Applicable Sites: Cambridge USA

Affected Areas: Manufacturing

RECORD ISSUANCE	
Product: BALTIMORE ANTI-BCMA02 CAR LLV SAP: 500250	Scale: 40 CS10 Location: ThermoFisher VVS Cambridge

This document has been Witnessed to be a legible, complete, and accurate reproduction of the current effective version of the Master Document.

Print _____ Signature _____ _____
Quality Assurance Quality Assurance Date

Print _____ Signature _____ _____
Manufacturing Manufacturing Date

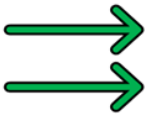
PERSONNEL IDENTIFICATION			
Print Name	**Title**	**Signature**	**Initials**

PERSONNEL IDENTIFICATION			
Print Name	**Title**	**Signature**	**Initials**

PERSONNEL IDENTIFICATION			
Print Name	**Title**	**Signature**	**Initials**

TABLE OF CONTENTS

OPERATIONAL NOTES AND ABBREVIATIONS

Symbol	Symbol Description
	Used when conditions exist that should be avoided or mitigated to prevent **personnel injury.**
	Caution, Hazard, or Safety warning Bio Hazard Processing – PPE must be worn at all times throughout biological hazard conditions, including viral positive processing.
	A pre-selected step in a procedure that identifies a point beyond which **work may not proceed until the required action is performed.**
	Provides user with additional information that aids in performance of an action.
	**Critical Step:** Used to call attention to any human action that will trigger immediate, irreversible, intolerable harm to product, if action(s) is(are) performed improperly.
	**Time Critical Step:** Step has time critical properties.
	**Attach to Batch Record**: A printout or supporting documentation is required to be attached to the record.
	**Decision Point**: A decision is required prior to forward processing
	**Parallel Process:** Process steps may be performed concurrently.

1.0 PASSAGE 5 (WI-000129569)

1.1. PASSAGE 5 (WI-000129569)

1.1.1 GROWTH MEDIA WARMING (WI-000129569)

RECORD AND ROOM PREPARATION		
Parameter	**Actual**	**Checked Initials/Date**
Thaw through P5 Record #	MMD-000123086-_____	
Production Room #	Room #	

EQUIPMENT FOR PASSAGE 5 MEDIA WARMING			
Equipment	**Equipment ID**	**Performed Initials/Date**	**Checked Initials/Date**
Incubator (SOP-000130281)			
VERIFY that all equipment and rooms listed above were cleaned and have been standardized/calibrated according to listed SOPs.			
VERIFY that line clearance is complete, and equipment is changed-in per SOP-000130371 and tagged for use per SOP-000130280.			

2-8ºC MATERIALS FOR MEDIA WARMING							
Material Name	**Material Number**	**Quantity Needed**	**Quantity Used**	**Batch**	**Expiry**	**Performed Initials/Date**	**Checked Initials/Date**
Growth Media	☐ MMD-000123096 (500221) or ☐ MMD-000132990 (503666)	2 x 24 kg		_____			

PROCEDURE FOR MEDIA WARMING				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
1. Incubator ID#	Record			
2. Incubator Temperature	36.0 – 38.0°C	°C		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
3. Growth media warming start Date/Time	Record	/		

1.1.2 PASSAGE 5 PREPARATION (WI-000129569)

RECORD AND ROOM PREPARATION		
Parameter	**Actual**	**Checked Initials/Date**
Production Room #	Room #	

EQUIPMENT FOR PASSAGE 5			
Equipment	**Equipment ID**	**Performed Initials/Date**	**Checked Initials/Date**
Biosafety Cabinet (SOP-000130283)			
HyPerforma Rocker (SOP-000129464)			
Incubator (SOP-000130281)			
VERIFY that all equipment and rooms listed above were cleaned and have been standardized/calibrated according to listed SOPs.			
VERIFY that line clearance is complete, and equipment is changed-in per SOP-000130371 and tagged for use per SOP-000130280.			

1.1.3 PASSAGE 5 MATERIAL (WI-000129569)

AMBIENT MATERIALS FOR PASSAGE 5 PREP							
Material Name	**Material Number**	**Quantity Needed**	**Quantity Used**	**Batch**	**Expiry**	**Performed Initials/Date**	**Checked Initials/Date**
50 L Rocker BPC	115558	2					
CS10	111694	40					
Cell Stack Transfer Caps	□112258 □121060	40					
Cell Stack Filter Caps	□112257 □121091	40					
AQG to MPC Insert	□ 114084 □ 113154 □ 413167 □ 113520	2					

PASSAGE 5 VISUAL INSPECTION OF MATERIALS				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
Visual inspection of Rocker 50 L BPC	Pass	□ Pass □ Fail		
Visual inspection of CS10 cell stacks	Pass	□ Pass □ Fail		

Operator in BSC	Performed Initials/Date	Witnessed Initials/Date
Operator performing activities in the BSC.		N/A
BEGIN Environmental Monitoring per SOP-000130321 and SOP-000130323 and document in form FORM-000130929.		N/A

ROCKER BPC ASSEMBLY PREPARATION AND INSTALLATION		
Parameter	**Performed Initials/Date**	**Checked Initials/Date**
CONFIRM 50L Rocker BPC (x2) connected to AQG to MPC connector (x2).		
Rocker BPC Installation #1		
Rocker BPC Installation #2		

PASSAGE 5 CS10 PREPARATION				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
1. Incubator ID#1 (CS10 #1 – #20)	Record			
2. Incubator ID#2 (CS10 #21 – #40)	Record			

ENVIRONMENTAL MONITORING	Performed Initials/Date	Witnessed Initials/Date
END Environmental Monitoring per SOP-000130321 and SOP-000130323 and document in form FORM-000130929. ☐ N/A if settling plates have not reached their 4hr maximum and manufacturing operations are continuous.		N/A

1.1.4 TRANSFER TO ROCKER BPC #1 (WI-000129569)

EQUIPMENT FOR TRANSFER TO ROCKER BPC			
Equipment	**Equipment ID**	**Performed Initials/Date**	**Checked Initials/Date**
Terumo Welder (SOP-000130295)			
TableTop Scale (SOP-000130289)			
Peristaltic Pump Masterflex 77200-62 (SOP-000130279)			
XS/S Clipster (SOP-000130478)			
L Clipster (SOP-000130478)			
VERIFY that all equipment and rooms listed above were cleaned and have been standardized/calibrated according to listed SOPs.			
VERIFY that line clearance is complete, and equipment is changed-in a per SOP-000130371 and tagged for use per SOP-000130280.			

AMBIENT MATERIALS FOR PASSAGE 5 SEEDING							
Material Name	**Material Number**	**Quantity Needed**	**Quantity Used**	**Batch**	**Expiry**	**Performed Initials/Date**	**Checked Initials/Date**
Mobius In/Out Manifold	□ 412253 □ 413166 □ N/A	2					
CS10 Feed Manifold	☐ 412251 ☐ 413169	4					
AQG 3/8” ID Tee Connector Or 3/8” AQG Wye Connector	☐ 113987 ☐ 114052	2					
AQG Reducer w/Plug	413166	2					
Custom Tubing Set, 36" L	☐ 113981 ☐ 113983 ☐ 113984	2					

PROCEDURE FOR TRANSFER TO ROCKER BPC #1				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
HyPerforma Rocker Equipment ID #1	Record			
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Growth Media Batch # / Expiration Date	□ MMD-000123096 (500221) or □ MMD-000132990 (503666)	_____/_____		
2. Growth media warming end Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
3. Total growth media warming time	12 – 24 hr	hrs mins Section 1.1.4, Step 2 – Section 1.1.1, Step 3		

PROCEDURE FOR ROCKER PARAMETER CHECK PRIOR TO WEIGHT MEASUREMENT				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
Rocker Stop Angle	0.0 °	°		

Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
4. Weight of Growth Media Added to Rocker BPC	22.0 kg (21.5– 22.5 kg)	kg		

PROCEDURE FOR ROCKER PARAMETER CHECK				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
Rocker Agitation Mode	1			
Rocker Speed Setpoint	10 RPM	RPM		

PROCEDURE FOR TRANSFER TO ROCKER BPC #1				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
5. Passage 5 Seed Bottle #1 used	Record Label			
6. Transfer of Seed Bottle #1 Contents Date/Time	Record	/		
7. Pump Speed	300 RPM (280 – 350 RPM)	RPM		
8. Final Rocker Weight	23.1 kg (22.6 – 23.6 kg)	kg		

	CONTINUE HyPerforma Rocker Mixing until CS10s #14.

PROCEDURE FOR ROCKER PARAMETER CHECK AFTER STARTING ROCKER				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
Rocker Angle Setpoint	6.0 °	°		

PROCEDURE FOR TRANSFER TO ROCKER BPC #1				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
9. Mixing after Seed Bottle Addition Start Date/Time	Record	/		

MFG Page Review Initials / Date		QA Page Review Initials / Date	

1.1.5 INOCULATION AND INCUBATION OF CS10 #1-20 (WI-000129569)

PROCEDURE FOR TRANSFER TO ROCKER BPC #1				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Pump ID	Record			
2. Pump Speed for Cell Transfer	300 RPM (280 – 350 RPM)	RPM		
3. Seeding Start CS10 #1 Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
4. HyPerforma Rocker Mix Time prior to seeding	10 – 90 min	min Section 1.1.5 step 3 – Section 1.1.4 step 9		

PROCEDURE FOR CS10S #1-20 INCUBATION				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
5. Incubator Equipment ID	Record			
6. Incubator Temperature	36.0 – 38.0°C	°C		
7. Incubator % CO2	4.0 – 6.0 %	%		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
8. CS10 # 1 Placed in Incubator Date/Time	Record	/		
9. CS10 # 10 Placed in Incubator Date/Time	Record	/		
10. CS10 # 11 Placed in Incubator Date/Time	Record	/		
11. CS10 # 20 Placed in Incubator Date/Time	Record	/		

PROCEDURE FOR ROCKER PARAMETER CHECK PRIOR TO CS10 #15				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
Rocker Stop Position	BACK			
Rocker Stop Angle	12.0 °	°		

1.1.6 TRANSFER TO ROCKER BPC #2 (WI-000129569)

PROCEDURE FOR TRANSFER TO ROCKER BPC #2				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
HyPerforma Rocker Equipment ID #2	Record			
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Growth Media Batch # / Expiration Date	□ MMD-000123096 (500221) or □ MMD-000132990 (503666)	_____/_____		
2. Growth media warming end Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
3. Total growth media warming time	12 – 24 hr	hr mins Section 1.1.6, Step 2 – Section 1.1.1, Step 3		

PROCEDURE FOR ROCKER PARAMETER CHECK PRIOR TO WEIGHT MEASUREMENT				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
Rocker Stop Angle	0.0 °	°		

Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
4. Weight of Growth Media Added to Rocker BPC	22.0 kg (21.5 – 22.5 kg)	kg		

PROCEDURE FOR ROCKER PARAMETER CHECK				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
Rocker Agitation Mode	1			
Rocker Speed Setpoint	10 RPM	RPM		

PROCEDURE FOR TRANSFER TO ROCKER BPC #2				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
5. Passage 5 Seed Bottle #2 used	Record Label			
6. Transfer of Seed Bottle #2 Contents Date/Time	Record	/		
7. Pump Speed	300 RPM (280-350 RPM)	RPM		
8. Final Rocker Weight	23.1 kg (22.6 – 23.6 kg)	kg		

CONTINUE HyPerforma Rocker Mixing until CS10 #34 is filled.

