used for calibration and quality control when determining the urine formed elements concentration of urine samples, so as to guarantee the accuracy of test results.

3. Traceability Documents

The urine formed elements analysis system is traced according to the related domestic and international standards and standard document designs. The reference documents are as follows:

1） GB/T 21415-2008/ISO 17511:2003 *In vitro diagnostic medical devices—measurement of quantities in biological samples — metrological traceability of values assigned to calibrators and control materials*

2） GB/T19702-2005/ISO 15193:2002 *In vitro diagnostic medical devices — measurement of quantities in samples of biological origin — description of reference measurement procedures*

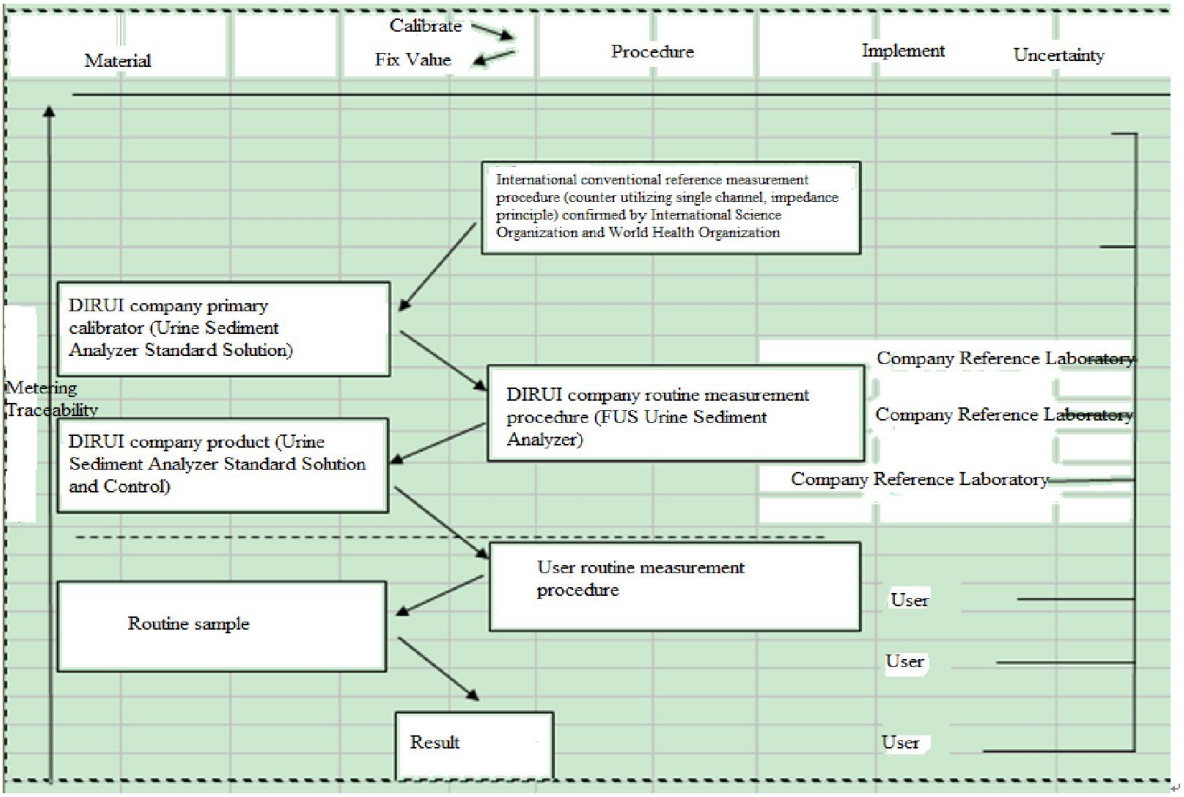
3） GB/T19703-2005/ISO 15194:2002 *In vitro diagnostic medical devices — measurement of quantities in samples of biological origin — description of reference materials*

4） NCCLS EP9-A2：2002 *Use patient samples for method comparison and bias assessment: approval guide*

4. Quantity Value Traceability

The RBC quantity values of Urine Sediment Analyzer Standard Solution and Control are traceable to the international conventional reference procedure: electronic counter utilizing single channel, impedance principle (Z2 cell counter). The traceability chains are as follows:

Urine Sediment Analyzer Standard Solution and Control Traceability Diagram



5. Traceability Confirmation

The developed traceability needs confirming. The confirming method is to use the routine measurement procedure (DIRUI Urine Sediment Analyzer and reagents) and the reference measure procedure (microscopic examination method) simultaneously to test enough, typical fresh urine samples from different individuals. Test each sample repeatedly and analyze whether the approximating degree of the results by the two methods is acceptable.

