Validation Protocol: CliniMACS Automated Cell Separator

A. Information

Protocol Title	Validation of the CliniMACS Automated Cell Separator
Protocol Number	
Version	
Effective Date	
Equipment ID	
Equipment Location	

1.0 Objective

This protocol defines the procedures and acceptance criteria for the Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) of the CliniMACS Automated Cell Separator. The objective is to provide documented evidence that the instrument is installed correctly, operates according to manufacturer specifications, and consistently performs its intended function to deliver a product meeting predefined Specifications of Purity and Viable Cell Recovery, in compliance with cGMP, 21 CFR Part 11, and FACT standards.

2.0 Scope

This protocol applies to the qualification of the CliniMACS (or CliniMACS Prodigy equivalent), an automated, closed-system instrument critical for magnetic cell separation (selection or depletion). The instrument's primary function is to deliver high purity and viable cell recovery of the target population, which are specifications for therapeutic product manufacture. The use of a closed tubing set inherently mitigates contamination risk, aligning with strict cGMP requirements for product safety.

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3.0 Responsibilities

- Protocol Author/QA: Responsible for protocol generation, review, and final approval.
- Validation Team/Lab Personnel: Responsible for the execution of the protocol, data collection, and documentation.
- Management: Responsible for review and provision of resources.
- Quality Assurance (QA): Responsible for final approval of the protocol and the completed validation report.

4.0 Materials and Reagents

No.	Item	Serial No.	Calibration Date	Calibration Due Date	Initials / Date
1	CliniMACS Instrument				
2	Balance				
3	Temperature Probe				
4	Data Logger				
5	Pressure Decay Tester				

No.	Item	Manufacturer	Cat. No.	Lot No.	Exp. Date	Initials / Date
1	CliniMACS Tubing Set					
2	Phosphate Buffered Saline (PBS)					
3	CD3 Antibody					
4	Cells					
5	Trypan Blue					
6	PI					

5.0 Deviations

Any deviation from this protocol must be documented on a Deviation Form, justified, and approved by Quality Assurance before the validation can be considered complete.

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B. Installation Qualification (IQ)

To verify that the CliniMACS system has been received as specified, installed correctly, and that all required documentation is present.

IQ Execution Sheet

Step #	Requirement	Acceptance Criteria	Operator /Date	Verified (Y/N)	Comments
IQ-1	Verify instrument model and serial number against purchase order.	Model and Serial Number match procurement documentation.			
IQ-2	Confirm installation of utility connections (power).	Instrument powers on and operates normally.			
IQ-3	Confirm installation of network connection	Network connectivity is established and functional			
IQ-4	Verify all operational manuals, and SOPs have been received.	All required documentation is present and filed.			

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Step #	Requirement	Acceptance Criteria	Operator /Date	Verified (Y/N)	Comments
IQ-5	Verify the installed software version.	Software version is as specified in the order.			
IQ-6	Document 21 CFR Part 11 compliant controls.	System is configured for unique user logins, password protection, and generates a secure, indelible audit trail.			
IQ-7	Document instrument location and environment.	Instrument is installed in a suitable environment (clean, stable surface, adequate clearance).			

IQ Summary and Approval

IQ Conclusion:	The installation of the CliniMACS system (serial number) has been verified and found to be acceptable.
Operator Name	
Signature:	

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IQ Conclusion:	The installation of the CliniMACS system (serial number) has been verified and found to be acceptable.
Date:	

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C. Operational Qualification (OQ)

To verify that the instrument operates according to its functional specifications across its intended operating ranges.

C.1. Fluidics and Pump Accuracy

Acceptance Criteria: Measured volume is within ±5% of the set point for each test.

Procedure:

1. Verify calibration status of the balance.
2. Connect a sterile, empty bag to the designated final product port and place it on the balance. Tare the balance.
3. Execute the specified wash or collection step using water or PBS.
4. Record the weight and convert to volume (assuming density = 1 g/mL).

Data Sheet:

Test Step	Set Point (mL)	Measured Weight (g)	Calculated Volume (mL)	Deviation (%)	Within ±5% (Y/N)
Wash Step (500 mL)	500.0				
Product Collection (20 mL)	20.0				

Operator: _____ **Date:** _____

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C.2. CentriCult Unit (CCU) Temperature Control

Acceptance Criteria: 37.0 °C ± 0.5 °C over 60 minutes.

Procedure:

1. Place a calibrated temperature probe within the CCU chamber at a representative location.
2. Set the unit to 37.0 °C and initiate temperature control.
3. After the unit indicates it has reached the set point, monitor and record the temperature every 10 minutes for 60 minutes.

Data Sheet:

Time Point (min)	**Temperature (°C)**	**Time Point (min)**	**Temperature (°C)**
0		40	
10		50	
20		60	
30			
Min Temp:		**Max Temp:**	
Conclusion:	Pass / Fail		

Operator: _____ **Date:** _____

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C.3. Alarm and Interlock Verification

Acceptance Criteria: All critical alarms activate immediately and safely stop the process.