PROCEDURE FOR ROCKER PARAMETER CHECK AFTER STARTING ROCKER				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
Rocker Angle Setpoint	6.0 °	°		

PROCEDURE FOR TRANSFER TO ROCKER BPC #2				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
9. Mixing after Seed Bottle Addition Start Date/Time	Record	/		

MFG Page Review Initials / Date		QA Page Review Initials / Date	

1.1.7 INOCULATION AND INCUBATION OF CS10 #21-40 (WI-000129569)

PROCEDURE FOR TRANSFER TO ROCKER BPC #2				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Pump ID	Record			
2. Pump Speed for Cell Transfer	300 RPM (280 – 350 RPM)	RPM		
3. Seeding Start CS10 #21 Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
4. HyPerforma Rocker Mix Time prior to seeding	10 – 90 min	min Section 1.1.7 Step 3 – Section 1.1.6 Step 9		

	RECORD weight of Cell Suspension transferred to each CS10 in Attachment 1.

PROCEDURE FOR CS10S #21-40 INCUBATION (CONT.)				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
5. Incubator Equipment ID	Record			
6. Incubator Temperature	36.0 – 38.0°C	°C		
7. Incubator % CO2	4.0 – 6.0 %	%		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
8. CS10 # 21 Placed in Incubator Date/Time	Record	/		
9. CS10 # 30 Placed in Incubator Date/Time	Record	/		
10. CS10 # 31 Placed in Incubator Date/Time	Record	/		
11. CS10 # 40 Placed in Incubator Date/Time	Record	/		

PROCEDURE FOR ROCKER PARAMETER CHECK PRIOR TO CS10 #35				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
Rocker Stop Position	BACK			
Rocker Stop Angle	12.0 °	°		

Action	**Performed Initials/Date**	**Checked Initials/Date**
PERFORM SAP Batch Lot Verification for materials consumed in this section per SOP-000130022.		

2.0 TRANSFECTION (WI-000129565)

2.1 TRANSFECTION MEDIA WARMING (WI-000129565)

2.1.1 TRANSFECTION MEDIA WARMING (WI-000129565)

RECORD AND ROOM PREPARATION		
Parameter	**Actual**	**Performed Initials/Date**
Production Room #	Room #	

EQUIPMENT FOR TRANSFECTION MEDIA WARMING			
Equipment	**Equipment ID**	**Performed Initials/Date**	**Checked Initials/Date**
Incubator (SOP-000130281)			
VERIFY that all equipment and rooms listed above were cleaned and have been standardized/calibrated according to listed SOPs.			
VERIFY that line clearance is complete, and equipment is changed-in a per SOP-000130371 and tagged for use per SOP-000130280.			

MATERIALS FOR MEDIA WARMING							
Material Name	**Material Number**	**Quantity Needed**	**Quantity Used**	**Batch**	**Expiry**	**Performed Initials/Date**	**Checked Initials/Date**
Transfection Media	□ MMD-000123097 (500222) or □ MMD-000132993 (503678)	4 x 11 kg		_____			

PROCEDURE FOR MEDIA WARMING				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
1. Incubator Temperature	36.0 – 38.0°C	°C		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
2. Transfection Media Warming Start Date/Time	Record	/		

2.1.2 PRODUCTION ROOM AND EQUIPMENT (WI-000129565)

RECORD AND ROOM PREPARATION		
Parameter	**Actual**	**Performed Initials/Date**
Production Room #	Room #	

EQUIPMENT FOR TRANSFECTION			
Equipment	**Equipment ID**	**Performed Initials/Date**	**Checked Initials/Date**
Biosafety Cabinet (SOP-000130283)			
TableTop Scale (SOP-000130289)			
Size 24 Peristaltic Pump w/ Time-Dispense Mode for BSC (SOP-000130279) Masterflex 77200-62			
Incubator (SOP-000130281)			
Micropipettor (SOP-000129639)			
Stir Plate (SOP-000130526)			
Terumo Welder (SOP-000130295)			
HyPerforma Rocker (SOP-000129464)			

Equipment	Equipment ID	Performed Initials/Date	Checked Initials/Date
Water Bath (SOP-000130287)			
XS/S Clipster (SOP-000130478)			
L Clipster (SOP-000130478)			
VERIFY that all equipment and rooms listed above were cleaned and have been standardized/calibrated according to listed SOPs.			
VERIFY that line clearance is complete, and equipment is changed-in per SOP-000130371 and tagged for use per SOP-000130280.			

2.1.3 TRANSFECTION MATERIAL (WI-000129565)

AMBIENT MATERIALS FOR TRANSFECTION							
Material Name	**Material Number**	**Qty Needed**	**Qty Used**	**Batch**	**Expiry**	**Performed Initials/Date**	**Checked Initials/Date**
3L Spinner Flask	110129	4					
Spinner Flask Diptube	411682	4					
Spinner Flask Transfer Cap	112259	4					
Plasmid Transfer Tubing Assembly	□ 412259 □ 413135	4					
Mobius In/Out Tubing assembly	□ 412253 □ 413166	4					
CS10 feed Manifold	□ 412251 □ 413169	10					
20L Rocker BPC	115557	4					
AQG 3/8” ID Tee Connector 3/8” AQG Wye Connector	□ 113987 □ 114052	4					
AQG to MPC Insert	□ 114084 □ 113154 □ 413167 □ 113520	4					
1L PETG Bottle	□ 110042 □ 115348	4					
1L WFI	411723	4					
AQG Reducer w/Plug	413166	4					

MFG Page Review Initials / Date		QA Page Review Initials / Date	

AMBIENT MATERIALS FOR TRANSFECTION							
Material Name	**Material Number**	**Qty Needed**	**Qty Used**	**Batch**	**Expiry**	**Performed Initials/Date**	**Checked Initials/Date**
Custom Tubing Set, 36" L	☐ 113981 ☐ 113983 ☐ 113984	4					
2x HBS Buffer Aliquots (900g)	☐ MMD-000123100 (500233) or ☐ MMD-000132996 503676	4		_____			
2M Calcium Chloride Aliquots (130g)	☐ MMD-000123101 (500234) or ☐ MMD-000132997 (503674)	4		_____			
50mL Conical Tube	110180	N/A	N/A				
20L BPC Bag	110060	4					
ArtBarrier Pipette Tips	112014	N/A	N/A				
5mL serological pipette	110151	N/A	N/A	□ N/A	□ N/A		
10mL serological pipette	110152	N/A	N/A	□ N/A	□ N/A		
50mL serological pipette	110154	N/A	N/A	□ N/A	□ N/A		

2.1.4 PLASMID CALCULATIONS (WI-000129565)

DRY ICE MATERIALS FOR PLASMID CALCULATIONS							
Material Name	**Material Number**	**Quantity Needed**	**Quantity Used**	**Batch**	**Expiry**	**Performed Initials/Date**	**Witnessed Initials/Date**
Vial Plasmid p633	□ 411717 or □ 413453 or □ 413458	1					
Vial Plasmid YN15	□ 411718 or □ 413452 or □ 413459	1					
Vials Plasmid HPV275	□413401 or □ 413456	6					
Vials Plasmid pBB-BCMA02	□ 412692 or □ 413460	8					

1. Plasmid p633 Volume Calculation

	1.8 mg	÷	**mg/mL**	=	**mL**
	Target Plasmid p633 mass per Spinner		**Plasmid Concentration per Cert of Analysis**		**Volume of Plasmid p633 Required per 3L Spinner Flask (A) (X.X)**

Performed Initials/Date		**Checked Initials/Date**	

2. Plasmid YN15 Volume Calculation

	0.9 mg	÷	**mg/mL**	=	**mL**
	Target Plasmid YN15 mass per Spinner		**Plasmid Concentration per Cert of Analysis**		**Volume of Plasmid YN15 Required per 3L Spinner Flask (B) (X.X)**

Performed Initials/Date		**Checked Initials/Date**	

3. Plasmid HPV275 Volume Calculation

	11.2 mg	÷	**mg/mL**	=	**mL**
	Target Plasmid HPV275 mass per Spinner		**Plasmid Concentration per Cert of Analysis**		**Volume of Plasmid HPV275 Required per 3L Spinner Flask (C) (X.X)**

Performed Initials/Date		**Checked Initials/Date**	

4. Plasmid pBB-BCMA02 Volume Calculation

	14.2 mg	÷	**mg/mL**	=	**mL**
	Target Plasmid pBB-BCMA02 mass per Spinner		**Plasmid Concentration per Cert of Analysis**		**Volume of Plasmid pBB-BCMA02 Required per 3L Spinner Flask (D) (X.X)**

Performed Initials/Date		**Checked Initials/Date**	

Signature Requirement	**Supervisor/Designee Signature / Date**
Supervisor or Designee Checked that all calculations for inoculation are correct.	

