KAISER PERMANENTE

Kaiser Permanente Medical Center, San Francisco
Northern California Region
********** **********

Work Instruction

Title:	**TQ - Proficiency Testing Details for Transfusion Service**	**WI Number** SFOWI-0150 **Revision:** 22
Department: Immunohematology **Area:** 2425 Geary Blvd SFO Hospital Lab	***Document is in the Final Approval Process. 2 - approvals are required***	
Type of Document: Policy		**Review Period -** 340 **Days**

I. PURPOSE

Proficiency testing (PT) is defined as determination of laboratory testing performance by means of interlaboratory comparisons, in which a PT program periodically sends multiple specimens to members of a group of laboratories for analysis and/or identification; the program then compares each laboratory's results with those of other laboratories in the group and/or with an assigned value.

The purpose of this Work Instruction is to describe the PT process that is unique to Transfusion Service. Details which are not addressed in this WI are covered in its associated SOPs, SFOSOP-0006, QS-NCAL Laboratory Proficiency Testing Policy and SFOWI-1223 NCAL Laboratory Testing Personnel Proficiency Testing Procedure.

II. QUALITY CONTROLS

A. The Transfusion Service Supervisor and Medical Director review all PT reports.
B. A second CLS reviews online data entry for accuracy prior to PT results submission.
C. Supervisor and ALAD are responsible to ensure that the laboratory participates in PT for all CLIA regulated analytes, i.e. blood typing, antibody screening, antibody identification and compatibility testing.

III. PROCEDURE

A. PT Participation and Enrollment

1. This laboratory is enrolled in the College of American Pathologists (CAP) proficiency testing program for all regulated analytes.
2. The laboratory policy requires all proficiency testing samples to be analyzed in our laboratory on site and prohibits referral to another laboratory with a different CLIA number.

B. Activity Menu

1. The Activity Menu submitted to CAP accurately reflects the laboratory's current

testing activities and is reviewed annually.

2. When changes in the test menu impact PT enrollment, CAP is notified in the manner they prescribe.
3. In addition, CAP is also notified accordingly when PT survey materials for discontinued test activities are received.

C. PT Ordering

1. Annually, the PT enrollment is assessed for accuracy and completeness by the supervisor based on the most current testing activities and regulated analytes.
2. Any changes to the previous year's PT orders will be submitted to the ALAD for processing before the submission deadline imposed by CAP.
3. The ALAD will receive an email from CAP once the survey kit has been shipped. The email will include the tracking number.
4. If the survey kit is not received within four days after the shipping date, the ALAD or designee will investigate and notify CAP for reorder if necessary.

D. PT Shipment Schedule

The schedule of the following subscribed PT surveys can be found at www.cap.org - Proficiency Testing - My PT Shipping Calendar:

PFG Code	Set	Program Code	Product Fulfillment Group Name
DAT	A	DAT	Direct Antiglobulin Testing
DAT	B	DAT	Direct Antiglobulin Testing
ELU	A	ELU	Elution
ELU	B	ELU	Elution
JAT	A	JAT	Transfusion Medicine (Automated)
JAT	B	JAT	Transfusion Medicine (Automated)
JAT	C	JAT	Transfusion Medicine (Automated)
EXM2	A	EXM2	Electronic Crossmatch
EXM2	C	EXM2	Electronic Crossmatch
RBCAT	A	RBCAT	Red blood cell antigen typing
RBCAT	B	RBCAT	Red blood cell antigen typing

E. PT Receiving and Storage

1. Survey packages are received in the facility's central receiving location and delivered to the laboratory by Materials Management.
2. **The laboratory personnel accepting the package must follow the instructions outlined below:**
    a. Remove accompanying survey paperwork and time stamp with receipt date and time.
    b. Inspect survey materials for acceptability or indication of improper shipping.
    c. Store the survey materials according to the storage instruction in the kit.
    d. Complete the relevant section on the **CAP Proficiency Testing Tracking Form**.
    e. Inform a supervisor/designee or ALAD of the survey kit's arrival and any problem observed. Leave the Tracking Form and all paperwork for supervisor.

