STEM CELL LABORATORY (STCL)

DOCUMENT NUMBER: STCL-EQUIP-011 FRM2

DOCUMENT TITLE:
OOS - Product Sterility FRM2

DOCUMENT NOTES:

Document Information

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Control Information

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STCL-EQUIP-011 FRM2
OOS –PRODUCT STERILITY

Product ISBT Barcode	Document Number

Description of Investigation
In accordance with STCL-EQUIP-011, the sterility of a processed product is required to be "negative". When a blood culture bottle is flagged by the BacT 3D Alert as positive, a product investigation must be documented. This form is utilized to document a thorough and consistent investigation by applicable laboratory personnel, laboratory supervisor/manager, and members of the team.

Positive Culture Discovery Date:		Select Cellular Therapy Product:	
Date of Sterility Testing:		Product Description:	
Discovered By:		Select Processing:	
Incubator Serial Number:		Study:	
Aerobic	**Anaerobic**		
Bottle Lot #:	Bottle Lot #:	**Recipient**	**Donor**
Bottle Exp.:	Bottle Exp.:	Initials:	Initials:
Bottle ID #:	Bottle ID #:	MR #:	MR #:
Days to detection:	Days to detection:	Physician Notified:	
Gram Stain: Organism:	Gram Stain: Organism:	Was cellular product infused? If yes, date of infusion:	

Processing Laboratory Assessment	**Yes**	**No**
1. Were product samples and BacT Alert bottles stored correctly and used prior to expiration date? If **No**, please explain in additional information section below.		
2. Was the BacT Alert performance acceptable during the incubation? If **No**, please explain in additional information section below.		
3. Did the BacT Alert incubation temperatures meet acceptance criteria during length of incubation? If **No**, please explain in additional information section below.		
4. Were all instruments and equipment used in the process calibrated and/or maintained (passed QC) as required? If **No**, please explain in additional information section below.		
5. Was all staff who participated in the processing and/or cryopreservation of the cellular therapy product current on their training requirements? If **No**, please explain in additional information section below.		
6. Were there any laboratory cleaning or environmental controls (BSC) issues reported during the time of processing? If **Yes**, please explain in additional information section below.		

STCL-EQUIP-011 FRM2
OOS –PRODUCT STERILITY

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Processing Laboratory Assessment	Yes	No
7. Is the BacT Alert assay considered valid?		
8. Was the positive bottle(s) sent to Duke Clinical Microbiology for ID and Sensitivity? If **No**, please explain in additional information section below.		
9. Did the subculture exhibit growth and facilitate organism(s) identity? If **Yes**, list all organisms identified below: Organism ID: Sensitivity: Organism ID: Sensitivity: Organism ID: Sensitivity:		

Facility EM Data	Yes	No
10. Did the lot of BacT Alert bottles pass verification testing with documented "Negative" sterility prior to QA release? If **No**, please explain in additional information section below.		
11. Were any events associated with the collection of this product? If **Yes**, Event #:		
12. Were any events associated with the processing at STCL or with the manufacturing of this product outside the STCL? If **Yes**, Event #:		
13. Were there any deviations (e.g., BSC filter failures) in the last 6 months? If **Yes**, Deviation #:		
14. Were any deviations noted in external vendor cleaning during the past 6 months? If **Yes**, Deviation #:		
15. Were any deviations noted in internal cleaning procedures during the past 6 months? If **Yes**, Deviation #:		
16. Has this organism been identified on any processed product positive sterility results in the past 3 months (starting from month of cellular therapy product processing)? If **Yes**, list all occurrences below and explain on the corrective action section below. Date: Organism ID: Date: Organism ID: Date: Organism ID:		
17. Has the most recent EM testing of the associated BSC indicated a lack of microbial control or any concerns about the contaminants? If **Yes**, please describe in additional information section below.		

STCL-EQUIP-011 FRM2
OOS –PRODUCT STERILITY

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Root Cause and Additional Information

Is Root cause of OOS identifiable?
If yes, please check all that apply.

- □ BacT Alert bottle Supply Contamination
- □ Other Supply Contamination (i.e. Hespan, Sepax kit)
- □ BacT Alert malfunction
- □ Suspected Birthing process contamination
- □ Sample Compromised during processing
- □ Sample Compromised during collection
- □ Sample Compromised during manufacturing
- □ Training/SOP not followed
- □ Unable to determine
- □ Other, explain below:

If no root cause identified, this field can be used to provide additional information.

Risk/Corrective Action	Yes	No
18. Risk to other product's quality? If **Yes**, Event #:		
19. Were any corrective or preventive actions identified as a result of this OOS? If **Yes**, please describe in additional information section above.		

STCL-EQUIP-011 FRM2
OOS –PRODUCT STERILITY

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ATTACHMENTS

Signature Manifest

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STCL-EQUIP-011 FRM2 OOS - Product Sterility

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Document Release

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