2.1.5 PLASMID THAWING (WI-000129565)

PROCEDURE FOR PLASMID THAWING				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Water Bath Temperature	29.0°C (28.0 – 30.0°C)	°C		
2. Plasmid p633 Thaw Start Date/Time	Record	/		
3. Plasmid p633 Thaw End Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
4. Total Plasmid p633 Thaw Duration	4 – 12 min	mins Section 2.1.5, Step 3 – Section 2.1.5, Step 2		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
5. Plasmid YN15 Thaw Start Date/Time	Record	/		
6. Plasmid YN15 Thaw End Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
7. Total Plasmid YN15 Thaw Duration	2 – 12 min	mins Section 2.1.5, Step 6 – Section 2.1.5, Step 5		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
8. Plasmid HPV275 Thaw Start Date/Time	Record	/		
9. Plasmid HPV275 Thaw End Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
10. Total Plasmid HPV275 Thaw Duration	7 – 19 min	mins Section 2.1.5, Step 9 – Section 2.1.5, Step 8		

Parameter	Control	Actual	Performed Initials/Date	Witnessed Initials/Date
11. Plasmid pBB-BCMA02 Thaw Start Date/Time	Record	/		
12. Plasmid pBB-BCMA02 Thaw End Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
13. Total Plasmid pBB-BCMA02 Thaw Duration	7 – 18 min	mins Section 2.1.5, Step 12 – Section 2.1.5, Step 11		

3.0 TRANSFECTION GROUP # 1 (WI-000129565)

3.1. COMPONENT WARMING (GROUP #1) (WI-000129565)

3.1.1 COMPONENT WARMING (GROUP # 1) (WI-000129565)

AMBIENT MATERIALS FOR COMPONENT WARMING (GROUP #1)							
Material Name	**Material Number**	**Quantity Needed**	**Quantity Used**	**Batch**	**Expiry**	**Performed Initials/Date**	**Checked Initials/Date**
2x HBS Buffer Aliquots	☐ MMD-000123100 (500233) or ☐ MMD-000132996 (503676)	1		_____			
2M Calcium Chloride Aliquots	☐ MMD-000123101 (500234) or ☐ MMD-000132997 (503674)	1		_____			
1L WFI Bottles	N/A	1					

PROCEDURE FOR COMPONENT WARMING				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Water Bath Temperature	29.0°C (28.0 – 30.0°C)	°C		
2. Component Warming Start Date/Time	Record	/		
3. Component Warming End Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
4. Total Component Warming Duration	≥ 30 min	mins Section 3.1.1 Step 3 – Section 3.1.1, Step 2		

PROCEDURE FOR X4 ROCKER BPC ASSEMBLY		
Parameter	**Performed Initials/Date**	**Witnessed Initials/Date**
Operator performing activities in the BSC.		N/A
BEGIN Environmental Monitoring per SOP-000130321 and SOP-000130323 and document in form FORM-000130929. ☐ N/A if settling plates have not reached their 4hr maximum and manufacturing operations are continuous.		N/A

PROCEDURE FOR x4 ROCKER BPC ASSEMBLY		
Parameter	**Performed Initials/Date**	**Witnessed Initials/Date**
CONFIRM Rocker BPC (x4) connected to AQG to MPC connectors (x4)		

3.1.2 TRANSFECTION MEDIA MIX (GROUP # 1) (WI-000129565)

ROCKER BPC INSTALLATION		
Parameter	**Performed Initials/Date**	**Witnessed Initials/Date**
CONFIRM Installation of Rocker BPC #1.		

PROCEDURE FOR TRANSFECTION MEDIA MIX GROUP # 1				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
HyPerforma Rocker Equipment ID	Record			
Transfection Media Batch# / Expiration Date	□ MMD-000123097 (500222) or □ MMD-000132993 (503678)	_____/_____		
1. Transfection Media Removed from incubator Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
2. Total Transfection Media Warming Duration	12 – 24 hrs	hrs mins Section 3.1.2 Step 1 – Section 2.1.1, Step 2		

PROCEDURE FOR ROCKER PARAMETER CHECK PRIOR TO WEIGHT MEASUREMENT				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
Rocker Stop Angle	0.0 °	°		

Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
3. Weight of Transfection Media added to Rocker BPC.	9.95 kg (9.85 – 10.05 kg)	kg		

PROCEDURE FOR ROCKER PARAMETER CHECK				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
Rocker Agitation Mode	1			
Rocker Speed Setpoint	10 RPM	RPM		

PROCEDURE FOR ROCKER PARAMETER CHECK AFTER STARTING ROCKER				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
Rocker Angle Setpoint	6.0 °	°		

3.1.3 COMPONENT ADDITION TO 3L SPINNER FLASK (GROUP #1) (WI-000129565)

Operator in BSC	Performed Initials/Date	Witnessed Initials/Date
Operator performing activities in the BSC.		N/A
END Environmental Monitoring per SOP-000130321 and SOP-000130323 and document in form FORM-000130929. ☐ N/A if settling plates have not reached their 4hr maximum and manufacturing operations are continuous.		N/A
BEGIN Environmental Monitoring per SOP-000130321 and SOP-000130323 and document in form FORM-000130929. ☐ N/A if settling plates have not reached their 4hr maximum and manufacturing operations are continuous.		N/A

PROCEDURE FOR COMPONENT ADDITION TO 3L SPINNER FLASK GROUP # 1				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Weight of WFI added to 1L PETG Bottle	716 g (714 – 718 g)	g		
2. Weight of 2x HBS per 3L Spinner Flask	856 g (854 – 858 g)	g		

3.1.4 PLASMID ADDITION TO WFI (GROUP # 1) (WI-000129565)

Parameter	Control	Actual	Performed Initials/Date	Witnessed Initials/Date
1. Volume of Plasmid p633 added to 1L PETG Bottle	**Section 2.1.4, Step 1(A)**	mL		
2. Volume of Plasmid YN15 added to 1L PETG Bottle	**Section 2.1.4, Step 2(B)**	mL		
3. Volume of Plasmid HPV275 added to 1L PETG Bottle	**Section 2.1.4, Step 3(C)**	mL		
4. Volume of Plasmid pBB-BCMA02 added to 1L PETG Bottle	**Section 2.1.4, Step 4(D)**	mL		
5. Weight of 2M Calcium Chloride Added to 1L PETG Bottle	130 g (125 – 135 g)	g		

3.1.5 TRANSFER PLASMID SOLUTION TO 3L SPINNER FLASK (GROUP # 1) (WI-000129565)

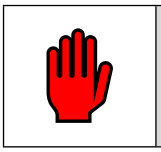
PROCEDURE FOR TRANSFER PLASMID SOLUTION TO 3L SPINNER FLASK GROUP # 1				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Spinner Flask Mixing Speed	50 RPM (49 – 51 RPM)	RPM		
2. Pump Dispense Time	30 sec (CPP) (25 – 35 sec)	sec		
3. Pump Setpoint	545 RPM (CPP)	RPM		
4. Plasmid Cocktail Mix Start Date/Time	Record	/		
5. Plasmid Cocktail mixing end Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
6. Total Plasmid Mix Duration	5 min (1 – 10 min)	mins Section 3.1.5 Step 5 – Section 3.1.5 Step 4		

3.1.6 TRANSFER PLASMID COCKTAIL TO MEDIA (GROUP # 1) (WI-000129565)

PROCEDURE FOR TRANSFER PLASMID COCKTAIL TO MEDIA GROUP # 1				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Pump Speed	320 RPM (280 – 350 RPM)	RPM		
2. Transfection Mix Hold End / Transfer to Media Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
3. Transfection Mix Hold Duration	0 – 10 min	mins Section 3.1.6 Step 2 – Section 3.1.5 Step 5		

3.1.7 CS10 TRANSFECTION AND INCUBATION (GROUP # 1) (WI-000129565)

PROCEDURE FOR CS10 REMOVAL FROM INCUBATOR				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. CS10 #1 Removed from Incubator Date/Time	Record	/		
2. CS10 #1 Batch #	MMD-000123092-XXXXXX	MMD-000123092-_____		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
3. Total Passage 5 Incubation Duration	Target: 76 hrs (74 - 80 hrs)	hrs mins Section 3.1.7, Step 1 – Section 1.1.5, Step 8		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
4. Visual inspection of Cell Stacks	Record	Pass / Fail		



NOTIFY a Supervisor or designee if Visual inspection for Damage and Contamination if the cell culture fails.

PROCEDURE FOR CS10 TRANSFECTION				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
5. Pump Speed for Waste Transfer	300 RPM	RPM		
6. Pump Speed for Feed Transfer	210 RPM	RPM		
7. Rocker Transfer Start Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
8. Total HyPerforma Rocker Mix Duration prior to Transfection	10 – 60 min	mins Section 3.1.7 Step 7 – Section 3.1.6 Step 2		

RECORD weight of Transfection mixture added to each CS10 in Attachment 2.

PROCEDURE FOR TRANSFECTION GROUP #1 INCUBATION				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
9. Incubator Equipment ID	Record			
10. Incubator Temperature	36.0 – 38.0°C	°C		
11. Incubator % CO2	4.0 – 6.0 %	%		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
12. CS10 # 1 Incubation Start Date/Time	Record	/		
13. CS10 # 10 Incubation Start Date/Time	Record	/		

PROCEDURE FOR STOPPING ROCKER PARAMETER CHECK				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
Rocker Stop Position	BACK			
Rocker Stop Angle	12.0 °	°		

4.0 TRANSFECTION GROUP #2 (WI-000129565)

4.1. COMPONENT WARMING (GROUP #2) (WI-000129565)

4.1.1 COMPONENT WARMING (GROUP #2) (WI-000129565)

AMBIENT MATERIALS FOR COMPONENT WARMING (GROUP #2)							
Material Name	**Material Number**	**Quantity Needed**	**Quantity Used**	**Batch**	**Expiry**	**Performed Initials/Date**	**Checked Initials/Date**
2x HBS Buffer Aliquots	☐ MMD-000123100 (500233) or ☐ MMD-000132996 (503676)	1		_____			
2M Calcium Chloride Aliquots	☐ MMD-000123101 (500234) or ☐ MMD-000132997 (503674)	1		_____			
1L WFI Bottles	N/A	1					

PROCEDURE FOR COMPONENT WARMING				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Water bath temperature	29.0°C (28.0 – 30.0°C)	°C		
2. Component Warming Start Date/Time	Record	/		
3. Component Warming End Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
4. Total Component Warming Duration	≥ 30 min	mins Section 4.1.1, Step 3 – Section 4.1.1, Step 2		

4.1.2 TRANSFECTION MEDIA MIX (GROUP # 2) (WI-000129565)

ROCKER BPC INSTALLATION		
Parameter	**Performed Initials/Date**	**Witnessed Initials/Date**
Confirm Installation of Rocker BPC #2		

PROCEDURE FOR TRANSFECTION MEDIA MIX GROUP # 2				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
HyPerforma Rocker Equipment ID	Record			
Transfection Media Batch # / Expiration Date	□ MMD-000123097 (500222) or □ MMD-000132993 (503678)	_____/_____		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Transfection Media Removed from incubator Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
2. Total Transfection Media Warming Duration	12 – 24 hrs	hrs mins Section 4.1.2, Step 1 – Section 2.1.1, Step 2		

PROCEDURE FOR ROCKER PARAMETER CHECK PRIOR TO WEIGHT MEASUREMENT				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
Rocker Stop Angle	0.0 °	°		

Parameter	Control	Actual	Performed Initials/Date	Witnessed Initials/Date
3. Weight of Transfection Media added to Rocker	9.95 kg (9.85 – 10.05 kg)	kg		

PROCEDURE FOR ROCKER PARAMETER CHECK				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
Rocker Agitation Mode	1			
Rock Speed Setpoint	10 RPM	RPM		

