



Psychiatry Control Kit 2

INDICATIONS FOR USE

Rx only

The Psychiatry Control Kit 2 is used in quality control (QC) of 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

The Psychiatry Control Kit 2 is a multianalyte control.

Control	Symbol	Quantity x Volume
Low	CON L	2 x 3 mL
Medium	CON M	2 x 3 mL
High	CON H	2 x 3 mL

		Low	CON L	Medium	CON M	High	CON H
Psychiatry Assay Kit	Unit	Analyte	Range	Analyte	Range	Analyte	Range
Clozapine	ng/mL	152	126 – 178	461	341 – 581	907	671 – 1143
Total Risperidone	ng/mL	35	30 – 40	65	55 – 75	100	85 – 115
Total Aripiprazole	ng/mL	50	38 – 62	200	177 – 223	700	621 – 779
Quetiapine	ng/mL	59	46 – 72	313	278 -348	569	505 - 634
Olanzapine	ng/mL	50	41 – 59	105	95 - 114	NA	

STANDARDIZATION

There is no internationally recognized standard for clozapine, risperidone, aripiprazole, quetiapine, or olanzapine. The Psychiatry Control Kit 2 is prepared gravimetrically by dilution of certified reference materials 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 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.
- The Safety Data Sheet (SDS) is available at https://www.saladax.com/bci_applications/

HANDLING

For explanations of the tests, refer to the Psychiatry assay package inserts for clozapine, total risperidone, total aripiprazole, quetiapine, and olanzapine.

Controls are provided as ready to use liquids. Use controls immediately upon removal from 2 - 8°C storage. 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 21 months within the expiration date.

PROCEDURE

Materials Provided

REF C82912 – Psychiatry Control 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 C82911 – Psychiatry Calibrator Kit 2

Quality Control (QC)

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

Each laboratory should establish its own QC procedures for the clozapine, total risperidone, total aripiprazole, quetiapine, and olanzapine assays. 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.

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

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 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










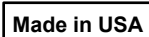

Analyte	ng/mL	nmol/L
Quetiapine	2.61	1
Olanzapine	3.20	1

LIMITATIONS OF THE PROCEDURE

Accurate and reproducible QC results of the Psychiatry assays 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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