Data Sheet:

Alarm	**Method of Simulation**	**Alarm Activated (Y/N)**	**Process Stopped (Y/N)**	**Event Logged (Y/N)**
Over-temperature (High)	Set CCU temperature above acceptable limit.			
Pressure Deviation (High/Low)	Occlude fluid path or simulate a leak.			
Fluid Path Occlusion	Clamp tubing during a pump operation.			

Operator: _____ **Date:** _____

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C.4. Closed System Integrity Check

Acceptance Criteria: No pressure decay or visual leakage detected.

Procedure:

1. Connect a new, unused CliniMACS tubing set to the instrument.
2. Perform a pressure decay test per SOP (SOP number) or manufacturer's instructions.
3. Record initial pressure, final pressure, and hold time.

Data Sheet:

Test Parameter	**Result**
Initial Pressure (psi)	
Final Pressure (psi)	
Hold Time (min)	
Pressure Decay (psi)	
Visual Leakage? (Y/N)	
Conclusion:	Pass / Fail

Operator: _____ **Date:** _____

OQ Summary and Approval

OQ Conclusion:	The operational qualification of the CliniMACS system (serial number) has been executed and all acceptance criteria have been met.
Operator Name	
Signature:	

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OQ Conclusion:	The operational qualification of the CliniMACS system (serial number) has been executed and all acceptance criteria have been met.
Date:	

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D. Performance Qualification (PQ)

To demonstrate that the CliniMACS system consistently produces a product meeting the specifications of purity and viable cell recovery when used with representative starting material under standard operating conditions.

PQ Acceptance Criteria

Test Parameter	**Requirement Type**	**Target**	**Acceptance Criteria**
Target Cell Purity (CD3+)	Specifications	≥ 95% CD3+	≥ 85%
Viable Cell Recovery (CD3+)	Process Performance	≥ 65% of viable input	≥ 60%

Note: The specific acceptance criteria must be justified based on process development data and regulatory guidance.

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PQ Execution Sheet - Run 1 (recovery)

Step #	Procedure	Operator/Date
PQ-1.1	Prepare starting material. Determine pre-selection viable cell count and CD3+ purity via flow cytometry. Record the results in the table below.	
PQ-1.2	Execute the standard CD3 Selection protocol using a valid CliniMACS tubing set.	
PQ-1.3	Collect the final product. Determine post-selection viable cell count and CD3+ purity. Record the results in the table below and calculate recovery/purity.	

PQ Data Sheet - Run 1

Parameter	Value
Pre-Selection	
Total Viable Nucleated Cells	
% Viability	
% CD3+ Purity	
Post-Selection	
Total Viable Nucleated Cells	
% Viability	

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Parameter	Value
% CD3+ Purity	
Calculated Results	
Viable CD3+ Cell Recovery	
Conclusion (Pass/Fail)	

Operator: _____ **Date:** _____

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PQ Execution Sheet - Run 2 (limits)

Step #	Procedure	Operator/Date
PQ-2.1	Prepare starting material at the maximum allowable input cell number. Determine pre-selection counts and purity. Record the results in the table below.	
PQ-2.2	Execute the standard CD3+ Selection protocol.	
PQ-2.3	Collect and analyze the final product. Record the results in the table below and calculate recovery/purity.	

PQ Data Sheet - Run 2

Parameter	Value
Pre-Selection	
Total Viable Nucleated Cells	
% Viability	
% CD3+ Purity	
Post-Selection	
Total Viable Nucleated Cells	
% Viability	
% CD3+ Purity	

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Parameter	Value
Calculated Results	
Viable CD3+ Cell Recovery	
Conclusion (Pass/Fail)	

Operator: _____ Date: _____

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PQ Execution Sheet - Run 3 (recovery)

Step #	Procedure	Operator/Date
PQ-3.1	Prepare starting material. Determine pre-selection counts and purity. Record the results in the table below.	
PQ-3.2	Execute the standard CD3+ Selection protocol.	
PQ-3.3	Collect and analyze the final product. Record the results in the table below and calculate recovery/purity.	

PQ Data Sheet - Run 3

Parameter	Value
Pre-Selection	
Total Viable Nucleated Cells	
% Viability	
% CD3+ Purity	
Post-Selection	
Total Viable Nucleated Cells	
% Viability	
% CD3+ Purity	

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Parameter	Value
Calculated Results	
Viable CD3+ Cell Recovery	
Conclusion (Pass/Fail)	

Operator: _____ **Date:** _____

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PQ Summary and Approval

PQ Conclusion:	The performance qualification of the CliniMACS system (serial number) has been executed. All three consecutive runs met the predefined acceptance criteria, demonstrating the system's suitability for its intended use.
Operator Name:	
Signature:	
Date:	

E. Protocol Deviations

Deviation ID	**Section**	**Description of Deviation**	**Justification and Impact Assessment**	**QA Approval**

F. Final Report and Summary of Results

Qualification Phase	**Date Executed**	**Conclusion (Pass/Fail)**	**Comments**
Installation (IQ)			
Operational (OQ)			
Performance (PQ)			

Overall Validation Statement:

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Based on the successful execution of this protocol, the CliniMACS system, serial number _____, has been qualified and is deemed validated for its intended use in the cGMP manufacturing of cellular therapy products.

G. Protocol Approval

Review	Name (Print)	Signature	Date
Author			
Laboratory Manager			
Quality Assurance			

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