PROCEDURE FOR ROCKER PARAMETER CHECK AFTER STARTING ROCKER				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
Rocker Angle Setpoint	6.0 °	°		

4.1.3 COMPONENT ADDITION TO 3L SPINNER FLASK (GROUP # 2) (WI-000129565)

Operator in BSC	Performed Initials/Date	Witnessed Initials/Date
Operator performing activities in the BSC.		N/A
END Environmental Monitoring per SOP-000130321 and SOP-000130323 and document in form FORM-000130929. ☐ N/A if settling plates have not reached their 4hr maximum and manufacturing operations are continuous.		N/A
BEGIN Environmental Monitoring per SOP-000130321 and SOP-000130323 and document in form FORM-000130929. ☐ N/A if settling plates have not reached their 4hr maximum and manufacturing operations are continuous.		N/A

PROCEDURE FOR COMPONENT ADDITION TO 3L SPINNER FLASK GROUP # 2				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Weight of WFI added to 1L PETG Bottle	716 g (714 – 718 g)	g		
2. Weight of 2x HBS Transferred into 3L Spinner Flask	856 g (854 – 858 g)	g		

4.1.4 PLASMID ADDITION TO WFI (GROUP # 2) (WI-000129565)

Parameter	Control	Actual	Performed Initials/Date	Witnessed Initials/Date
1. Volume of Plasmid p633 added to 1L PETG Bottle	**Section 2.1.4, Step 1 (A)**	mL		
2. Volume of Plasmid YN15 added to 1L PETG Bottle	**Section 2.1.4, Step 2 (B)**	mL		
3. Volume of Plasmid HPV275 added to 1L PETG Bottle	**Section 2.1.4, Step 3 (C)**	mL		
4. Volume of Plasmid pBB-BCMA02 added to 1L PETG Bottle	**Section 2.1.4, Step 4 (D)**	mL		
5. Weight of 2M Calcium Chloride Added to 1L PETG Bottle	130 g (125 – 135 g)	g		

4.1.5 TRANSFER PLASMID SOLUTION TO 3L SPINNER FLASK (GROUP # 2) (WI-000129565)

PROCEDURE FOR TRANSFER PLASMID SOLUTION TO 3L SPINNER FLASK GROUP # 2				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Spinner Flask Mixing Speed	50 RPM (49 – 51 RPM)	RPM		
2. Pump Dispense Time	30 sec (CPP) (25 – 35 sec)	sec		
3. Pump set Point	545 RPM (CPP)	RPM		
4. Plasmid Cocktail Mix Start Date/Time	Record	/		
5. Plasmid Cocktail mixing end Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
6. Total Plasmid Mix Duration	5 min (1 – 10 min)	mins Section 4.1.5, Step 5 – Section 4.1.5, Step 4		

4.1.6 TRANSFER PLASMID COCKTAIL TO MEDIA (GROUP # 2) (WI-000129565)

PROCEDURE FOR TRANSFER PLASMID COCKTAIL TO MEDIA GROUP # 2				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Pump Speed	320 RPM (280 – 350 RPM)	RPM		
2. Transfection Mix Hold End / Transfer to Media Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
3. Transfection Mix Hold Duration	0 – 10 min	mins Section 4.1.6 Step 2 – Section 4.1.5 Step 5		

4.1.7 CS10 TRANSFECTION AND INCUBATION (GROUP # 2) (WI-000129565)

PROCEDURE FOR TRANSFECTION GROUP # 2				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. CS10 #11 Removed from Incubator Date/Time	Record	/		
2. CS10 #11 Batch #	MMD-000123092-XXXXXX	MMD-000123092-_____		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
3. Total Passage 5 Incubation Duration	Target: 76 hrs (74 - 80 hrs)	hrs mins (Section 4.1.7, Step 1 – Section 1.1.5, Step 10)		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
4. Visual inspection of Cell Stacks	Record	Pass / Fail		

NOTIFY a Supervisor or designee if Visual inspection for Damage and Contamination if the cell culture fails.

PROCEDURE FOR TRANSFECTION GROUP # 2				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
5. Pump Speed for Waste Transfer	300 RPM	RPM		
6. Pump Speed for Feed Transfer	210 RPM	RPM		
7. HyPerforma Rocker Transfer Start Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
8. Total HyPerforma Rocker Mix Duration prior to Transfection	10 – 60 min	mins Section 4.1.7 Step 7 – Section 4.1.6 Step 2		

RECORD weight of Transfection mixture added to each CS10 in Attachment 2

PROCEDURE FOR TRANSFECTION GROUP #2 INCUBATION				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
9. Incubator Equipment ID	Record			
10. Incubator Temperature	36.0 – 38.0°C	°C		
11. Incubator % CO2	4.0 – 6.0 %	%		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
12. CS10 # 11 Incubation Start Date/Time	Record	/		
13. CS10 # 20 Incubation Start Date/Time	Record	/		

PROCEDURE FOR STOPPING ROCKER PARAMETER CHECK				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
Rocker Stop Position	BACK			
Rocker Stop Angle	12.0 °	°		

5.0 TRANSFECTION GROUP #3 (WI-000129565)

5.1. COMPONENT WARMING (GROUP #3) (WI-000129565)

PERFORM Refeed Media warming in Section 7.0.

5.1.1 COMPONENT WARMING (GROUP # 3) (WI-000129565)

AMBIENT MATERIALS FOR COMPONENT WARMING (GROUP #3)							
Material Name	**Material Number**	**Quantity Needed**	**Quantity Used**	**Batch**	**Expiry**	**Performed Initials/Date**	**Checked Initials/Date**
2x HBS Buffer Aliquots	☐ MMD-000123100 (500233) or ☐ MMD-000132996 (503676)	1		_____			
2M Calcium Chloride Aliquots	☐ MMD-000123101 (500234) or ☐ MMD-000132997 (503674)	1		_____			
1L WFI Bottles	N/A	1					

PROCEDURE FOR COMPONENT WARMING				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Water bath temperature	29.0°C (28.0 – 30.0°C)	°C		
2. Component Warming Start Date/Time	Record	/		
3. Component Warming End Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
4. Total Component Warming Duration	≥ 30 min	mins Section 5.1.1, Step 3 – Section 5.1.1, Step 2		

5.1.2 TRANSFECTION MEDIA MIX (GROUP # 3) (WI-000129565)

ROCKER BPC INSTALLATION		
Parameter	**Performed Initials/Date**	**Witnessed Initials/Date**
CONFIRM Installation of Rocker BPC #3.		

PROCEDURE FOR TRANSFECTION MEDIA MIX GROUP # 3				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
HyPerforma Rocker Equipment ID	Record			
Transfection Media Batch # / Expiration Date	□ MMD-000123097 (500222) or □ MMD-000132993 (503678)	_____/_____		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Transfection Media Removed from incubator Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
2. Total Transfection Media Warming Duration	12 – 24 hrs	hrs mins Section 5.1.2, Step 1 – Section 2.1.1, Step 2		

PROCEDURE FOR ROCKER PARAMETER CHECK PRIOR TO WEIGHT MEASUREMENT				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
Rocker Stop Angle	0.0 °	°		

Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
3. Weight of Transfection Media added to Rocker	9.95 kg (9.85 – 10.05 kg)	kg		

PROCEDURE FOR ROCKER PARAMETER CHECK				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
Rocker Agitation Mode	1			
Rock Speed Setpoint	10 RPM	RPM		

PROCEDURE FOR ROCKER PARAMETER CHECK AFTER STARTING ROCKER				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
Rocker Angle Setpoint	6.0 °	°		

5.1.3 COMPONENT HBS ADDITION TO 3L SPINNER FLASK (GROUP # 3) (WI-000129565)

OPERATOR IN BSC	Performed Initials/Date	Witnessed Initials/Date
Operator performing activities in the BSC.		N/A
END Environmental Monitoring per SOP-000130321 and SOP-000130323 and document in form FORM-000130929. ☐ N/A if settling plates have not reached their 4hr maximum and manufacturing operations are continuous.		N/A
BEGIN Environmental Monitoring per SOP-000130321 and SOP-000130323 and document in form FORM-000130929. ☐ N/A if settling plates have not reached their 4hr maximum and manufacturing operations are continuous.		N/A

PROCEDURE FOR COMPONENT ADDITION TO 3L SPINNER FLASK GROUP # 3				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Weight of WFI added to 1L PETG Bottle	716 g (714 – 718 g)	g		
2. Weight of 2x HBS per 3L Spinner Flask	856 g (854 – 858 g)	g		

5.1.4 PLASMID ADDITION TO WFI (GROUP # 3) (WI-000129565)

Parameter	Control	Actual	Performed Initials/Date	Witnessed Initials/Date
1. Volume of Plasmid p633 added to 1L PETG Bottle	**Section 2.1.4, Step 1 (A)**	mL		
2. Volume of Plasmid YN15 added to 1L PETG Bottle	**Section 2.1.4, Step 2 (B)**	mL		
3. Volume of Plasmid HPV275 added to 1L PETG Bottle	**Section 2.1.4, Step 3 (C)**	mL		
4. Volume of Plasmid pBB-BCMA02 added to 1L PETG Bottle	**Section 2.1.4, Step 4 (D)**	mL		
5. Weight of 2M Calcium Chloride Added to 1L PETG Bottle	130 g (125 – 135 g)	g		

5.1.5 TRANSFER PLASMID SOLUTION TO 3L SPINNER FLASK (GROUP # 3) (WI-000129565)

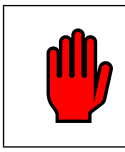
PROCEDURE FOR TRANSFER PLASMID SOLUTION TO 3L SPINNER FLASK				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Spinner Flask Mixing Speed	50 RPM (49 – 51 RPM)	RPM		
2. Pump Dispense Time	30 sec (CPP) (25 – 35 sec)	sec		
3. Pump Set Point	545 RPM (CPP)	RPM		
4. Plasmid Cocktail Mix Start Date/Time	Record	/		
5. Plasmid Cocktail mixing end Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
6. Total Plasmid Mix Duration	5 mins (1 – 10 mins)	mins Section 5.1.5, Step 5 – Section 5.1.5, Step 4		

5.1.6 TRANSFER PLASMID COCKTAIL TO MEDIA (GROUP # 3) (WI-000129565)

PROCEDURE FOR TRANSFER PLASMID COCKTAIL TO MEDIA				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Pump Speed	320 RPM (280 – 350 RPM)	RPM		
2. Transfection Mix Hold End / Transfer to Media Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
3. Transfection Mix Hold Duration	0 – 10 mins	mins Section 5.1.6 Step 2 – Section 5.1.5 Step 5		

5.1.7 CS10 TRANSFECTION AND INCUBATION (GROUP # 3) (WI-000129565)

PROCEDURE FOR CS10 GROUP # 3 REMOVAL				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. CS10 #21 Removed from Incubator Date/Time	Record	/		
2. CS10 #21 Batch #	MMD-000123092-XXXXXX	MMD-000123092-_____		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
3. Total Passage 5 Incubation Duration	Target: 76 hrs (74 – 80 hrs)	hrs mins (Section 5.1.7, Step 1 – Section 1.1.7, Step 8)		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
4. Visual inspection of Cell Stacks	Record	Pass / Fail		



NOTIFY a Supervisor or designee if Visual inspection for Damage and Contamination of the cell culture fails.

