REF MCP1-CON

MyCare Psychiatry Control 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.

CUSTOMER SERVICE

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IVD	*in vitro* 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 Control Kit 1 is for use in quality control of 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

Control	Symbol	Risperidone ng/mL	Risperidone Range ng/mL	Quantity x Volume
Low	CON L	35	30 – 40	2 x 3 mL
Medium	CON M	65	55 - 75	2 x 3 mL
High	CON H	100	85 - 115	2 x 3 mL

STANDARDIZATION

There is no internationally recognized standard for risperidone. The MyCare Psychiatry Control Kit 1 is prepared gravimetrically by dilution of USP risperidone into a buffer matrix.

WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic Use Only.
- The controls in this set 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 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 control 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. Controls are provided as ready to use liquids. Use controls immediately upon removal from 2-8°C storage and 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 (35-46°F). 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.
- Opened controls are stable for six weeks within the expiration date.

MATERIALS PROVIDED

REF CP1-CON – MyCare Psychiatry Control Kit 1

MATERIALS REQUIRED – PROVIDED SEPARATELY:

REF MCP1-CON – MyCare Psychiatry Calibrator Kit 1

PROCEDURE

Quality Control (QC)

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

Each laboratory should establish its own QC procedures for the MyCare Total Risperidone Assay Kit and the MyCare Paliperidone Assay Kit. All quality control requirements and testing should be performed in accordance with local, state and/or federal regulations or accreditation requirements. 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.

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 x ng/mL = 1 nmol/L risperidone. The conversion factor from ng/mL paliperidone is 2.35 x ng/mL = 1 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.