Saladax BIOMEDICAL

eurobio bmd

MyCare™

Busulfan Therapeutic Drug Monitoring

Receive blood levels within hours instead of days

Rapid enough to provide multiple AUCs early in treatment

CE Marked and Health Canada Licensed

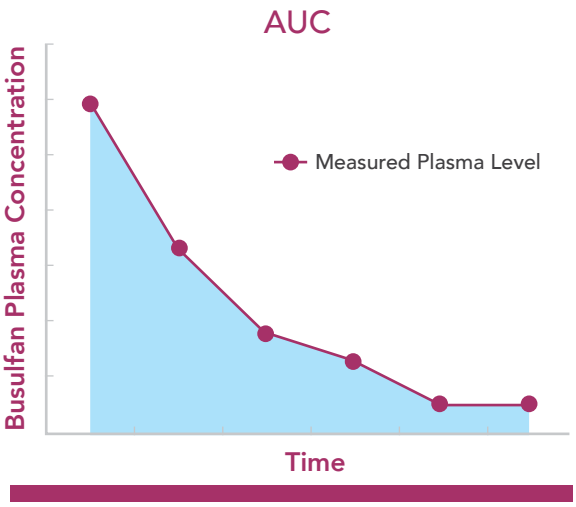
ASSAY HIGHLIGHTS

- Rapid, accurate, and easy to perform
- Ready for use on automated analysers already present in clinical labs
- Proprietary technology with unprecedented stability of liquid controls and calibrators
- No reagent preparation or sample pretreatment
- Validated according to FDA recognized and IVDD harmonized standards
- ISO 13485 and FDA cGMP compliant manufacturing process
- Only commercially available assay
- Cost effective

MyCareTests.com

About Busulfan Testing

- Busulfan is used before hematopoietic stem cell transplantation (HSCT)[1]
- HSCT is the standard treatment in various malignant diseases including leukemia (acute, chronic myeloid, acute lymphocytic), non-Hodgkin's lymphoma, Hodgkin's disease and non-malignant diseases such as metabolic diseases, immunodeficiencies, and hemoglobinopathy
- Busulfan exposure is calculated as the area under concentration-time curve (AUC)
- Optimal exposure is essential for successful hematopoietic stem cell transplantation outcomes



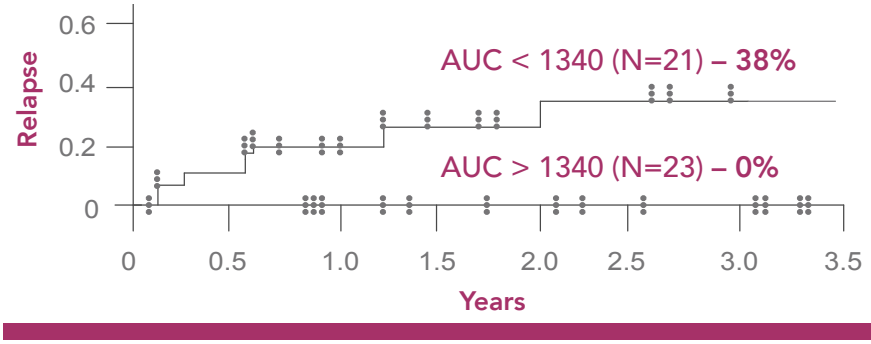
Patients Must Reach Target Exposure

- Busulfan dose is determined by patient's body weight
- Only 60 – 70% of patients achieve target busulfan exposure when dosed by weight[2]
- AUC should be between 900 and 1350 μM·min[3]

High exposure associated with increased risk of toxicity including:
- Mucositis
- Graft-verus-host disease
- Veno-occlusive disease (VOD)
- Transplantation-related mortality

Low exposure associated with increased risk of:
- Graft rejection
- Disease relapse

Outcomes of Busulfan Monitoring



Lower incidence of VOD:[4]

- 0 – 5% with TDM-based dose adjustment
- 24 – 75% without TDM or dose adjustment

Lower incidence of relapse 3 years post transplantation[5]

Busulfan Assay Kit

Test Parameters

Measuring Range	0 to 2,000 ng/mL (up to 6,000 ng/mL with dilution)
Sample Type	Sodium Heparin Plasma
Sample Volume	10 µL

Onboard Stability*

Reagent Stability	30 days
Calibration Stability	14 days

*Analyser Dependent

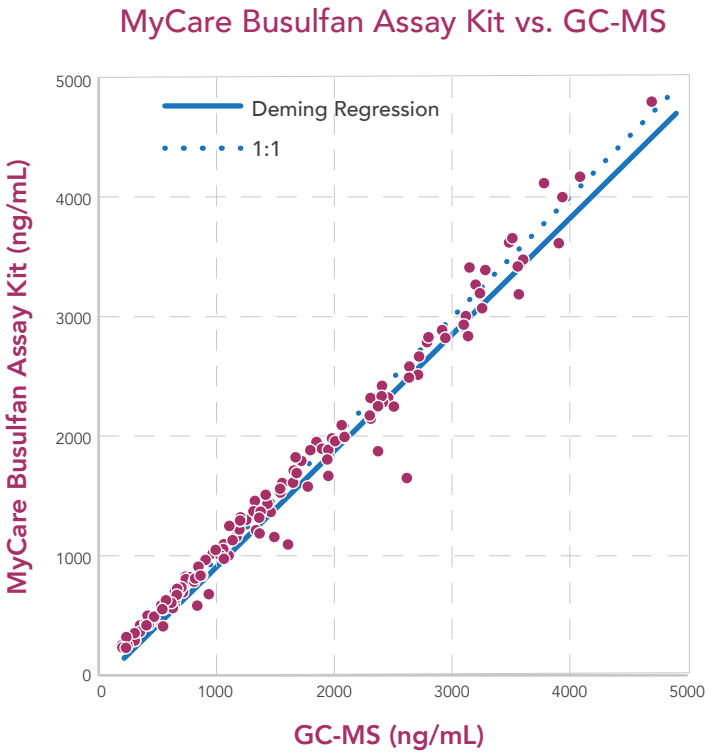
Shelf Life

Reagent	10 months
Calibrators and Controls	10 months

Stable Calibrators & Controls

A unique, patented busulfan analog in the calibrators and controls negates the need for special handling and and simplifies work flow

Method Comparison



Slope = 0.97, Y-Intercept = 18
Correlation Coefficient (r) = 0.9917, N = 208

Precision

Sample Type		Assigned Value (ng/mL)	N	Mean (ng/mL)	Repeatability %CV	Within-Laboratory %CV
Controls	Low	225	80	250	4.6	6.1
	Medium	450	80	461	3.1	3.9
	High	900	80	910	1.8	2.8
Plasma	Spike 1	325	80	328	4.7	5.7
	Spike 2	600	80	615	4.0	4.8
	Spike 3	1100	80	1124	2.1	2.9
	Spike 4	1500	80	1531	2.6	3.1

Ordering Information

MyCare™

Order Codes

Busulfan Reagent	BSF-RGT
Busulfan Calibrators	BSF-CAL
Busulfan Controls	BSF-CON

Contact Us

To place an order:
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2. Palmer, et al. 2016. Biol Blood Marrow Transplant; 22: 1915-1925
3. Otsuka Pharma Co. 2015. Busulfex Package Insert
4. Grochow, et al. 1993. Semin Oncol; 20: 18-25
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