ACTG Leukapheresis External Quality Assurance Program, Investigation Report Form: Leukapheresis Qualification

EXTERNAL QUALITY ASSURANCE (EQA) INFORMATION

Note: Please complete all sections of this investigation report except where stated for "ACTG Network Use Only". Submit the report to the IQA (carmela.archual@duke.edu) and ACTG Laboratory Science Group (ACTG.labcenter@fstrf.org). Troubleshooting for leukapheresis processing must be completed and approved before qualification is complete.

CRS # :		EQA Provider: IQA (Leukapheresis Qualification)	
Laboratory Name:			
LDMS #:			
EQA Name:	IQA/ACTG Leukapheresis Qualification	Leukapheresis Processing Technicians (First and Last Name):	
		1.	4.
		2.	5.
		3.	6.
Date Leukapheresis was Performed:			
PID			
Visit			
Leukopak Processing SOP# and Version Number:			
Leukopak LDMS#			
Date Leukapheresis PBMC Aliquots were Submitted to the IQA for EQA Evaluation:			
Previous Leukapheresis Processing Problems (If yes, explain):			
Investigation Performed By (Name, Title, Email):		Date:	

Protocol Sample Processing Incident/Deviation (completed by ACTG/IQA):

Leukopak PBMC Processing QA					
Unacceptable Leukapheresis EQA Aliquot Identifier	IQA Reported % Viability	Acceptable % Viability	IQA Reported Viable Recovery	Acceptable Viable Recovery Range	Comment
		>85%		80-120%	
		>85%		80-120%	
		>85%		80-120%	
		>85%		80-120%	
		>85%		80-120%	
		>85%		80-120%	

ROOT CAUSE ANALYSIS

PRE-PROCESSING FACTORS:	YES	NO	N/A
1. Did laboratory and site review LPC and coordinate activities? Comments:	☐	☐	☐
2. Was leukopak received by processing lab within 2 hours of collection? Comments:	☐	☐	☐
3. Were transport conditions appropriate to protect leukopak from temperature extremes? Comments:	☐	☐	☐
4. Were any problems noted with the leukopak prior to processing? (e.g., labeling issues, leaking container, obvious clotting) Comments:	☐	☐	☐
5. Were there any other pre-processing factors that may pertain to this investigation? If yes, please explain. Comments:	☐	☐	☐
PROCESSING FACTORS:	YES	NO	N/A
1. Was the leukopak processed in accordance with the ACTG/IMPAACT PBMC Isolation from Leukapheresis Standard Operating Procedure (SOP)? Comments:	☐	☐	☐
2. Were reagents examined for acceptability (*quality, kept at proper storage temperatures, used within defined shelf life, other QC)*? Comments:	☐	☐	☐
2. Was the leukopak material diluted adequately prior to lymphocyte separation? (i.e. diluted with WDR to at least 600mL for a whole leukopak or to 300mL for a half leukopak) Comments:	☐	☐	☐
3. Was an automated cell counter utilized? If yes, provide make and model and verify that all QC was performed and valid prior to use. Please indicate if this is the same system utilized for routine PBMC cryopreservation. Comments:	☐	☐	☐
4. Was a manual (hemacytometer) used to perform the cell counts? If yes, indicate if this is the same system used for routine PBMC cryopreservation. Comments:	☐	☐	☐
5. Were additional dilutions required to obtain valid cell count? Please verify that the final correction factors used to calculate the total cell count were accurate. Comments:	☐	☐	☐
6. Was a PBMC Processing record worksheet utilized in real-time to document reagents, dilutions, calculations, other factors? Comments:	☐	☐	☐
7. Were harvested cells resuspended in CPS in batches to minimize exposure to CPS? Comments:	☐	☐	☐
8. Was gentle mixing of the cells in CPS employed during distribution into aliquot vials? Comments:			

10 Was processing completed and aliquots in freezer within 8 hours of collection (Leukapheresis procedure stop time)? Comments:	☐	☐	☐
11. Are questionable results reviewed by supervisor and is that review documented? Comments:	☐	☐	☐
12. If applicable, was prior EQA performance for leukapheresis processing reviewed, investigated and problems resolved? Comments:	☐	☐	☐
13. If applicable, was prior EQA performance for routine PBMC processing reviewed, investigated and problems resolved? Comments:	☐	☐	☐
14. Any other processing factors that may pertain to this investigation? Comments:	☐	☐	☐
PROCESSING FACTORS:	YES	NO	N/A
1. Were leukapheresis aliquots shipped and stored appropriately according to temperature requirements to the IQA for this EQA program? Comments:	☐	☐	☐
2. Was the shipment prepared according to ACTG and IQA shipment guidelines for cryopreserved PBMCs? Comments:	☐	☐	☐
3. Was proper temperature of aliquots maintained during shipment (was the laboratory notified by the IQA that temperature control failed during shipment)? Comments:	☐	☐	☐
4. Was the shipment delivered to IQA on time? If not, explain reason for delay. Comments:	☐	☐	☐
5. Any other post-processing factors that may pertain to this investigation? Comments:	☐	☐	☐

INVESTIGATIVE ACTIONS AND ROOT CAUSE

Briefly discuss what actions were taken in this investigation:

What do you believe is/are the primary cause (s) of this problem?

Type of Error:

- ☐ Methodological
- ☐ Technical
- ☐ Clerical
- ☐ EQA evaluation problem
- ☐ Other (explain)

Future Preventative Measures/Actions
Discuss how you will prevent this problem from occurring in the future:

Investigative Report Prepared by:

Name/Title	Date	Signature
PI Name/Title	Date	Signature

FOR ACTG NETWORK USE ONLY- IQA REVIEW

COMMENTS:

		☐	Acceptable and complete Investigation.
Name/Title	Date	☐	Investigation is incomplete. See comments.

Study Impact

If applicable, were study participant results assessed for adverse effects?

If applicable, review participant results, amend results and notify the following---physicians, study staff and network representatives.

Comments:

Table for Supporting Documents:	
Attachment #	Description