

MyCare Psychiatry Control Kit 2

INTENDED USE

Rx only

The MyCare Psychiatry Control Kit 2 is used in quality control of the MyCare Psychiatry Clozapine Assay Kit.

CONTENTS

Control	Symbol	Clozapine ng/mL	Clozapine Assigned ng/mL	Quantity x Volume
Low	CON L	152	126 – 178	2 x 3 mL
Medium	CON M	461	341 – 581	2 x 3 mL
High	CON H	907	671 - 1143	2 x 3 mL

STANDARDIZATION

There is no internationally recognized standard for clozapine. The MyCare Psychiatry Control Kit 2 is prepared gravimetrically by dilution of USP clozapine into a buffer matrix.

WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic Use Only.
- The controls in this kit are designed for use as a unit. Do not substitute or mix controls with those from other lots.
- Exercise normal precautions required for handling all laboratory reagents.
- All components of the MyCare Psychiatry Control 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 control aspiration that could impact results.

HANDLING

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

STORAGE AND STABILITY

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

Improper storage of controls can affect assay performance.

When stored and handled as directed:

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

PROCEDURE

Materials Provided

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

Materials Required – Provided Separately:

REF CLZ-RGT – MyCare Psychiatry Clozapine Assay Kit

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

Quality Control (QC)

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

Each laboratory should establish its own QC procedures for the MyCare Psychiatry Clozapine Assay Kit. All quality control requirements and testing should be performed in accordance with local, state and/or federal regulations or accreditation requirements. Good laboratory practice suggests that at least two QC concentrations be tested each day patient samples are measured, and each time calibration is performed. Ensure that the quality control results meet the acceptance criteria before reporting patient results.

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 $3.06 \text{ x ng/mL} = 1 \text{ nmol/L clozapine}$.

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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