REF BSF-CAL

MyCare™ Oncology Busulfan Calibrator 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
	Biological Risk	CE	CE Mark

Indications For Use

The MyCare Oncology Busulfan Calibrator Kit is for calibrating the MyCare Oncology Busulfan Assay Kit.

Contents

Calibrator	Symbol	Busulfan ng/mL	Quantity x Volume
A	CAL A	0	1 x 3 mL
B	CAL B	150	1 x 3 mL
C	CAL C	300	1 x 3 mL
D	CAL D	600	1 x 3 mL
E	CAL E	1200	1 x 3 mL
F	CAL F	2000	1 x 3 mL

Standardization

There is no internationally recognized standard for busulfan. The MyCare Oncology Busulfan Calibrator Kit calibrators are prepared gravimetrically by dilution of stable busulfan derivative into a plasma matrix. These stable calibrators are traceable to master calibrators maintained by Saladax Biomedical, Inc. Master calibrators are prepared gravimetrically by dilution of USP busulfan with values confirmed by a reference method.

Warnings and Precautions

- For In Vitro Diagnostic Use Only.
- The calibrators in this kit 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 Oncology Busulfan Calibrator 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 calibrator 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. 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. Do not freeze.

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

Procedure

Materials Provided:

REF BSF-CAL – MyCare Oncology Busulfan Calibrator Kit

Materials Required – Provided Separately

REF BSF- RGT – MyCare Oncology Busulfan Assay Kit

REF BSF-CON – MyCare Oncology Busulfan Control Kit

Calibration

Perform a full calibration using the six calibrators from the Busulfan Calibrator Kit. Verify the calibration by testing the low, medium, and high controls from the Busulfan Control Kit.

Calibration Frequency

Calibration is recommended:

- After a reagent kit lot change,
- After performance of monthly instrument maintenance,
- As required following quality control procedures.

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.