PROCEDURE FOR GROUP # 3 TRANSFECTION				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
5. Pump Speed for Waste Transfer	300 RPM	RPM		
6. Pump Speed for Feed Transfer	210 RPM	RPM		
7. HyPerforma Rocker Transfer Start Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
8. Total HyPerforma Rocker Mix Duration prior to Transfection	10 – 60 mins	mins Section 5.1.7 Step 7 – Section 5.1.6 Step 2		

RECORD weight of Transfection mixture added to each CS10 in Attachment 2

PROCEDURE FOR TRANSFECTION GROUP #3 INCUBATION				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
9. Incubator Equipment ID	Record			
10. Incubator Temperature	36.0 – 38.0°C	°C		
11. Incubator % CO2	4.0 – 6.0 %	%		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
12. CS10 # 21 Incubation Start Date/Time	Record	/		
13. CS10 # 30 Incubation Start Date/Time	Record	/		

PROCEDURE FOR STOPPING ROCKER PARAMETER CHECK				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
Rocker Stop Position	BACK			
Rocker Stop Angle	12.0 °	°		

6.0 TRANSFECTION GROUP #4 (WI-000129565)

6.1. COMPONENT WARMING (GROUP #4) (WI-000129565)

6.1.1 COMPONENT WARMING (GROUP #4) (WI-000129565)

MATERIALS FOR COMPONENT WARMING (GROUP #4)							
Material Name	**Material Number**	**Quantity Needed**	**Quantity Used**	**Batch**	**Expiry**	**Performed Initials/Date**	**Checked Initials/Date**
2x HBS Buffer Aliquots	☐ MMD-000123100 (500233) ☐ MMD-000132996 (503676)	1		_____			
2M Calcium Chloride Aliquots	☐ MMD-000123101 (500234) ☐ MMD-000132997 (503674)	1		_____			
1L WFI Bottles	N/A	1					

PROCEDURE FOR MEDIA DISPENSING				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Water bath temperature	29.0°C (28.0 – 30.0°C)	°C		
2. Component Warming Start Date/Time	Record	/		
3. Component Warming End Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
4. Total Component Warming Duration	≥ 30 mins	mins Section 6.1.1., Step 3 – Section 6.1.1, Step 2		

6.1.2 TRANSFECTION MEDIA MIX (GROUP # 4) (WI-000129565)

ROCKER BPC INSTALLATION		
Parameter	**Performed Initials/Date**	**Witnessed Initials/Date**
Confirm Installation of Rocker BPC #4.		

PROCEDURE FOR TRANSFECTION MEDIA MIX GROUP # 4				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
HyPerforma Rocker Equipment ID	Record			
Transfection Media Batch # / Expiration Date	□ MMD-000123097 (500222) or □ MMD-000132993 (503678)	_____/_____		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Transfection Media Removed from incubator Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
2. Total Transfection Media Warming Duration	12 – 24 hrs	hrs mins Section 6.1.2, Step 1 – Section 2.1.1 Step 2		

PROCEDURE FOR ROCKER PARAMETER CHECK PRIOR TO WEIGHT MEASUREMENT				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
Rocker Stop Angle	0.0 °	°		

Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
3. Weight of Transfection Media added to Rocker	9.95 kg (9.85 – 10.05 kg)	kg		

PROCEDURE FOR ROCKER PARAMETER CHECK				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
Rocker Agitation Mode	1			
Rock Speed Setpoint	10 RPM	RPM		

PROCEDURE FOR ROCKER PARAMETER CHECK AFTER STARTING ROCKER				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
Rocker Angle Setpoint	6.0 °	°		

6.1.3 COMPONENT HBS ADDITION TO 3L SPINNER FLASK (GROUP # 4) (WI-000129565)

Operator in BSC	Performed Initials/Date	Witnessed Initials/Date
Operator performing activities in the BSC.		N/A
END Environmental Monitoring per SOP-000130321 and SOP-000130323 and document in form FORM-000130929. ☐ N/A if settling plates have not reached their 4hr maximum and manufacturing operations are continuous.		N/A
BEGIN Environmental Monitoring per SOP-000130321 and SOP-000130323 and document in form FORM-000130929. ☐ N/A if settling plates have not reached their 4hr maximum and manufacturing operations are continuous.		N/A

PROCEDURE FOR COMPONENT ADDITION TO 3L SPINNER FLASK GROUP # 4				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Weight of WFI added to 1L PETG Bottle	716 g (714 – 718 g)	g		
2. Weight of 2x HBS per 3L Spinner Flask	856 g (854 – 858 g)	g		

6.1.4 PLASMID ADDITION TO WFI (GROUP # 4) (WI-000129565)

Parameter	Control	PETG Bottle # 4	Performed Initials/Date	Witnessed Initials/Date
1. Volume of Plasmid p633 added to 1L PETG Bottle	**Section 2.1.4, Step 1 (A)**	mL		
2. Volume of Plasmid YN15 added to 1L PETG Bottle	**Section 2.1.4, Step 2 (B)**	mL		
3. Volume of Plasmid HPV275 added to 1L PETG Bottle	**Section 2.1.4, Step 3 (C)**	mL		
4. Volume of Plasmid pBB-BCMA02 added to 1L PETG Bottle	**Section 2.1.4, Step 4 (D)**	mL		
5. Weight of 2M Calcium Chloride Added to 1L PETG Bottle	130 g (125 – 135 g)	g		

6.1.5 TRANSFER PLASMID SOLUTION TO 3L SPINNER FLASK (GROUP # 4) (WI-000129565)

PROCEDURE FOR TRANSFER PLASMID SOLUTION TO 3L SPINNER FLASK GROUP # 4				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Spinner Flask Mixing Speed	50 RPM (49 – 51 RPM)	RPM		
2. Pump Dispense Time	30 sec (CPP) (25 – 35 sec)	sec		
3. Pump set Point	545 RPM (CPP)	RPM		
4. Plasmid Cocktail Mix Start Date/Time	Record	/		
5. Plasmid Cocktail mixing end Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
6. Total Plasmid Mix Duration	5 mins (1 – 10 mins)	mins Section 6.1.5, Step 5 – Section 6.1.5, Step 4		

ENVIRONMENTAL MONITORING	Performed Initials/Date	Witnessed Initials/Date
END Environmental Monitoring per SOP-000130321 and SOP-000130323 and document in form FORM-000130929.		N/A

6.1.6 TRANSFER PLASMID COCKTAIL TO MEDIA (GROUP # 4) (WI-000129565)

PROCEDURE FOR TRANSFER PLASMID COCKTAIL TO MEDIA GROUP # 4				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Pump Speed	320 RPM (280 – 350 RPM)	RPM		
2. Transfection Mix Hold End / Transfer to Media Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
3. Transfection Mix Hold Duration	0 – 10 mins	mins Section 6.1.6 Step 2 – Section 6.1.5 Step 5		

6.1.7 CS10 TRANSFECTION AND INCUBATION (GROUP # 4) (WI-000129565)

PROCEDURE FOR CS10 TRANSFECTION AND INCUBATION GROUP # 4				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. CS10 #31 Removed from Incubator Date/Time	Record	/		
2. CS10 #31 Batch #	MMD-000123092-XXXXXX	MMD-000123092-_____		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
3. Total Passage 5 Incubation Duration	Target: 76 hrs (74 - 80 hrs)	hrs mins Section 6.1.7, Step 1 - Section 1.1.7, Step 10		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
4. Visual inspection of Cell Stacks	Record	Pass / Fail		

NOTIFY a Supervisor or designee if Visual inspection for Damage and Contamination of the cell culture fails.

MFG Page Review Initials / Date		QA Page Review Initials / Date	

PROCEDURE FOR CS10 TRANSFECTION GROUP # 4				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
5. Pump Speed for Waste Transfer	300 RPM	RPM		
6. Pump Speed for Feed Transfer	210 RPM	RPM		
7. HyPerfoma Rocker Transfer Start Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
8. Total HyPerforma Rocker Mix Duration prior to Transfection	10 – 60 mins	mins Section 6.1.7 Step 7 – Section 6.1.6 Step 2		

	RECORD weight of Transfection mixture added to each CS10 in Attachment 2

PROCEDURE FOR TRANSFECTION GROUP #4 INCUBATION				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
9. Incubator Equipment ID	Record			
10. Incubator Temperature	36.0 – 38.0°C	°C		
11. Incubator % CO2	4.0 – 6.0 %	%		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
12. CS10 # 31 Incubation Start Date/Time	Record	/		
13. CS10 # 40 Incubation Start Date/Time	Record	/		

PROCEDURE FOR STOPPING ROCKER PARAMETER CHECK				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
Rocker Stop Position	BACK			
Rocker Stop Angle	12.0 °	°		

Action	**Performed Initials/Date**	**Checked Initials/Date**
PERFORM SAP Batch Lot Verification for materials consumed for Section 3.0, Section 4.0, Section 5.0 and Section 6.0 per SOP-000130022.		

7.0 REFEED (WI-000129727)

7.1. REFEED MEDIA WARMING (WI-000129727)

7.1.1 REFEED MEDIA WARMING (WI-000129727)

RECORD AND ROOM PREPARATION		
Parameter	**Actual**	**Performed Initials/Date**
Production Room #	Room #	

EQUIPMENT FOR REFEED MEDIA WARMING			
Equipment	**Equipment ID**	**Performed Initials/Date**	**Checked Initials/Date**
Incubator (SOP-000130281)			
VERIFY that all equipment and rooms listed above were cleaned and have been standardized/calibrated according to listed SOPs.			
VERIFY that line clearance is complete, and equipment is changed-in a per SOP-000130371 and tagged for use per SOP-000130280.			

