



Psychiatry Calibrator Kit 2

INDICATIONS FOR USE

Rx only

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

REF C82914 – Psychiatry Clozapine Assay Kit*

REF C82917 – Psychiatry Quetiapine Assay Kit*

REF C82918 – Psychiatry Total Risperidone Assay Kit*

REF C82915 – Psychiatry Olanzapine Assay Kit*

REF C82913 – 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	CAL A	1 x 3 mL	0	0	0	0	0
B	CAL B	1 x 3 mL	75	25	25	31	30
C	CAL C	1 x 3 mL	121	40	75	88	43
D	CAL D	1 x 3 mL	248	60	250	195	71
E	CAL E	1 x 3 mL	539	80	500	438	114
F	CAL F	1 x 3 mL	1423	120	1000	700	NA

STANDARDIZATION

There are no internationally recognized standards for clozapine, risperidone, aripiprazole, quetiapine, or olanzapine. The 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. 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 Beckman Coulter 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 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.
- The Safety Data Sheet (SDS) is available at https://www.saladax.com/bci_applications/

HANDLING

Refer to the 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 C82911 – Psychiatry Calibrator Kit 2

Materials Required – Provided Separately

REF C82914 – Psychiatry Clozapine Assay Kit

REF C82918 – Psychiatry Total Risperidone Assay Kit

REF C82913 – Psychiatry Total Aripiprazole Assay Kit

REF C82917 – Psychiatry Quetiapine Assay Kit

REF C82915 – Psychiatry Olanzapine Assay Kit

REF C82912 – 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 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 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

	<i>in vitro</i> Diagnostic Device		Consult Instructions for Use
	Catalog Number		Use By
	Batch Code		Temperature Limitation
	Manufacturer	Rx only	For Prescription Use Only
	CE mark		Authorized Representative in the European Community
	Made in USA		UK Mark

For technical assistance:

Contact the Customer Technical Support Center at 1-800-854-3633 (USA & Canada).

In other countries, please contact your local Beckman Coulter representative.

ADDITIONAL INFORMATION

For more detailed information on AU Systems, refer to the appropriate system manual. Since Beckman Coulter does not manufacture the reagent or perform quality control or other tests on individual lots, Beckman Coulter cannot be responsible for the quality of the data obtained which is caused by performance of the reagent, any variation between lots of reagent, or protocol changes by the manufacturer.

SHIPPING DAMAGE

Please notify your Beckman Coulter Clinical Support Center if this product is received damaged.

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