

## MyCare Psychiatry Calibrator Kit 2

**For Research Use Only. Not for use in diagnostic procedures.**

### INTENDED USE

The MyCare Psychiatry Calibrator Kit 2 is used for calibrating MyCare Psychiatry assays for total aripiprazole, clozapine, olanzapine, quetiapine, and total risperidone. For research use only. Not for use in diagnostic procedures.

### CONTENTS

Calibrator	Symbol	Quantity x Volume
A	CAL A	1 x 3 mL
B	CAL B	1 x 3 mL
C	CAL C	1 x 3 mL
D	CAL D	1 x 3 mL
E	CAL E	1 x 3 mL
F	CAL F	1 x 3 mL

Calibrator	Total Aripiprazole ng/mL	Clozapine ng/mL	Olanzapine ng/mL	Quetiapine ng/mL	Total Risperidone ng/mL
A	0	0	0	0	0
B	25	75	30	31	25
C	75	121	43	88	40
D	250	248	71	195	60
E	500	539	114	438	80
F	1000	1423	NA	700	120

### STANDARDIZATION

There are no internationally recognized standards for aripiprazole, clozapine, olanzapine, quetiapine or risperidone. The MyCare Psychiatry Calibrator Kit 2 calibrators are prepared gravimetrically by dilution of certified reference materials into a buffer matrix. Saladax Biomedical, Inc. maintains single analyte master calibrators for aripiprazole, clozapine, olanzapine and quetiapine that have been confirmed by a reference method. MyCare Psychiatry Calibrator Kit 2 calibrators are traceable to this master set of calibrators.

## WARNINGS AND PRECAUTIONS

- **For Research 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 assay package inserts for total aripiprazole, clozapine, olanzapine, quetiapine, and total risperidone for explanations of the tests. 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 21 months within the expiration date.

## PROCEDURE

### **Materials Provided**

**REF** MCP2-CAL-RUO – MyCare Psychiatry Calibrator Kit 2

### **Materials Required – Provided Separately**

**REF** MCP2-CON-RUO – MyCare Psychiatry Control Kit 2

**REF** ARI-RGT-RUO – MyCare Psychiatry Total Aripiprazole Assay Kit

**REF** CLZ-RGT-RUO - MyCare Psychiatry Clozapine Assay Kit

**REF** OLZ-RGT-RUO - MyCare Psychiatry Olanzapine Assay Kit

**REF** QTP-RGT-RUO - MyCare Psychiatry Quetiapine Assay Kit

**REF** RSP-RGT-RUO - MyCare Psychiatry Total Risperidone Assay Kit

### **Calibration**

To perform a calibration, see the instrument specific RUO application sheet and appropriate analyzer operator's manual. Perform a full calibration using the calibrators in the MyCare Psychiatry Calibrator Kit 2. Verify the calibration by testing the 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 factors from ng/mL to nmol/L are shown in the table below. Multiply ng/mL results by the conversion factor to obtain nmol/L.

Analyte	ng/mL	nmol/L
Aripiprazole	2.23	1
Clozapine	3.06	1
Olanzapine	3.20	1
Quetiapine	2.61	1
Risperidone	2.44	1

## 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.

## SYMBOLS USED

	Consult Instructions for Use		Catalog Number		Use By
	Batch Code		Temperature Limitation		Manufacturer

## MANUFACTURED BY



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