ESfEQA
European Society for External Quality Assessment

Survey for Urine Sediment – Flow Cytometry/Light-Scattering Methods (USEDL4, USEDL2)

EQA Provider:	ESfEQA GmbH Heidelberg
Survey Coordinator:	Dr. H. Depner

Instructions for Use

Notes:

The usual precautions in the laboratory for potential hazardous samples apply for these samples. Contains human urine and human blood cells. All blood donor units comprising the human cell source material used in the manufacturing of these samples have been tested and found to be non-reactive for HBsAg, anti-HIV 1/2 and anti-HCV. The samples should be used and disposed of in accordance with regulatory requirements.

Various tasks of the proficiency testing scheme may occasionally be given over to qualified subcontractors. However, ESfEQA is responsible to the participants for the subcontractor's work.

Results from sample analysis may only be disclosed to colleagues from other laboratories after the testing period has been concluded.

By registering for and participating in this EQA participants agree to accept the general terms and conditions of ESfEQA GmbH. These can be retrieved online at www.esfeqa.eu

1. Intended Use

The samples are intended for use as qualitative, semiquantitative and quantitative control material, respectively, for External Quality Assessment (EQA) in medical laboratories for the following analytes:

Bacteria (qualitative, semi-quantitative, and quantitative)

Casts (qualitative, semi-quantitative, and quantitative)

Crystals (qualitative, semi-quantitative, and quantitative)

Red Blood Cells (qualitative, semi-quantitative, and quantitative)

White Blood Cells (qualitative, semi-quantitative, and quantitative)

Semi-quantitative and quantitative results shall be reported as "particles/µL" only.

2. Product Description

The liquid samples are simulated midstream urine specimens. They are prepared from human urine and need to be prepared as described in section 4.

3. Storage and Stability

The samples should be stored upright at 2-8 °C. They are stable at least until the deadline for data submission as indicated on the sample labels.

4. Sample Preparation and Analysis

In general, the samples should be treated the same way as patient samples and analyzed in accordance with the instructions of the instrument and reagent manufacturer.

Sysmex UF-devices: Please analyze the samples in the manual / STAT mode.

Allow the samples to equilibrate to room temperature for 15 minutes prior to testing. Mix the controls thoroughly by inverting the vial at least 20 times to assure homogeneity of the contents. Avoid foaming. Thorough mixing with each use is important in order to obtain reproducible results.

If required, transfer an adequate amount of urine suspension into a test cup according to the specifications of your instrument manufacturer and analyze immediately.

5. Dates and Submission of Test Results

Testing Periods: Please refer to the sample labels. Results can be submitted anytime within the testing period indicated on the sample labels.

Prior to results submission please check/adjust the indication of your instrument and method ('lab configuration') in TEQA available at https://teqa.esfeqa.eu by following the guidelines for instrument and method selection for the Urine Sediments EQA available at www.esfeqa.eu.

Please submit your results electronically to ESfEQA at https://teqa.esfeqa.eu.

Contact your local distributor of ESfEQA programs or ESfEQA directly if you need assistance with registration in TEQA. Alternatively, though not preferred, use the result form provided on the ESfEQA website. In both cases indicate the instrument and method used for the analysis of the samples.

Quantitative results are generally reported with a value and a unit. The participant determines the number of digits for reporting. Results specified as e.g. '< below measuring range' or '< 0.02' are not valid. If the analyzer system displays such results, they shall be interpreted as following: For results within the measuring range and below the Limit of Quantification (LoQ) the obtained value should be reported.

ESfEQA GmbH
Siemensstr. 38
69123 Heidelberg
Germany

Phone: + 49 6221 4166-700
Fax: + 49 6221 4166-790
info@esfeqa.eu
www.esfeqa.eu

For results below the Limit of Detection (LoD), this limit should be reported. For samples that have analyte concentrations above the test range, the sample can be diluted (if recommended for particular applications) or the upper test range limit can be reported as result.

6. Deadline for Data Submission

The deadlines for submitting results are indicated on the sample labels (time zone GMT +1).

7. Reports and Certificates

The data will be evaluated by ESfEQA. The individual laboratory reports and certificates can be retrieved online at https://teqa.esfeqa.eu.

ESfEQA GmbH
Siemensstr. 38
69123 Heidelberg
Germany

Phone: + 49 6221 4166-700
Fax: + 49 6221 4166-790
info@esfeqa.eu
www.esfeqa.eu