2-8°C MATERIALS FOR REFEED MEDIA WARMING							
Material Name	**Material Number**	**Quantity Needed**	**Quantity Used**	**Batch**	**Expiry**	**Performed Initials/Date**	**Checked Initials/Date**
Refeed Media	☐ MMD-000123099 (500224) or ☐ MMD-000132994 (503677)	2x 22 kg		_____			

PROCEDURE FOR MEDIA WARMING				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
1. Incubator Temperature	36.0 – 38.0 °C	°C		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
2. Refeed Media warming start Date/Time	Record	/		

7.1.2 PRODUCTION ROOM (WI-000129727)

RECORD AND ROOM PREPARATION		
Parameter	**Actual**	**Performed Initials/Date**
Production Room #	Room #	

EQUIPMENT FOR REFEED			
Equipment	**Equipment ID**	**Performed Initials/Date**	**Checked Initials/Date**
Incubator (SOP-000130281)			
Terumo Welder (SOP-000130295)			
Size 24 Peristaltic Pump for CS10 Feed (SOP-000130279)			
Size 24 Peristaltic Pump for CS10 Waste (SOP-000130279)			
Table Top Scale #1 for CS10 Feed (SOP-000130289)			
Table Top Scale #2 for CS10 Feed (SOP-000130289)			
Microscope (SOP-000130310)			
L Clipster (SOP-000130478)			
XS/S Clipster (SOP-000130478)			
VERIFY that all equipment and rooms listed above were cleaned and have been standardized/calibrated according to listed SOPs.			
VERIFY that line clearance is complete, and equipment is changed-in per SOP-000130371 and tagged for use per SOP-000130280.			

MFG Page Review Initials / Date		QA Page Review Initials / Date	

7.1.3 PREPARATION OF CS10S # 1 - 20 (WI-000129727)

AMBIENT MATERIALS FOR PREPARATION OF CS10 #1 - #20							
Material Name	**Material Number**	**Quantity Needed**	**Quantity Used**	**Batch**	**Expiry**	**Performed Initials/Date**	**Checked Initials/Date**
CS10 feed Manifold	☐ 412251 ☐ 413169	6					
50L BPC	110247	2					
Refeed Media Bag #1	☐ MMD-000123099 (500224) or ☐ MMD-000132994 (503677)	1		_____			

PROCEDURE FOR PREPARATION OF CS10 #1 - #20				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Refeed media bag #1 warming end Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
2. Total Refeed Media Bag #1 warming duration	12 – 24 hrs	hrs mins Section 7.1.3 Step 1 – Section 7.1.1 Step 2		

7.1.4 MEDIA CHANGE AND INCUBATION OF CS10S # 1 – 20 (WI-000129727)

PROCEDURE FOR MEDIA CHANGE AND INCUBATION OF CS10S #1 - #20				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
1. Incubator Equipment ID	Record			
2. Incubator Temperature	36.0 – 38.0°C	°C		
3. Incubator % CO2	4.0 – 6.0 %	%		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
4. Transfection CS10 #1 Incubation End Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
5. Transfection CS10 #1 Incubation Duration	16 hrs (14 – 17 hrs)	hrs mins Section 7.1.4, Step 4 – Section 3.1.7, Step 12		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
6. Visual Inspection of Cell Stacks	Record	Pass / Fail		

NOTIFY a Supervisor or designee if Visual inspection for Damage and Contamination of the cell culture fails.

RECORD weight of Media transferred to each CS10 in Attachment 3.

PROCEDURE FOR MEDIA CHANGE AND INCUBATION OF CS10S #1 - #20				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
7. Waste Pump Speed	300 RPM	RPM		
8. Feed Pump Speed	210 RPM (185 – 243 RPM)	RPM		
9. CS10 #1 Incubation Start Date/Time	Record	/		
10. CS10 #10 Incubation Start Date/Time	Record	/		
11. Transfection CS10 #11 Incubation End Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
12. Total Transfection CS10 #11 Incubation Duration	16 hrs (14 – 17 hrs)	hrs mins Section 7.1.4 Step 11 – Section 4.1.7 Step 12		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
13. CS10 #11 Incubation Start Date/Time	Record	/		
14. CS10 #20 Incubation Start Date/Time	Record	/		

7.1.5 PREPARATION OF CS10S # 21 – 40 (WI-000129727)

2-8°C MATERIALS FOR PREPARATION OF CS10 #21 - #40							
Material Name	**Material Number**	**Quantity Needed**	**Quantity Used**	**Batch**	**Expiry**	**Performed Initials/Date**	**Checked Initials/Date**
Refeed Media Bag #2	☐ MMD-000123099 (500224) or ☐ MMD-000132994 (503677)	1		_____			

PROCEDURE FOR PREPARATION OF CS10 #21 - #40				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Refeed media bag #2 warming end Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
2. Total Refeed Media Bag #2 warming duration	12 – 24 hrs	hrs mins Section 7.1.5 Step 1 – Section 7.1.1 Step 2		

7.1.6 MEDIA CHANGE AND INCUBATION OF CS10s # 21 – 40 (WI-000129727)

PROCEDURE FOR MEDIA CHANGE AND INCUBATION OF CS10S #21 - #40				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
1. Incubator Equipment ID	Record			
2. Incubator Temperature	36.0 – 38.0°C	°C		
3. Incubator % CO2	4.0 – 6.0 %	%		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
4. Transfection CS10 #21 Incubation End Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
5. Transfection CS10 #21 Incubation Duration	16 hrs (14 – 17 hrs)	hrs mins Section 7.1.6, Step 4 – Section 5.1.7, Step 12		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
6. Visual Inspection of Cell Stacks	Record	Pass /Fail		

NOTIFY a Supervisor or designee if Visual inspection for Damage and Contamination of the cell culture fails.

RECORD weight of media transferred to each CS10 in Attachment 3.

PROCEDURE FOR MEDIA CHANGE AND INCUBATION OF CS10S #21 - #40				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
7. Waste Pump Speed	300 RPM	RPM		
8. Feed Pump Speed	210 RPM (185 – 243 RPM)	RPM		
9. CS10 #21 Incubation Start Date/Time	Record	/		
10. CS10 #30 Incubation Start Date/Time	Record	/		
11. Transfection CS10 #31 Incubation End Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
12. Total Transfection CS10 #31 Incubation Duration	16 hrs (14 – 17 hrs)	hrs mins Section 7.1.6 Step 11 – Section 6.1.7 Step 12		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
13. CS10 #31 Incubation Start Date/Time	Record	/		
14. CS10 #40 Incubation Start Date/Time	Record	/		

Action	Performed Initials/Date	Checked Initials/Date
PERFORM SAP Batch Lot Verification for materials consumed in this section per SOP-000130022.		

8.0 HARVEST (WI-000129571)

8.1. HARVEST ROOM PREPARATION (WI-000129571)

8.1.1 PRODUCTION ROOM (WI-000129571)

RECORD AND ROOM PREPARATION		
Parameter	**Actual**	**Performed Initials/Date**
Production Room #	Room #	

EQUIPMENT FOR HARVEST			
Equipment	**Equipment ID**	**Performed Initials/Date**	**Checked Initials/Date**
Biosafety Cabinet (SOP-000130283)			
Incubator (SOP-000130281)			
Peristaltic Pump Masterflex 77200-62 (SOP-000130279)			
Peristaltic Pump Masterflex 77601-60 (SOP-000130279)			
Vi-Cell Counter (SOP-000130292)			
Floor Scale (SOP-000130302)			
Terumo Welder (SOP-000130295)			
L Clipster (SOP-000130478)			
XS/S Clipster (SOP-000130478)			
Microscope (SOP-000130310)			
VERIFY that all equipment and rooms listed above were cleaned and have been standardized/calibrated according to listed SOPs.			
VERIFY that line clearance is complete, and equipment is changed-in per SOP-000130371 and tagged for use per SOP-000130280.			

8.1.2 HARVEST MATERIAL (WI-000129571)

MATERIALS FOR HARVEST PREPARATION							
Material Name	**Material Number**	**Quantity Needed**	**Quantity Used**	**Batch**	**Expiry**	**Performed Initials/Date**	**Checked Initials/Date**
50L BPC w/ AQG	113374	1					
1L Biosimplex Bottle	112368	1					
CS10 feed Manifold	☐ 412251 ☐ 413169	2					
120” Mobius line	☐ 112766 ☐ 115331	1					

8.1.3 CS10 HARVEST (WI-000129571)

SCALE TARE		
Parameter	**Performed Initials/Date**	**Witnessed Initials/Date**
Confirm floor scale with 50L BPC has been tared		

PROCEDURE FOR HARVEST GROUP #1				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Pump Speed for Harvest Transfer	300 RPM (280 – 350 RPM)	RPM		
2. Incubator Equipment ID	Record			
3. Incubator Temperature	36.0 – 38.0 ℃	℃		
4. Incubator % CO2	4.0 – 6.0 %	%		
5. Date/Time of first CS10 removed from incubator	Record	/		
6. CS10 #1 Batch #	MMD-000123092-XXXXXX	MMD-000123092-_____		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
7. Total CS10 #1 Incubation Duration	Target: 48 hrs (46 - 50 hrs)	hrs mins Section 8.1.3 Step 5 – Section 7.1.4 Step 9		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
8. Visual Inspection	Record	Pass / Fail		

PROCEDURE FOR HARVEST GROUP #2				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
9. Incubator Equipment ID	Record			
10. Incubator Temperature	36.0 – 38.0 ℃	℃		
11. Incubator % CO2	4.0 – 6.0 %	%		
12. Date/Time CS10 #21 removed from incubator	Record	/		
13. CS10 #21 Batch #	MMD-000123092-XXXXXX	MMD-000123092-_____		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
14. Total CS10 #21 Incubation Duration	Target: 48 hrs (46 - 50 hrs)	hrs mins Section 8.1.3 Step 12 – Section 7.1.6 Step 9		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
15. Visual Inspection	Record	Pass / Fail		
16. Weight of Crude Harvest (Floor scale)	Record	kg		
17. Crude Harvest Completion/Settling Start Date/Time	Record	/		

8.1.4 CRUDE HARVEST SUPERNATANT (WI-000129571)

PROCEDURE FOR CRUDE HARVEST SUPERNATANT				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Pump Equipment ID	Masterflex 77601-60			
2. Pump Speed	10% (< 22%)	%		
3. Crude Harvest Supernatant Transfer Start / Settling End Date/Time	Record	/		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
4. Total Crude Harvest Settling Time	25 mins (20 – 30 mins)	mins Section 8.1.4 Step 3 – Section 8.1.3 Step 17		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
5. Crude Harvest transferred end weight	0.0 (±) 1.0 kg	kg		

8.1.5 SETTLED CRUDE HARVEST SAMPLE COLLECTION (WI-000129571)

PROCEDURE FOR SETTLED CRUDE HARVEST SAMPLE COLLECTION				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
1. Volume of Settled Crude Harvest Transferred	500 mL (400 – 900 mL)	mL		
2. Settled Crude Harvest Sample Date/Time	Record	/		

