STEM CELL LABORATORY (STCL)

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DOCUMENT TITLE:

Immune Reconstitution Alternate Performance Assessment Process JA1

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IMMUNE RECONSTITUTION ALTERNATE PERFORMANCE ASSESSMENT PROCESS

PURPOSE:

For tests for which the College of American Pathologists (CAP) does not require proficiency testing (PT), the laboratory at least semi-annually exercises an alternative performance assessment system for determining the reliability of analytic testing. This procedure is to be used when carrying out alternative performance assessment required by the College of American Pathologist (CAP). This testing shall be performed semi-annually in concert with the first and last CAP lymphocyte immunophenotyping surveys.

INTRODUCTION:

Although Proficiency testing for lymphocyte antigens CD3, CD19, CD16+56, CD4, and CD8, is provided by the CAP PT program, there is no such PT available for many of the markers or marker combinations that are used to monitor immune reconstitution of transplant recipients. Currently there is no available peer group test available for the specific antibody combinations that we utilize in the Stem Cell Lab to define NK T-cells, recent thymic emigrants (RTE), cytotoxic T-lymphs (CTL), T-regs, cell activation, and dendritic cell subsets. For this reason we have defined an alternate performance assessment process.

PROCESS:

Semi-annually we will obtain 1 peripheral blood draw from each of 2 healthy donors which have been assayed no fewer than 10 times previously and from which the statistical mean and 95% confidence limits are established. Testing will be carried out as is done for patient testing (see FLOW-GEN-007) and results will be recorded and compared to the established assay range (Example A). Results for each test will be compared to the assayed mean to monitor trends over time.

Although they will be included for quality control purposes, the major lymphocyte subsets (CD3, CD19, CD16+56, CD4, and CD8) will not be subject to the alternative performance measure since these markers are included in the CAP proficiency test surveys.
If results fail to meet the established criteria for acceptability (outside 2SD) then an investigational report form (Example B) will be initiated and submitted to the lab director upon completion. The investigational report is based on the Duke Pathology Investigational Report and has been modified to apply to our needs. Based on the findings from the investigation, a corrective action plan will be submitted to the lab director for approval.

Example A:

Testing Date:	
Test ID:	

Donor ID:	Donor 001			Donor 002		
	Result	Result compared to mean	PASS/FAIL	Result	Result compared to mean	PASS/FAIL

Example B:

Stem Cell Laboratory

ALTERNATIVE PROFICIENCY TEST RESULT(S) Outlier – INVESTIGATION FORM

Date of testing: _____ **Due date for completion of investigation:** _____

Survey Name:	
Survey Number:	
Laboratory Section:	
Source material:	
Date Analysis Performed:	
Date testing completed:	
Investigation Performed by:	

Result 1	
Survey/Specimen Number:	
Analyte:	
Reported Result:	
Intended Result/Range:	
Repeated Test Result:	
ID of Performing Tech:	
Result 2	
Survey/Specimen Number:	
Analyte:	
Reported Result:	
Intended Result/Range:	
Repeated Test Result:	
ID of Performing Tech:	

Evaluation of Possible Sources of Error	YES	NO	NA	If NO, what contributed to this factor being an issue?	Is this a root cause of the event? YES	Is this a root cause of the event? NO
Clerical						
Was the result correctly transcribed from the instrument read-out report?						
Was the correct instrument/method/reagent reported on the result form?						
Do the units of measure match between the result form and the instrument results?						
A response of NO to any of these questions may indicate a clerical error. Although reporting of proficiency results is unlike those for patient results, clerical errors may indicate a need for additional staff training, review of instructions provided with the proficiency testing or investigation of reporting format provided by the testing device. If results reported on the result form do not match the results found on the evaluation report, please contact your proficiency testing provider.						
Procedural						
Was the written procedure followed?						
Were the reagents prepared according to procedure?						
Were the reagents within their open stability acceptable range						
Were the QC results acceptable						
Was staining performed and interpreted correctly?						
A response to NO to any of these questions may indicate a procedural error. These errors indicate inappropriate operation of equipment or performance of a method. A review of the instructions provided with the proficiency testing material and/or review of laboratory procedures may be required.						
Analytical						
Was the most recent calibration acceptable and within established stability limits at the time proficiency testing was						
Does a review of the past proficiency testing results indicate evenly distributed data without bias?						
Was the intended result within the measuring range for the instrument?						
Was the instrument maintenance performed on schedule?						
Does a review of records indicate that there were no related instrument/test problems noted prior to or after the proficiency testing was performed?						
A response of NO to any of these questions may indicate an analytical error. These types of errors could indicate a failure to follow recommended instrument maintenance and calibration.						

Evaluation of Possible Sources of Error	YES	NO	NA	If NO, what contributed to this factor being an issue?	Is this a root cause of the event? YES	
Specimen Handling						
Was the healthy donor experiencing any health symptoms at the time of sampling?						
Were the Survey specimens stored as indicated in the Kit instructions?						
Were any special instructions provided in the Kit instructions performed as indicated?						
Were the correct tests performed on the correct vial of proficiency testing material?						
A response of No to any of these questions may indicate a specimen handling error. These types of errors could indicate a failure to read the material provided with the Survey materials.						
Proficiency Testing Material						
Was proficiency testing material tested within 24 hours of sample draw?						
Were the results compared to the correct assay mean?						
A response of No to any of these questions may indicate a problem with the PT material. If a delay in receipt of material in the laboratory is an issue, contact your in-house receivables department to ensure timely receipt of Surveys after arrival in your institution. If you believe your result was compared to an inappropriate peer group, verify the method reported on the result form. Contact your proficiency testing provider for additional information if needed.						

Evaluation Factors	YES	NO	Explain details of Corrective Action	Performed by:
Patient data generated during the unacceptable PT?				
Review of Calibration and QC during PT event acceptable?				
If review of Calibration and QC unacceptable, were patient results reviewed with laboratory director?				
Comments:				

Corrective Action Plan

Reviewer Name		Signature	Date	Comment
Lab Manager				
Lab Medical Director				

INVESTIGATIONAL REVIEW

(To be filled out by Laboratory Director)

Type of Problem: ☐ Methodological ☐ Technical ☐ Clerical ☐ Survey

☐ Systemic ☐ No Explanation after Investigation

Severity:

0 Extramural Factors
- Computer error
- Problems with survey material
- Lack of referee consensus

1 Deviations without risk of clinical impact
- Clerical errors in result reporting without counterpart in institutional laboratory practice (i.e., mis-transcription onto response form of results from correct laboratory determination)

2 Differences with expected variance of applicable methods
- Statistical variance without evidence of adverse trends
- Defensible interpretive differences arising from use of qualitative or imprecise methods
  - Morphologic Hematology
  - Clinical Microscopy
  - Dipstick Colorimetry

3 Deviations with minimal risk of misinterpretation or adverse clinical impact
- Screening test results that would lead to follow-up or confirmatory testing
- Clinically implausible results

4 Deviations with significant risk of misinterpretation or inappropriate clinical intervention
- Generation of clinically plausible, incorrect test results that could lead directly to improper clinical intervention

5 Non-standard laboratory practices with potentially grave consequences
- Failure to use appropriate controls
- Professional misconduct

Comments:

_____ _____ / _____ / _____

Laboratory Director or Designee **Date**

Signature Manifest

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All dates and times are in Eastern Time.

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