

MyCare Psychiatry Control Kit 2

INDICATIONS FOR USE

The MyCare Psychiatry Control Kit 2 is used in quality control (QC) of MyCare Psychiatry assays for clozapine, total risperidone, total aripiprazole, quetiapine, and olanzapine, and for use in quality control of the MyCare Insite Clozapine Test.*

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*


REF CLZ-MCI-32.2 – MyCare Insite Clozapine Test*


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

CONTENTS

The MyCare 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
MyCare Psychiatry	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	

		Low	CON L	Medium	CON M	High	CON H
MyCare Insite	Unit	Analyte	Range	Analyte	Range	Analyte	Range
Clozapine	ng/mL	NA		550	358 - 743	NA	

STANDARDIZATION

There is no internationally recognized standard for clozapine, risperidone, aripiprazole, quetiapine, or olanzapine. The MyCare 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 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.

When Used on Clinical Chemistry Analysers

- Avoid bubbles in the sample cup. Bubbles may interfere with proper level detection causing insufficient control aspiration that could impact results.

When Used On MyCare Insite

- Ensure the correct volume of QC fluid is used as directed in the test package insert.

HANDLING

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

Controls are provided as ready to use liquids. 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.

- For QC of the MyCare Psychiatry assays, use controls immediately upon removal from 2 – 8°C storage.
- For QC of MyCare Insite tests, allow controls to warm-up to room temperature for at least 10 minutes.

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 MCP2-CON – MyCare Psychiatry Control 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 CLZ-MCI-32.2 – MyCare Insite Clozapine Test

REF MCP2-CAL – MyCare Psychiatry Calibrator Kit 2 (except for MyCare Insite Tests)

Quality Control (QC)

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

Each laboratory should establish its own QC procedures for the clozapine, total risperidone, total aripiprazole, quetiapine, and olanzapine assays. Ensure that the quality control results meet the acceptance criteria before reporting patient results.

To perform quality control for MyCare Insite tests, refer to the user manual for the MyCare Insite and the package insert for the MyCare Insite Clozapine Test.

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 MyCare Psychiatry assays are dependent upon properly functioning instruments, reagents, calibrators, storage of product as directed, and good laboratory technique.

Accurate and reproducible QC results of the MyCare Insite Test are dependent upon properly functioning instruments, tests, storage of product as directed, and following the directions carefully.

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		Authorized Representative in the European Community



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