

MyCare Psychiatry Calibrator Kit 1

This package insert must be read carefully prior to product use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

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

INTENDED USE

The MyCare Psychiatry Calibrator Kit 1 is used for calibrating MyCare Psychiatry assays for total risperidone and paliperidone.

REF RSP-RGT - MyCare Psychiatry Total Risperidone Assay Kit

REF PAL-RGT - MyCare Psychiatry Paliperidone Assay Kit

CONTENTS

Calibrator	Symbol	Risperidone ng/mL	Quantity x Volume
A	CAL A	0	1 x 3 mL
B	CAL B	25	1 x 3 mL
C	CAL C	40	1 x 3 mL
D	CAL D	60	1 x 3 mL
E	CAL E	80	1 x 3 mL
F	CAL F	120	1 x 3 mL

STANDARDIZATION

There is no internationally recognized standard for risperidone. The MyCare Psychiatry Calibrator Kit 1 calibrators are prepared gravimetrically by dilution of USP risperidone into a buffer matrix. Saladax Biomedical, Inc. maintains master calibrators that have been confirmed by a reference method. MyCare Psychiatry Calibrator Kit 1 calibrators are traceable to this master set of calibrators.

WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic Use Only.
- The calibrators in this set 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 1 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 Total Risperidone Assay Kit and MyCare Psychiatry Paliperidone Assay Kit package inserts for a complete summary and explanation of the test. 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 (35-46°F). 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.
- Opened calibrators are stable for 6 weeks within the expiration date.

MATERIALS PROVIDED

REF MCP1-CAL – MyCare Psychiatry Calibrator Kit 1

MATERIALS REQUIRED – PROVIDED SEPARATELY:

REF MCP1-CON – MyCare Psychiatry Control Kit 1

PROCEDURE

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 1. Verify the calibration by testing the low, medium, and high controls in the MyCare Psychiatry Control Kit 1.

Calibration Frequency - Calibration is recommended:

- After a calibrator or reagent (kit) lot change,
- After performance of monthly 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 factor from ng/mL risperidone is $2.44 \times \text{ng/mL} = 1 \text{ nmol/L}$ risperidone. The conversion factor from ng/mL paliperidone is $2.35 \times \text{ng/mL} = 1 \text{ nmol/L}$ paliperidone.

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.

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