

 Equipment Out of Calibration	Dept:	324316
	Dept Name	Stem Cell Transplant and Cellular Therapy Program
	Effective Date:	4/16/20
	Revised Date:	4/16/20
Name & Title: CLIA Laboratory Medical Director	Contact:	JH Simmons/C Warren
Signature: G. Pomper	Date:	4/10/20

1. General Procedure Statement:

A. Purpose: Each piece of equipment has an individual procedure that describes what to do if the equipment is not functioning, including identifying backup equipment. This procedure describes actions to take in the event that equipment is functioning, but maintenance values are not within the established acceptable range for operation.

B. Responsible Department/Scope:

- i. Procedure owner/Implementer: Julie H. Simmons/ C. Warren/Emily H. Wilson
- ii. Procedure prepared by: Emily H. Wilson
- iii. Who performs procedure: Department staff/management

C. Definitions: n/a

D. Sections: I. Equipment Out-of-Calibration

E. Protocols:

- Products processed with out-of-calibration equipment are only infused at the discretion of the medical director.

2. Procedure:

Chemical Risk Assessment: None
 Biological Risk Assessment: Low
 Protective Equipment: None

Supplies: n/a

Reagents: n/a

Equipment: Applies to all equipment

Specimen Requirements: n/a

SECTION I. EQUIPMENT OUT-OF-CALIBRATION

STEPS	INSTRUCTIONS	CHANGE/ APPROVAL
1.0	When any equipment is found to be out of calibration, immediately notify management and the medical director.	
2.0	Place a sign on the piece of equipment that reads “DO NOT USE”.	
3.0	Refer to procedure specific to the piece of equipment to identify backup equipment to use during the out-of-calibration equipment’s downtime.	
4.0	Initiate an Occurrence Report.	
5.0	Contact Biomedical Engineering to initiate service on the out-of-calibration equipment.	
6.0	Identify when last calibration was performed on piece of equipment.	
7.0	Identify all products processed with the out-of-calibration equipment since the time of its last correct calibration and list on the Occurrence Report.	
8.0	If possible, use backup equipment to verify results in question for patient product.	
9.0	If out-of-calibration equipment results in incorrect values for product that cannot be verified, (example: product is frozen) document on the Occurrence Report and file a copy in the patient chart. 9.1 Note the out-of-calibration value on the Technical Release Criteria Checklist.	
10.0	The Technical Release Criteria Checklist describing the out-of-calibration equipment used must be signed by the medical director prior to transplant. 10.1 Products processed with out-of-calibration equipment are only infused at the discretion of the medical director.	
11.0	When equipment is back in service, remove “DO NOT USE” signage and obtain any reports generated by Biomedical Engineering.	
	EXPECTED OUTCOME RESULTS: Products should be identified that were processed with out-of-calibration equipment.	
	ACCEPTABLE RANGES: n/a	

3. Review/Revised/implemented:

All procedures must be reviewed according to the document change control policy.

All new procedures and procedures that have major revisions must be signed by the CLIA Director.

All reviewed procedures and procedures with minor revisions can be signed by the designated section medical Director or designee

4. Related Procedures: n/a

5. References: n/a

6. Attachments: n/a

7. Revised/Reviewed Dates and Signatures:

See Document Change Control stored electronically in Title 21