3. Supervisor or designee performs the following:

a. If there is any discrepancy or survey materials are unacceptable, notify the CAP via email or phone call on the same day or the next business day for replacement kit.
b. Supervisor or designee reviews Kit Instructions for any special handling and/or revision.

c. **Fill out and affix the following label on the styrofoam box except for JAT surveys:**
   i. PT Product Code: _____
   ii. PT Kit #: _____
   iii. Received Date: _____
   iv. Received By: _____
   v. Assay Within: _____
d. **For JAT Surveys:**
   i. Centrifuge specimens immediately upon receipt and check for hemolysis. Contact CAP for replacement if moderately or grossly hemolyzed.
   ii. Place samples in a rack and affix a completed label mentioned above on the rack.
e. **For Donor Cells:**
   i. Write or affix a label "DONOR" to the vial/tube of donor cells without covering any information.
   ii. For JAT-A and JAT-C kits, enter the donor# into the LIS inventory.
      - Select CAP Proficiency Testing as Supplier.
      - Select a long dated unit of pRBC in actual inventory with the same ABORh to scan other quadrants.
   iii. Confirm the donor blood type in LIS for JAT-A and JAT-C kits. For all others, write results on Supplemental Worksheet.
   iv. Write the donor blood type on the CAP PT Instructions handout sheets.
f. Complete the relevant section on the CAP Proficiency Testing Tracking Form.
g. Place the PT samples in the designated BB CAP storage refrigerator; bottom shelf of Fridge#4.

F. PT Assignment

1. CLS Assignment
   a. Proficiency samples are analyzed within the routine laboratory workload and rotated among testing personnel on all shifts using the same primary methods.
   b. Proficiency testing events will be rotated between identical analyzers which are routinely used concurrently for patient testing unless the designated analyzer is out of service at the time of PT testing, i.e. JAT-A on Analyzer 1 and JAT-B on Analyzer 2.
   c. Each PT 'patient' sample in the survey kit is assigned to only one CLS.
   d. Within 3 days after the survey kits are received in the laboratory, supervisor or designee assigns the testing personnel who are informed via email:
      i. Tentative and confirmed CLS and instrument assignments are documented on an Excel worksheet titled 'CAP Proficiency Assignments'.
      ii. Supervisor or designee fill out the appropriate CAP PT Instruction form and assign the samples.
      iii. The in-lab due date is 7 days (except for EXM2 surveys) prior to actual CAP submission deadline and is indicated on the Instruction form. The in-lab due date for EXM2 surveys should at the latest be on the Friday before the CAP deadline. The EXM2 has longer in-lab due date because the EXM cannot be performed before the JAT TYSC is performed and verified.
      iv. Supervisor or designee distribute the CAP PT Instruction form (other information sheet will be included when relevant) to the assigned CLS.
      v. Instructions on how to order PT samples in the LIS may be included in the email for JAT-A, JAT-C and EXM2 surveys. (Instructions are located in

the Millennium Quick Reference binder).

vi. Copy(ies) of Kit Instructions and CAP Result Form will also be given to CLS if there are pertinent patient history or when special specimen handling/testing is required or results cannot be documented on laboratory worksheets/LIS.

vii. The CLS is responsible to notify the supervisors or ALAD as soon as possible if he/she is also assigned the same survey sample at their other employment so he/she can be excused from the current PT assignment.

2. **Assignment of Name and MRN for PT Samples**
Note: Supervisor or designee submit a written request for PT MRNs to be created in Millennium for JAT-A and JAT-C surveys (JAT-A and JAT-C include the EXM2 surveys) from RILIS Central prior to receiving the kits.

PFG Code	Set	Name	MRN
JAT	A	SFOCAP, YYJA-XX	TBD
JAT	B	N/A	N/A
JAT	C	SFOCAP, YYJC-XX	TBD
DAT	A	N/A	N/A
DAT	B	N/A	N/A
ELU	A	N/A	N/A
ELU	B	N/A	N/A
EXM2	A	N/A	N/A
EXM2	C	N/A	N/A
RBCAT	A	N/A	N/A
RBCAT	B	N/A	N/A

YY - last 2 digits of the year
XX - 2 digit of the sample number e.g. 01.
TBD - To be determined as MRNs can only be generated by RILIS Central when requested.

Assignment of DIN for PT Donor cells

PFG Code	Set	Donor	DIN
JAT	A	JAT-06	JA06RYYYY
JAT	B	JAT-13	N/A
JAT	C	JAT-20	JC20RYYYY
EXM2	A	EXM2-01, EXM2-02, EXM2-03	Provided by CAP
EXM2	C	EXM2-04, EXM2-05, EXM2-06	Provided by CAP

G. PT Testing

1. Testing should commence within 10 working days of the survey materials' receipt date or sooner when specifically noted on the CAP PT Instructions sheet.
2. PT samples will be run in a batch with actual patient samples whenever possible.
3. Proficiency test samples are never referred to another laboratory and never accepted

for testing from another laboratory.

