



Health Technology Review	
Technology Ref.:	HTA-23064
Technology Name:	My Care Oncology Busulfan Assay Kit Assay Kit-/ BSF-RGT.
Approvals by International Bodies:	ISO-13485:2016
Company name:	SALADAX
Agent in UAE:	Al Nawras Medi-Lab Supplies
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Short Description of the Technology:	<p>The MyCare Oncology Busulfan Assay Kit is a rapid, fully automated immunoassay kit designed to simplify and streamline busulfan therapeutic drug monitoring (TDM). It is intended for the in vitro quantitative measurement of busulfan in human plasma on automated clinical chemistry analyzers.</p> <p>Busulfan is an alkylating agent used in allogeneic hematopoietic stem cell transplantation for various malignant and nonmalignant disorders. It has a narrow therapeutic index, meaning that there is a small difference between the dose that is effective and the dose that is toxic. TDM is used to measure busulfan levels in the blood during treatment to ensure that they are within the target range. This helps to reduce the risk of both under-dosing and over-dosing.</p> <p>The MyCare Oncology Busulfan Assay Kit is a fast and accurate test that can be performed in less than 30 minutes. It is also easy to use, requiring only a small sample of plasma. This makes it a valuable tool for clinicians who need to monitor busulfan levels in their patients.</p>
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Health Technology Assessment Team Recommendation:	Approve
Summary of Review:	
<p>The My Care Busulfan Assay plays a critical role in maintaining busulfan exposure within the optimal range, helping to mitigate these potential risks and improve the overall success of transplant procedures.</p> <p>The MyCare Busulfan Assay represents a significant advancement in busulfan monitoring, promising improved healthcare delivery and patient care.</p>	
Advantages	Disadvantages
Regulatory Approvals: It holds both CE Mark and ISO13485.	Increased risk of infection
The assay offers a cost-effective solution,	Bruising and bleeding and Breathlessness

contributing to more efficient healthcare practices.	
The kit offers a quick result (within 30 minutes), precise.	
No reagent preparation or sample pretreatment is required, simplifying the testing procedure.	

We recommend an **approval this technology** with the following conditions:

1. MyCare Oncology Busulfan Assay Kit / BSF-RGT.
2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
3. Provision of regular updates and reports about the product to DOH upon request.

technology Image





Population, setting and intended user for Technology “My Care Oncology Busulfan.”

- **Population/ Intended User;**
 - A patient with multiple myeloma who is receiving busulfan conditioning prior to HSCT (haematopoietic stem cell transplantation).
 - A patient with sickle cell disease who is receiving busulfan conditioning prior to HSCT.
 - A patient with aplastic anemia who is receiving busulfan conditioning prior to HSCT.
 - A patient with thalassemia who is receiving busulfan conditioning prior.
- **To be performed by:**
 - Medical Lab Technology,
- **Clinical Setting:**
 - Hospitals, Medical laboratories.
- **Condition of use:**
 - NA
- **Exclusion criteria:**
 - pregnant women.
 - Terminal illness