8.1.6 SETTLED CRUDE HARVEST SAMPLE ANALYSIS (WI-000129571)

PROCEDURE FOR SAMPLE ANALYSIS				
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
1. Sample ID	MMD-000123092-XXXXXX-Sett Crud Harv	MMD-000123092 - _____		
2. Sample volume	0.8mL	0.8mL		
3. Cell type	BALTIMORE HEK293T	BALTIMORE HEK293T		
Parameter	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
4. Vi-Cell Sample Analysis Date/Time	Record	/		
5. Settled Crude Harvest Total Cell Density	Record	tc/mL		

8.1.7 SAMPLE VOLUME CALCULATIONS (WI-000129571)

1. **CALCULATION FOR SAMPLE VOLUME**					
	1.2 x 10^8 tc	÷	tc/mL	=	mL
	Target Sample Total Cells		**Settled Crude Harvest Total Cell Density (Section 8.1.6 Step 5)**		**Volume of Crude Settled Crude Harvest RCL Samples (A) (X.X)**
Performed Initials/Date	/	**Checked Initials/Date**	/		

AMBIENT MATERIALS FOR SAMPLE VOLUME

Material Name	Material Number	Quantity Needed	Quantity Used	Batch	Expiry	Performed Initials/Date	Checked Initials/Date
125mL PETG bottle	☐ 110039	2 bottles (Any combination of bottles totaling 2)	□ N/A ___ ea.	□ N/A	□ N/A		
	☐ 115345		□ N/A ___ ea.	□ N/A	□ N/A		
250mL PETG bottle	☐ 110040		□ N/A ___ ea.	□ N/A	□ N/A		
	☐ 115346		□ N/A ___ ea.	□ N/A	□ N/A		
500mL PETG bottle	☐ 110041		□ N/A ___ ea.	□ N/A	□ N/A		
	☐ 115347		□ N/A ___ ea.	□ N/A	□ N/A		

SAMPLING FOR CRUDE HARVEST				
Assay	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
Crude Harvest RCL	Attach Label			
	Aliquot 1 (Section 8.1.7 Step 1A)	mL		
	Aliquot completion Date/Time	/		
	Control	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
	Storage Location (< -65 ℃)	(XX-FRZ-XXX)		
	Control	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
	Settled Crude Harvest Sample aliquot (RCL) Storage Date/Time	/		

SAMPLING FOR CRUDE HARVEST				
Assay	**Control**	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
Crude Harvest RCL - Retain	Attach Label			
	Aliquot 1 (Section 8.1.7 Step 1A)	mL		
	Aliquot completion Date/Time	/		
	Control	**Actual**	**Performed Initials/Date**	**Checked Initials/Date**
	Storage Location (< -65 ℃)	(XX-FRZ-XXX)		
	Control	**Actual**	**Performed Initials/Date**	**Witnessed Initials/Date**
	Settled Crude Harvest Sample aliquot (RCL) Storage Date/Time	/		

9.0 COMMENTS

Required Information	Response	Initial/Date
☐ N/A Initials/Date: /		
Step #:		
Date & Time:		
Description of Event:		
Personnel Informed:		
Response:		
Required Information	**Response**	**Initial/Date**
☐ N/A Initials/Date: /		
Step #:		
Date & Time:		
Description of Event:		
Personnel Informed:		
Response:		

Required Information	Response	Initial/Date
☐ N/A Initials/Date: /		
Step #:		
Date & Time:		
Description of Event:		
Personnel Informed:		
Response:		

Required Information	Response	Initial/Date
☐ N/A Initials/Date: /		
Step #:		
Date & Time:		
Description of Event:		
Personnel Informed:		
Response:		

10.0 ATTACHMENTS

Attachment 1: WEIGHT OF CELL SUSPENSION (PASSAGE 5)

Parameter	Control	Actual	Performed Initials / Date	Witnessed Initials / Date
Weight transferred to CS10 # 1	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 2	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 3	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 4	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 5	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 6	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 7	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 8	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 9	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 10	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 11	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 12	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 13	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 14	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 15	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 16	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 17	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 18	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 19	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 20	1100 g (1090 – 1110 g)	g		

Attachment 1 (Continued): WEIGHT OF CELL SUSPENSION (PASSAGE 5)

Parameter	Control	Actual	Performed Initials / Date	Witnessed Initials / Date
Weight transferred to CS10 # 21	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 22	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 23	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 24	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 25	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 26	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 27	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 28	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 29	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 30	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 31	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 32	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 33	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 34	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 35	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 36	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 37	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 38	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 39	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 40	1100 g (1090 – 1110 g)	g		

Attachment 2: WEIGHT OF TRANSFECTION MIXTURE

Parameter	Control	Actual	Performed Initials / Date	Witnessed Initials / Date
Weight transferred to CS10 # 1	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 2	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 3	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 4	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 5	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 6	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 7	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 8	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 9	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 10	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 11	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 12	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 13	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 14	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 15	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 16	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 17	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 18	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 19	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 20	1100 g (1090 – 1110 g)	g		

Attachment 2 Continued: WEIGHT OF TRANSFECTION MIXTURE

Parameter	Control	Actual	Performed Initials / Date	Witnessed Initials / Date
Weight transferred to CS10 # 21	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 22	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 23	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 24	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 25	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 26	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 27	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 28	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 29	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 30	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 31	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 32	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 33	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 34	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 35	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 36	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 37	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 38	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 39	1100 g (1090 – 1110 g)	g		
Weight transferred to CS10 # 40	1100 g (1090 – 1110 g)	g		

Attachment 3: WEIGHT OF REFEED MEDIA

Parameter	Control	Actual	Performed Initials / Date	Witnessed Initials / Date
Weight transferred to CS10 # 1	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 2	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 3	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 4	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 5	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 6	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 7	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 8	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 9	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 10	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 11	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 12	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 13	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 14	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 15	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 16	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 17	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 18	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 19	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 20	1000 g (990 – 1010 g)	g		

Attachment 3 Continued: WEIGHT OF REFEED MEDIA

Parameter	Control	Actual	Performed Initials / Date	Witnessed Initials / Date
Weight transferred to CS10 # 21	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 22	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 23	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 24	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 25	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 26	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 27	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 28	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 29	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 30	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 31	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 32	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 33	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 34	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 35	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 36	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 37	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 38	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 39	1000 g (990 – 1010 g)	g		
Weight transferred to CS10 # 40	1000 g (990 – 1010 g)	g		

11.0 RECORD APPROVAL

Supervisor Review of Record per SOP-000129404
This completed production record has been reviewed and has been found to be complete, correct, and in conformance with relevant SOPs and related documents. **Signature/Date: _____** **Manufacturing**

Action	Performed Initials/Date	Checked Initials/Date
COMPLETE SAP Batch Lot Verification per SOP-000130022.		
VERIFY All appropriate attachments including forms, labels, and additional pages are included with completed record.		

Record Approval	
This completed production record has been reviewed and has been found to be complete, correct, and in conformance with relevant SOPs and related documents.	
Signature/Date: _____ **Manufacturing**	**Signature/Date: _____** **Quality Assurance**

12.0 APPENDICIES

Appendix 1: Action Limits

Parameter	Section(s)	Action Limits	Action
Passage 5 Incubation Duration	N/A	< 66 hrs or > 80 hrs	If a parameter value exceeds the corresponding action limit, notify supervisor before proceeding. The supervisor should contact manufacturing sciences and client for approval to proceed.
WFI Mass Added to Cocktail	N/A	< 714 or > 718 g	
CaCl2 Mass Added to Cocktail	N/A	< 125 or > 135 g	
2X HBS Mass Added to Spinner Flask	N/A	< 854 or > 858 g	
Spinner Flask Mixing Speed	N/A	< 49 or > 51 rpm	
Pump Dispense Time	N/A	< 25 or > 35 sec	
Total Plasmid Mix Duration	N/A	< 1 or > 10 mins	
Weight of Transfection Media added to Rocker BPC	N/A	< 9.85 or > 10.05 kg	
Transfection Volume per CS10	N/A	< 1090 or > 1110 g	
Transfection Incubation Duration	N/A	< 14 or > 17 hrs	
Post-Refeed Incubator Duration	N/A	< 46 or > 50 hrs	

13.0 REFERENCES

Document Number	Document Title
MMD-000123086	Thaw Through Passage 5 of Baltimore HEK293T Adherent Cells
MMD-000123096	Baltimore Growth Media 160L
MMD-000132990	Baltimore Growth Media 160 kg
MMD-000123097	Baltimore Transfection Media 100L
MMD-000123100	Baltimore 2X HBS Buffer 8L
MMD-000132993	Baltimore Transfection Media 190 kg
MMD-000132994	Baltimore Refeed Media 190 kg
MMD-000123099	Baltimore Refeed Media 100L
MMD-000132996	Baltimore 2X HBS Buffer 20 kg
MMD-000132997	Baltimore 2M Calcium Chloride Solution 20 kg
MMD-000123101	Baltimore 2M Calcium Chloride Solution 2L
SOP-000130279	Cleaning and Operation of Peristaltic Pumps
SOP-000130280	Tagging Requirements for Cambridge Mfg
SOP-000130281	Monitoring and Cleaning of Incubators
SOP-000130283	Use of Biosafety Cabinets
SOP-000129639	Operation of Micropipettes
SOP-000130287	Water Bath
SOP-000130289	Use of Table Top and Analytical Balances
SOP-000130292	Operation of the Beckman Coulter Vi-Cell Analyzer
SOP-000130295	Operation and Maintenance of the Terumo Sterile Welder

Document Number	Document Title
SOP-000129404	Record Review Process
SOP-000130302	Toledo Floor Scales
SOP-000130310	Operation of the Inverted Light Microscopes
SOP-000130321	Supply and Use of Contact Plates, Personnel Plates, and Settling Plates for Microbiological Monitoring
SOP-000130323	Dynamic Environmental Monitoring for Manufacturing Activities
SOP-000129464	Operation of the Thermo Scientific HyPerforma Rockers
SOP-000130526	Operation of the Stirrer and Hot Plate Stirrer
SOP-000130478	Operation of Clipster
SOP-000130022	SAP Reconcile Process Orders
SOP-000130371	Cambridge Room/Equipment Change Procedure
WI-000129565	Baltimore HEK293T Transfection
WI-000129569	Baltimore HEK293T Passage 5 With Rocker
WI-000129727	Baltimore HEK293T Refeed of 40 x CS10s
WI-000129571	Baltimore HEK293T Harvest of Anti-BCMA02 CAR LVV
FORM-000130929	Dynamic EM Sampling Form

