

MyCare Psychiatry Calibrator Kit 2

INTENDED USE

Rx only

The MyCare Psychiatry Calibrator Kit 2 is used for calibrating the MyCare Psychiatry Clozapine Assay Kit.

CONTENTS

Calibrator	Symbol	Clozapine ng/mL	Quantity x Volume
A	CAL A	0	1 x 3 mL
B	CAL B	75	1 x 3 mL
C	CAL C	121	1 x 3 mL
D	CAL D	248	1 x 3 mL
E	CAL E	539	1 x 3 mL
F	CAL F	1423	1 x 3 mL

STANDARDIZATION

There is no internationally recognized standard for clozapine. The MyCare Psychiatry Calibrator Kit 2 calibrators are prepared gravimetrically by dilution of USP clozapine into a buffer matrix. Saladax Biomedical, Inc. maintains master calibrators with values confirmed by a reference method. MyCare Psychiatry Calibrator Kit 2 calibrators are traceable to the master calibrators. The master calibrator levels have been value assigned to produce MyCare Psychiatry Clozapine Assay Kit results that correlate to LC-MS/MS methods for clinical samples. Third party controls, contrived / spiked samples, including proficiencies, will not recover 100% of their expected value because of the calibrator value assignment. Please contact Saladax for assistance with external quality assurance programs.

WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic Use Only.
- The calibrators in this kit are designed for use as a unit. Do not substitute or mix calibrators with those from other lots.
- Exercise normal precautions required for handling all laboratory reagents.
- All components of the MyCare Psychiatry Calibrator Kit 2 contain less than 0.1% sodium azide. Avoid contact with skin and mucous membranes. Flush affected areas with copious amounts of water. Seek immediate medical attention if reagents are ingested or come into contact with eyes. When disposing of such reagents, always flush with large amounts of water to prevent accumulation of azide.
- Avoid bubbles in the sample cup. Bubbles may interfere with proper level detection causing insufficient calibrator aspiration that could impact results.

HANDLING

Refer to the MyCare Psychiatry package insert for clozapine for a complete summary and explanation of the test. Calibrators are provided as ready to use liquids. Use calibrators immediately upon removal from 2 - 8°C storage and mix each calibrator by gentle inversion several times before dispensing. After each use, tightly close the caps and return calibrators to 2 - 8°C storage.

STORAGE AND STABILITY

Store calibrators refrigerated at 2 - 8°C. Do not freeze.

Improper storage of calibrators can affect assay performance.

When stored and handled as directed:

- Unopened calibrators are stable until the expiration date printed on the label.
- Opened calibrators are stable for 19 months within the expiration date.

PROCEDURE

Materials Provided

REF MCP2-CAL-US – MyCare Psychiatry Calibrator Kit 2

Materials Required – Provided Separately

REF CLZ-RGT – MyCare Psychiatry Clozapine Assay Kit

REF MCP2-CON-US – MyCare Psychiatry Control Kit 2

Calibration

To perform a calibration, see the instrument specific application sheet and appropriate analyzer operator's manual.

Perform a full calibration using the six calibrators in the MyCare Psychiatry Calibrator Kit 2. Verify the calibration by testing the low, medium, and high controls in the MyCare Psychiatry Control Kit 2.

Calibration Frequency - Calibration is recommended:

- After a calibrator or reagent (kit) lot change,
- After performance of major instrument maintenance,
- As required following quality control procedures.

RESULTS





The concentration result is automatically calculated from the non-linear calibration curve by the analyzer. Report results in ng/mL or nmol/L. The conversion factor from ng/mL clozapine is $3.06 \times \text{ng/mL} = 1 \text{ nmol/L clozapine}$.

LIMITATIONS OF THE PROCEDURE

Accurate and reproducible results are dependent upon properly functioning instruments, reagents, calibrators, storage of product as directed and good laboratory technique.

All testing should be performed in accordance with local, state and/or federal regulations or accreditation requirements.

SYMBOLS USED

IVD	<i>in vitro</i> Diagnostic Device		Consult Instructions for Use
REF	Catalog Number		Use By
LOT	Batch Code		Temperature Limitation
	Manufacturer		



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