REF BSF-CON

MyCare™ Oncology Busulfan Control Kit

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IVD	*in vitro* Diagnostic Device	LOT	Batch Code
	Consult Instructions for Use		Manufacturer
	Temperature Limitation		Use By Date
REF	Catalog Number	EC REP	Authorized Representative in the European Community
CON L CON M CON H	Low Control Medium Control High Control		Biological Risk
		CE	CE Mark

Indications For Use

The MyCare Oncology Busulfan Control Kit is for use in quality control (QC) of the MyCare Oncology Busulfan Assay Kit.

Contents

Control	Symbol	Busulfan ng/mL	Busulfan Range ng/mL	Quantity x Volume
Low	CON L	225	180 – 270	2 x 3 mL
Medium	CON M	450	383 – 518	2 x 3 mL
High	CON H	900	765 - 1035	2 x 3 mL

Standardization

There is no internationally recognized standard for busulfan. The MyCare Oncology Busulfan Control Kit is prepared gravimetrically by dilution of stable busulfan derivative into a plasma 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 Oncology Busulfan Control Kit 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.
- Materials of human origin were tested for syphilis, HIV1 and HIV2, Hepatitis B and Hepatitis C by FDA-approved methods and the findings were negative. However, as no test method can rule out the potential risk of infection with absolute certainty, the material must be handled just as carefully as a patient sample. In the event of exposure, the directives of the responsible health authorities should be followed.
- 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 Oncology Busulfan Assay Kit package insert 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. Do not freeze.

Opened controls are stable until the expiration date printed on the label.

Procedure

Materials Provided:

REF BSF-CON – MyCare Oncology Busulfan Control Kit

Materials Required – Provided Separately

REF BSF- RGT – MyCare Oncology Busulfan Assay Kit

REF BSF-CAL – MyCare Oncology Busulfan Calibrator Kit

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 Oncology Busulfan 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

Results are reported in ng/mL. The conversion factor for µM is 0.0041 x ng/mL = 1 µmol/L.

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.