Familiar with the instrument operation procedure and referring to *Use patient*

samples for method comparison and bias assessment: approval guide which is approved by NCCLS, the experimenter decides a quantity of research samples and carries out the analysis of comparison between the test results of DIRUI Urine Sediment Analyzer and the microscopic examination method.

5.1 Test Devices and Materials

DIRUI Urine Sediment Analyzer and reagents, microscope, centrifuge, standardized sediment counting plate (the LBH of each small box of the counting unit of the counting cell is 2×5×0.1mm, namely 1μL), horizontal centrifuge, and 200 fresh urine samples.

5.2 Test Methods

5.2.1 DIRUI Routine Urine Formed Elements Analysis Test

Turn on the urine sediment analyzer and set parameters according to the requirements, and use Standard Solution for calibration; test Negative Control and Positive Control respectively and repeatedly for 3 times; if calibration and control have passed, test 200 fresh urine samples in sequence and in inverted sequence, two turns respectively for each sample. Record the test results.

5.2.2 Centrifugal Microscopic Examination

5.2.2.1 Centrifugation

Put 10ml well-mixed urine into a 12ml centrifuge tube, and do centrifugation for 5 minutes (RCF 400×g). Pour or remove the supernatant after centrifugation. The left liquid at the bottom of the centrifuge tube should be 0.2ml. It's concentrated fiftyfold.

5.2.2.2 Microscopic Examination

After mixing sediment liquid well, drip a drop of 15—20μl urine to a plastic urine sediment test plate. Observe it at low power first, and then count at high power. Count the cast or cell population in 1μl calculation area (namely ××/μl). Urinary crystal, cast, and parasites are reported at every high power +, ++, +++ and ++++.

5.2.3 Non-centrifugal Microscopic Examination

Mix a urine sample well, use a pipettor to take urine, drip it to two disposable, exclusive urine sediment counting plates, let them stand for a while, observe the cell distribution at low power first, and then count the RBC and WBC number in 10 big

squares at high power. The microscopic examinations are done by 2 experienced experimenters. Both the experimenters and experimenters and urine sediment analyzers are double blind. Obtain the mean of the 2 test results for the report. The tests of all the samples mentioned above are finished in 2 hours.

5.3 Analysis Results Comparison

5.3.1 DIRUI urine formed elements analysis system and centrifugal microscopic examination results comparison

Through the comparison between the results of the urine sediment analyzer and artificial microscopic examinations, the coincidence between the instrumental automatic recognition and artificial microscopic examination, and the coincidence between the artificial review and artificial microscopic examination are shown as follows:

List of coincidence between DIRUI urine formed elements analysis system and centrifugal microscopic examination results

No.	Item	Coincidence between instrumental automatic recognition and artificial microscopic examination	Coincidence between artificial review and artificial microscopic examination
1	RBC	80.5% (161/200)	92%
2	WBC	83.5% (167/200)	93%
3	Epithelium	91% (182/ 200)	96%
4	Cast	87% (174/200)	98%
5	Crystal	89% (178/200)	95%

5.3.2 DIRUI urine formed elements analysis system and non-centrifugal microscopic examination results comparison

Set DIRUI urine formed elements analysis system results as X, and non-centrifugal microscopic examination results as Y; use X and Y for the linear regression method; the results are as follows:

(1) Urine RBC Result: $Y=0.895X- 3.128$, $R^2=0.987$

(2) Urine WBC Result: $Y=0.776X- 2.881$, $R^2=0.976$

(3) Urine Epithelium Result: Y=0.910X- 5.310, R^2=0.982

According to the comparison results, it's concluded that DIRUI urine formed elements analysis system can obtain urine formed elements analysis results accurately.