14.0 REVISION HISTORY

Version Number	Change List
19.0	Per QR-268292 • Updated document title to add "With Rocker" to distinguish which documents to use for each process. Operators will use MMD-000245545 for the 10L Mobius bag as an alternative. Per QR-308650 • Update incubation duration and assigned as critical process parameter in section 3.1.7 step 3, 4.1.7 step 3, 5.1.7 step 3 and 6.1.7 step 3. Per QR- 272274 • Insert Post-refeed incubation duration calculation after section 8.1.3 Step 13. Administrative: • Section 3.1.7, 4.1.7, 5.1.7, 6.1.7: Per client request, change 'CPP' in step 3 to 'target' • Section 9.0: Per client request, Replace "Int/Date" with "Initials/Date" for clarity. • Section 8.1.3 step 14: Identify '48 hrs' in 'control' column as target. • Section 8.1.4 step 4: Corrected reference mistake "Section 8.1.3 Step 16" to "Section 8.1.3 Step 17".
18.0	Per QR-307516 • Section 1.1.3 added alternative material for Cell Stack Transfer Caps and Cell Stack Filter Caps. • Section 7.1.3 updated quantity needed for CS10 feed Manifold from 4 to 6. Administrative change • Section 1.1.4 removed notation in Mobius In/Out Manifold under material number at table" Ambient Materials for Passage 5 Seeding" • Added N/A boxes for Section 9.0 Comment boxes • Removed "Choose 1 material #" throughout document • Revised "Record" to "Record Label" in Section 1.1.4 Step 5 and Section 1.1.6 Step 5 • Corrected reference numbers o at Section 3.1.7 step 3 o at section 4.1.7 step 3
17.0	Per QR-276434: • Added material #110041 and #115347 (500mL PETG) as alternatives to 250mL PETG in Section 8.1.7. Administrative changes: • In Section 2.1.4 adjusted significant digits in Plasmid calculation table to (X.X) for consistency. • In Section 8.1.7 Step 1, Adjusted Calculation for Sample Volume to align with significant digits (X.X) for consistency. • In Section 8.1.7 "Ambient Materials for Sample Volume' table, removed instruction to "Choose one material #", Removed N/A from Performed and Checked columns, and revised Qty Needed instruction. • Added references to MMD-000123096, MMD-000123097, MMD-000123100, MMD-000123101, and MMD-000123099 to Section 13.0.
16	Per QR-231311: • In Section 8.1.7, added alternative material #110040 and #115346. Administrative changes: • Added reference to SOP-000130371 to Sections 1.1.1, 1.1.2, 1.1.4, 2.1.1, 2.1.2, and 13.0.

	• Revised 8.1.6 Step 1 Control to "MMD-000123092_XXXXXX-Sett Crud Harv" to line up with # of spaces available. • Added Checked By box to Batch Lot Verification table in Sections 1.1.7, 6.1.7, and 7.1.6 • In Section 2.1.3, added N/A boxes to serological pipettes.
15.0	Per QR-184124: • Revised Section 1.1.1 Media Aliquots to 2 x 24kg from 2 x 25kg. Per QR-86659: • Added alternative parts #413458 and #413453 for p633. • Added alternative parts #413452 and #413459 for YN15. • Added alternative part #413456 for HPV275. • Added alternative part #413460 for PBB-BCMA02 Per CAPA QR-77485: • Revised parameters recorded in hours to include minutes in the following sections: 1.1.4, 1.1.6, 3.1.2, 3.1.7, 4.1.2, 4.1.7, 5.1.2, 5.1.7, 6.1.2, 6.1.7, 7.1.3, 7.1.4, 7.1.5, 7.1.6, 8.1.3. Per QR-149988: • Revised to include a N/A checkbox if manufacturing operations are continuous, and the settling plates have not reached the 4-hour max. in Sects 3.1.1, 3.1.3, 4.1.3, 5.1.3, 6.1.3 Per QR-108344: • Added single line to record result of visual inspection of CS10 cell stacks. Admin changes: • Corrected table header in 1.1.7 to BPC#2 • Removed Unused LIMS ID field from "Sampling for Crude Harvest" table in Sect. 8.1.7 • Added Equipment ID format to "Storage Condition" field in "Sampling for Crude Harvest" table in Sect. 8.1.7 • Updated "Environmental Monitoring" table to new format in sections 1.1.3, 3.1.3, 4.1.3, 5.1.3, 6.1.3, 6.1.5. • Moved the word "Aliquots" from before the 2x HBS Buffer and 2M CaCl buffer to after in Sects. 2.1.3, 3.1.1, 4.1.1, 5.1.1, 6.1.1 • Added freezer ID format to indicate correct entry. • In Section 8.1.7, updated equipment steps from Witness to Checked. • In sects.3.1.1, 4.1.1, 5.1.1, and 6.1.1 corrected aliquot qty to 1 from 4 for 2x HBS Buffer Aliquots and 2M Calcium Chloride Aliquots • In Sect 1.1.4 Materials table, Added N/A box to Mobius In/Out Manifold when performing in Vector. • Added "Fail" option to the visual inspection in section 1.1.3. • Added N/A options to media expiration recordings in sections 1.1.4, 1.1.6, 3.1.2, 4.1.2, 5.1.2, and 6.1.2. • Removed "10L" from Water Bath equipment in section 2.1.2 to align with WI. • Removed recording of 125 mL PETG bottles in the "Sampling for Crude Harvest" tables in section 8.1.7

14.0	As Per QR-115430 following changes were made: -**Section 1.1.3 and 2.1.3:** Added Material #113154 (Tubing Assembly, AQG to 3/8" Male MPC), #413167 (Baltimore AQG to MPC), and #113520 (AQG HT to MPC Insert) as alternates to #114084 -**Section 1.1.4 and 2.1.3**: Added Material #113983 (AQG, Custom Tubing Set, 3/8" ID, 36" L) and #113984 (AQG, Custom Tubing Set, ½" ID, 36" L) as alternates to #113981. -**In section 2.1.3** Corrected, Custom Tubing Set, ¼" ID, 36" L should have the following materials: #113983, #113984, and #113981. -The material name updated from, Custom Tubing Set, ¼" ID, 36" L to "Custom Tubing Set, 36" L. As Per QR-71929 (Thermo SUMs for Solutions) the following changes were made: -Growth media alternative MMD-000132990 added to sections 1.1.1, 1.1.4, and 1.1.6. -Transfection media alternative MMD-000132993 added to section 2.1.1. -2X HBS Buffer alternative MMD-000132996 added to sections 2.1.3, 3.1.1, 4.1.1, 5.1.1, and 6.1.1. -2M CaCl Buffer alternative MMD-000132997 added to sections 2.1.3, 3.1.1, 4.1.1, 5.1.1, and 6.1.1. -Refeed media alternative MMD-000132994 added to sections 7.1.1, 7.1.3, 7.1.5. -Step references fixed in sections 6.1.7 and 8.1.7. -Revision History updated from ETQ SOP, REC, WI numbers to Documentum numbers. Format Update.
13.0	The following changes were made per QR-71254: • Sections 1.1.4, 1.1.5, 1.1.6, 1.1.7, 3.1.2, 3.1.7, 4.1.2, 4.1.7, 5.1.2, 5.1.7, 6.1.2, and 6.1.7 – Updated rocker parameter check tables throughout document to align to parameters required on equipment and added separate tables throughout document for setting a parameter after starting the rocker (Rocker Angle Setpoint). The following change was made per QR-86659: • Section 2.1.4 – Updated plasmid material number for HPV275 to 413401 from 411719. The following change was made per QR-68753: • Section 10 – Updated attachments to include value for each line of control range. The following administrative change was made: • Section 8.1.4 – Updated verbiage of Step 4 to "Total Crude Harvest Settling Time." • Section 8.1.6 – Updated Sample Analysis table to provide space for recording Sample ID. • Section 8.1.7 – Updated to remove units of Celsius from actual column of Crude Harvest storage locations.
12.0	The following changes were made per QR-35815: • Alternative part numbers for PETG Bottles. • Section 2.1.3 - alternative part numbers for 110042 – added material #115348. • Section 8.1.7 – alternative part numbers for 110039 – added material #115345. • Section 2.1.2 equipment table- Removed Microscope from equipment table, as it is not needed. Section 6.1.2 Added recording steps to better align with WI-000129565. The following changes were made per QR-71254: • Section 1.1.2 equipment listed = welder, pumps XS/S Clipster and L-Clipster removed and added to section 1.1.4. • Section 1.1.3 added materials needed for transfer to Rocker BPC/inoculation.

	• Section 1.1.3 – Updated to separate materials table to prep and seeding. Moved seeding materials to Section 1.1.4. • Section 1.1.3 added AQG to MPC 114084, AQG reducer 413166, and Custom tubing length ¼" 113981 • Section 6.1.2 Added recording steps to better align with WI-000129565. • Section 1.1.4 and Section 1.1.6 – split up the recording steps for seed bottle #1/Rocker BPC #1 and seed bottle #2 Rocker BPC #2. • Section 2.1.3 Transfection Material – AQG wye or AQG tee connectors 113987/114052, AQG to MPC 114084, AQG reducer 413166, and Custom tubing length ¼" 113981 • Section 3.1.1 added recording steps for Rocker BPC modifications • Added Rocker BPC parameter Check in each transfection group, after "weight of transfection media added" parameter is record. • Added HyPerforma Rocker ID and transfection batch/Expiration recording in each transfection media mix group section to align with WI-000129565. <u>The following administrative changes were made:</u> • Formatting updates throughout document. • Updated equipment and calculation tables throughout document from "Witnessed" to "Checked" to align with SOP-001348. • Section 2.1.2 – Updated to only 2 entries for incubator equipment IDs. • Section 7.1.1 – Updated Incubator Temperature row to include an open cell for actual field. • Section 8.1.4 – Updated to include target of 0.0 kg crude harvest transferred end weight. • Section 8.1.6 – Updated to include entries for control and actual column that were omitted for sample analysis. • Updated to ensure "Witness" and "Check" steps state "Witnessed" and "Checked" to align with site standard. • Updated step references throughout document. • Added additional rows for signature log. • Updated "Lot" to "Batch" throughout document to align with site standard for material tables. • Updated References section. <u>The following changes were made per QR-95214:</u> • Updated to move tabletop scale from Section 1.1.2 to Section 1.1.4.
For previous history refer to REC history file.	

Electronic Signatures

Author: Lam, Steven

Document Number	Version	Status	Effective Date
MMD-000123092	19.0	Effective	Thu Jul 21 06:07:48 UTC 2022

User	Date	Justification
Rao, Ashwini	16-Jun-2022 19:18:51 (GMT)	Technical Approval
Yue, Yiren	16-Jun-2022 20:49:57 (GMT)	Quality Approval
Yue, Yiren	06-Jul-2022 20:54:28 (GMT)	External Approval Received