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Calibration Specification for Automatic Urinary Sediment Analyzers

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(English Translation)

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9 Recalibration time interval (3)

Appendix A Calibration Record Format (4)

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Appendix C Examples of Uncertainty Evaluation of Indication Error of Automatic Urine Sediment Analyzer (7)

Introduction

This specification mainly refers to YY/T 0996-2015 "urinary formed component analyzer (digital imaging automatic recognition no) ", according to JJF 1071-2010 "Rules for Compiling National Measurement and Calibration Specifications", JJF 1059.1-2012

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"Measurement "Uncertainty Evaluation and Expression" and other standards have been completed. In the process of formulating this specification, reference is also made to the current effective JJG714-2012 "Blood Cell Analyzer".

This specification is the first release.

Calibration specification of automatic urine sediment analyzer

1 Scope

This specification applies to automatic urine sediment analyzer based on the principle of flow cytometry or automatic identification of microscopic images Calibration of red blood cell and white blood cell test items, red blood cell and white blood cell of other types of automatic urine sediment analyzer the test items can be calibrated according to this specification.

2 Reference documents this specification refers to the following documents.

JJF 1059.1-2012 Evaluation and expression of measurement uncertainty YY/T 0996-2015 Urine formation analyzer (digital imaging automatic recognition) for dated reference documents, only the dated version applies to this specification; for those without date references the latest version (including all amendments) is applicable to this specification.

3 Terminology

3.1 Urinary sediments urine the urine samples were precipitated by standard centrifugation, and the formed components observed under the microscope. Including cells, casts, knots Crystals, bacteria, sperm, and other formed ingredients.

4 Overview

The automatic urine sediment analyzer uses microscopic image automatic identification technology or flow cytometric impedance technology to analyze urine Inspection equipment for automatic identification and classification counting of the formed elements in the.

Microscopic image automatic identification type urine sediment analyzer uses automatic digital microscope to analyze the urine in the flow counting cell the samples are scanned, and the collected images are automatically identified by morphology software to obtain various detection data. Flow cytometry the principle of impedance analysis of urine sediment is. after the cells in the urine are stained with fluorescent pigments, under the action of sheath fluid, Form a single, vertical column of cell flow, through the argon laser detection area, the instrument detects changes in fluorescence, scattered light and electrical impedance;

When the instrument is capturing fluorescence intensity, forward fluorescence pulse width, forward scattered light intensity, forward scattered light pulse width After the degree and electrical impedance signals, the size, length, volume and chromatin length of the corresponding cell are comprehensively identified and calculated Data, and make

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scattergrams and quantitative reports of red blood cells, white blood cells, bacteria, casts, etc.

5 Metrological characteristics the measurement characteristics are shown in Table 1.

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