IFU_CLZins, Ver_001

Survey for Clozapine tested with the MyCare Insite Test

EQA Provider:	ESfEQA GmbH Heidelberg
Survey Coordinator:	Dr. D. Groche

Instructions for Use

Notes:

The samples for this program contain buffers and salts in an aqueous solution. The controls do not contain human or biological materials. The samples should be handled by trained personnel only.

WARNING: Contains sodium azide.

H400: Very toxic to aquatic life.

The samples contain less than 0.1% sodium azide. Avoid contact with skin and mucous membranes. When disposing of these samples, always flush/dilute with large amounts of water.

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 quantitative control material for External Quality Assessment (EQA) in medical laboratories or point-of-care testing sites for the following analytes:

Clozapine determination with the MyCare Insite Test

2. Product Description

The samples are liquid and ready to use.

3. Storage and Stability

The samples should be stored upright at 2 - 8 °C. Do not freeze. After opening, the samples are stable at least until the deadline for data submission as indicated below. After each use, tightly close the caps and return the samples to 2 - 8 °C storage.

4. Sample Preparation and Analysis

Prior to testing, allow samples to warm-up to room temperature for at least 10 minutes.

Before dispensing, mix each sample by gently inverting the vial several times. Avoid bubbles in the sample cup since bubbles may interfere with proper sample analysis.

After each use, tightly close the caps and return samples to 2 - 8 °C storage.

Further sample handling and testing has to be done according to the test manufacturer's instructions for QC sample testing. In detail: EQA controls are run as samples. Transfer exactly 20 µL of sample into a test cuvette. Place the sample reagent cap in the cuvette. Firmly snap the reagent cap in place to close the test cartridge. The cuvette containing sample and sealed with the reagent cap is used as a test cartridge. The test cartridge is now ready to measure.

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.

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. In general result should be reported as measured, however, results specified '< test range' (e.g. '< 10) and '> test range' (e.g. '>2000') are not valid. If the analyzer system displays such results, they shall be interpreted as follows: for results below the test range, the lower test range limit should be reported (e.g. "10"). For samples that have analyte concentrations above the test range the upper test range limit (e.g. "2000") can be reported as the 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.

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