

## MyCare Psychiatry Calibrator Kit 2

### INDICATIONS FOR USE

#### Rx only

The MyCare Psychiatry Calibrator Kit 2 is used for calibrating MyCare Psychiatry assays for clozapine, total risperidone, total aripiprazole, quetiapine, and olanzapine.\*

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

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

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

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

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

\*Contact your sales representative for a list of reagent kits available in your market

### CONTENTS

Calibrator	Symbol	Quantity x Volume	Clozapine ng/mL	Total Risperidone ng/mL	Total Aripiprazole ng/mL	Quetiapine ng/mL	Olanzapine ng/mL
A	<b>CAL A</b>	1 x 3 mL	0	0	0	0	0
B	<b>CAL B</b>	1 x 3 mL	75	25	25	31	30
C	<b>CAL C</b>	1 x 3 mL	121	40	75	88	43
D	<b>CAL D</b>	1 x 3 mL	248	60	250	195	71
E	<b>CAL E</b>	1 x 3 mL	539	80	500	438	114
F	<b>CAL F</b>	1 x 3 mL	1423	120	1000	700	NA

### STANDARDIZATION

There are no internationally recognized standards for clozapine, risperidone, aripiprazole, quetiapine, or olanzapine. 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 clozapine, risperidone, aripiprazole, quetiapine, and olanzapine with values confirmed by a reference method. MyCare Psychiatry Calibrator Kit 2 calibrators are traceable to the master calibrators.

For the clozapine and quetiapine assays, the master calibrator levels have been value assigned to produce assay 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 assay package inserts for clozapine, total risperidone, total aripiprazole, quetiapine, and olanzapine for complete summaries and 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 – MyCare Psychiatry Calibrator Kit 2

### Materials Required – Provided Separately

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

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

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

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

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

**REF** MCP2-CON – 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. For the olanzapine assay use five calibrators A – E. Verify the calibration by testing the low, medium, and high controls in the MyCare Psychiatry Control Kit 2. For the olanzapine assay use the low and medium controls.

**Calibration Frequency** - Calibration is recommended:

- After a 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. Multiple ng/mL results by the conversion factor to obtain nmol/L.

Analyte	ng/mL	nmol/L
Clozapine	3.06	1
Risperidone	2.44	1
Aripiprazole	2.23	1






Analyte	ng/mL	nmol/L
Quetiapine	2.61	1
Olanzapine	3.20	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.

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

**SYMBOLS USED**

<b>IVD</b>	<i>in vitro</i> Diagnostic Device		Consult Instructions for Use
<b>REF</b>	Catalog Number		Use By
<b>LOT</b>	Batch Code		Temperature Limitation
	Manufacturer		Authorized Representative in the European Community



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