Applicable Sites: Berry Park, St Louis USA

Affected Area: Field Lab

Legal Entity Name: MO Bio Labs

BATCH PRODUCTION RECORD – ISSUE APPROVAL	
Issued By:	**Date:**

TABLE OF CONTENTS

1.0 General SOP References

Title	Reference #
N/A	N/A

2.0 Bill of Materials

Description	Material Master Number	Common Name / Intended use	Recommended Quantity
15 mL Screw-cap Falcon Conical Tube	XXXXXX	15 mL Falcon Tube	1
50 mL Screw-cap Falcon Conical Tube	XXXXXX	50 mL Falcon Tube	1
10 mL sterile syringe	XXXXXX	10 mL syringe	1
5 mL sterile pipette	XXXXXX	5 mL pipette	2
1.5 mL microcentrifuge tube	XXXXXX	1.5 mL tube	1
Gloves			2
5L Bag	XXXXXX		1
10L Bag	XXXXXX		1
Phosphate-Buffered Saline	XXXXXX	PBS	
Media	XXXXXX		
Acid	XXXXXX		
Base	XXXXXX		

3.0 Equipment

3.1 Serological pipette (aka Pipette Aid)

3.2 Bioreactor

3.3 Cell Counter

4.0 EHS Information

Identifier	Pictogram/ Signal Word	Hazard/Precaution Statement
MEDIA Description	**CONSULT EHS**	**CONSULT EHS**

5.0 Operational Instructions

5.1	Sample Collection	Initial / Date	
		Performer	Verifier
5.1.1	Put on gloves and sterilize.		
5.1.2	Take a clean 10 mL syringe and attach to the sampling port. Pull set volume (3-5mL). Measure as you pull the volume for each assay. Label, Initial, and date each tube. **Cell Count** **pH** **Gas** **Nutrients** **Ensure sample port is closed once samples are collected.**		
5.1.3	Check the following to ensure the bioreactor is operating as is 1. Agitator is going 2. pH has plummeted 3. No changes in pumps that got bumped 4. Didn't turn something on/off accidentally		
5.1.4	Gas sample. This is done in case off gassing has occurred. Any environmental factors would distort the sample.		
5.1.5	Prep sample for cell count.		

5.1	Sample Collection	Initial / Date	
		Performer	Verifier
5.1.6	Measure cell count. **Equipment #** **Calibration Date**		
5.1.7	Perform dilutions if over 10M cells/mL. **Use PBS or buffer in dilutions** and NOT water. **Count over 10M cells/mL** **Yes / No** **Dilution Factor** **Cell Count** Record results in Appendix A.		
5.1.8	Measure the glucose levels and determine whether they are within range or not. Determine if media needs to be added and how much. Follow these steps: 1) Determine how much glucose is needed (subtraction) 2) Calculate amount of glucose to add (C1V1=C2V2) Record glucose levels and media amounts in Appendix B.		
5.1.9	Measure the pH and determine whether they are within range or not. Adjust the pH to be within range. Record starting pH, ending pH, and acid or base amounts in Appendix C..		
5.1.10	Visually inspect the sample. Note its appearance (ex/ cloudy or clear) and smell in the Appendix D. Prep sample for imaging.		

SAP Material Verification:	Production Supervisor Review:	QA Review:
☐ N/A		

5.1	Sample Collection	Initial / Date	
		Performer	Verifier
5.1.11	Make images with Bac (Viacell images). Save images to designated location and label as follows: PN_BN_Date_Time_Initials		
5.1.12	Visually inspect the image for signs of contamination. Record results in Appendix A		

END of this protocol.

Appendix A. Time course of cell count measurements

Remove cells when Total Cell Count is within **1,000,000 - 1,100,000** total cell count.

	Date/Time Collected	Cell Count	Dilution Factor	Total Cell Count	Additional Comments
Sample 1	**Monday 8:00 AM**	**3 x 10^2 Cells/mL**	**1**		
Sample 2	**Monday 12:00 PM**	**6 x 10^3 Cells/mL**	**1**		
Sample 3	**Monday 4:00 PM**	**7 x 10^3 Cells/mL**	**2**		
Sample 4	**Tuesday 8:00 AM**	**8 x 10^4 Cells/mL**	**1**		
Sample 5	**Tuesday 12:00 PM**	**4 x 10^4 Cells/mL**	**4**		
Sample 6	**Tuesday 4:00 PM**	**2 x 10^4 Cells/mL**	**15**		
Sample 7	**Wednesday 8:00 AM**	**4 x 10^3 Cells/mL**	**190**		
Sample 8	**Wednesday 12:00 PM**	**3 x 10^3 Cells/mL**	**350**		
Sample 9	**Wednesday 4:00 PM**	**6 x 10^3 Cells/mL**	**400**		

SAP Material Verification: ☐ N/A	Production Supervisor Review:	QA Review:

Appendix B. Time course of glucose level measurements

Glucose readings should be **above 3.0 g/L.** When adding more glucose, bring glucose level **back to 5.0 g/L.**.

	Date/Time Collected	Glucose Level (g/L)	Volume (L)	In range	Glucose (200 g/L) added (mL)	Additional Comments
Sample 1	**Monday 8:00 AM**	**5.0**	**3.5**	**Y / N**		
Sample 2	**Monday 12:00 PM**	**4.2**	**3.5**	**Y / N**		
Sample 3	**Monday 4:00 PM**	**3.5**	**3.5**	**Y / N**		
Sample 4	**Tuesday 8:00 AM**	**2.3**	**3.5**	**Y / N**		
Sample 5	**Tuesday 12:00 PM**	**5.0**	**3.5**	**Y / N**		
Sample 6	**Tuesday 4:00 PM**	**3.8**	**3.5**	**Y / N**		
Sample 7	**Wednesday 8:00 AM**	**1.8**	**3.5**	**Y / N**		
Sample 8	**Wednesday 12:00 PM**	**5.0**	**3.5**	**Y / N**		
Sample 9	**Wednesday 4:00 PM**	**4.1**	**3.5**	**Y / N**		

SAP Material Verification: ☐ N/A	Production Supervisor Review:	QA Review:

Appendix C. Time course of pH level measurements

	Date/Time Collected	pH	Volume (L)	In range	Volume added (mL)	Additional Comments
Sample 1	**Monday 8:00 AM**			**Y / N**		
Sample 2	**Monday 12:00 PM**			**Y / N**		
Sample 3	**Monday 4:00 PM**			**Y / N**		
Sample 4	**Tuesday 8:00 AM**			**Y / N**		
Sample 5	**Tuesday 12:00 PM**			**Y / N**		
Sample 6	**Tuesday 4:00 PM**			**Y / N**		
Sample 7	**Wednesday 8:00 AM**			**Y / N**		
Sample 8	**Wednesday 12:00 PM**			**Y / N**		
Sample 9	**Wednesday 4:00 PM**			**Y / N**		

6.0 COMMENTS LOG

Comment Number	Step Number	Time (hhmm)	Comment

7.0 MANUFACTURING REVIEW

SAP Final Confirmation/ Clear Reservation (COR6)

SAP Material Verification: ☐ N/A	Production Supervisor Review:	QA Review:

Signature / Date	

SAP Review and TECO – COOISPI-(Review of material consumption) AND COR2- (final closure in SAP)	
Signature / Date	

Manufacturing Batch Record Review	
As a Manufacturing representative responsible for the review of this Batch Record, my signature indicates that the record has been reviewed.	
Comments [ ] N/A	
Signature / Date	

8.0 REVISION HISTORY

not included in this protocol