4. Any interlaboratory communication about proficiency test samples is strictly prohibited before the deadline for submission of results to CAP.
5. Proficiency test sample is analyzed once only as replicate analysis of patient sample is not routinely performed.
6. The assigned CLS is responsible:
    a. To read and follow the CAP PT Instructions sheet and any included Kit instructions.
    b. To accurately identify the assigned PT sample and PT donor sample.
    c. For knowing the respective SOPs associated with the assigned PT survey.
    d. To handle the PT sample and perform the tests according to current SOPs unless otherwise instructed by CAP, i.e. compatibility testing is performed on CAP samples even when the donor cells are of an incompatible blood group or antigen positive.
    e. To record results in the same manner as in routine patient testing. Reactions are recorded as the tests are being read.
    f. To print automated testing results with the instrument's unique identification.
    g. To enter results into the LIS when instructed except for crossmatch with donor cells of incompatible blood group.
    h. To use Supplemental worksheets and antigrams for recording manual tests results, extended workup and results that cannot be entered into the LIS.
    i. To sign the attestation on the CAP PT Instructions form that he/she is not working on the same survey sample at their other employment.
    j. To submit all paperwork including instructions sheets, result forms, printouts, worksheets and antigrams to a supervisor by the deadline (a week or 2 weeks before the actual CAP deadline) indicated on the CAP PT Instructions form.

H. PT Raw Data Review and Results Submission

Note: For details on how to access CAP PT results form online, refer to SFOSOP-0006, QS-NCAL Laboratory Proficiency Testing Policy.

1. As soon as possible, preferably 5 days before the actual due date, supervisor or designee reviews completed proficiency tests' raw data and interpretations, and then transcribes the results onto the online survey form (cap.org - Proficiency Testing - Result Form).
2. The person performing the online data entry must change any pre-populated data that no longer reflect current practice, e.g. test methods and reagents.
3. Before online submission, a second CLS or supervisor or ALAD reviews the online result entry for accuracy and completeness (all required fields are populated and all pages saved) then prints a copy. He or she then initials and date for performing the 2nd review.
4. Immediately after online approval/submission, the submitter (who can also be the 2nd reviewer) prints a copy of the submitted results and printscreens the ‘Result Form Data Entry and Receipt Verification’ window to capture the RECEIVED status of the survey. The submitter must also make sure that **all pages of the online form is in RECEIVED status**.
5. The PT attestation statement on the CAP paper form is signed by the Transfusion Service Medical Director and the CLS who performed the tests.
6. All PT paperwork are then filed in the current year's CAP PT binder.

I. Evaluation of the Proficiency Test Report and Scorecard

Note: For more information, please refer to SFOSOP-0006, QS-NCAL Laboratory

Proficiency Testing Policy.

1. The CAP Evaluation report is printed from the CAP website once an email notification of online availability is received.
2. **Supervisor or Designee review:**
   - **a. Graded Analytes marked as 'Good:**
     - i. If a trend or bias is observed, investigate causes such as calibration, maintenance, and take corrective actions as necessary and document accordingly.
     - ii. Investigation is unnecessary if no trend or bias.
   - **b. Graded Analytes marked as 'Unacceptable:**
     - i. Refer to the SFOSOP-0269 NCAL Proficiency Testing Report Investigation and Corrective Action Policy which provides work instructions for investigating and completing corrective action for a report of unacceptable proficiency testing (PT), unacceptable alternate proficiency testing (PT) results, or results with exception reason codes evaluated to be unacceptable.
     - ii. Investigation and corrective action must be completed within 45 days of report receipt.
     - iii. Supervisor or designee will complete the online CAP Laboratory Accreditation Program Investigation Response form based on the investigation and then print it out.
     - iv. The corrective action plan may include one or more of the following measures:
       - Repeat testing on Proficiency samples and evaluate for acceptability.
       - Monitor daily QC, calibration, and maintenance for unusual trends or problems.
       - Revise testing process or methodology if necessary. If the test system is inaccurate, repeat of patient samples may be required from the time of problem discovery and look back to the last accurate result. The trace back of samples may be limited to stability requirements and/or sample retention period.
       - Re-train personnel if indicated.
       - Notify Transfusion Service Medical Director and the provider of any significant error or when patient(s) must be recalled.
       - The effectiveness of any corrective action must be assessed at the next survey event.
       - If validation material is available through CAP, the material may be purchased and used to validate the corrective action as soon as possible.
   - **c. Ungraded Analytes:**
     - i. These are results that were intended to be graded, but were not, for reasons such as: lack of consensus; results submitted after the cut-off date; did not submit results; did not complete the result form correctly (e.g, wrong method code or result recording in the wrong place).
     - ii. Determine the code provided in the Your Grade column and follow the instructions for that code in the CAP Participant Summary Report.
     - iii. If due to late/no submission or incomplete result form and/or worksheet, perform self-evaluation using the criteria in the table below. Write 'Acceptable' next to the ungraded analyte if the result meets the criteria.

Analyte	Evaluation Criteria
ABO Group	95% Participant or 100 % Referee Consensus
Rh Type	95% Participant or 100 % Referee Consensus
Antibody Detection	95% Participant or 95 % Referee Consensus
Antibody Identification/ elution	95% Participant or 95 % Referee Consensus
Compatibility Testing	95% Participant or 100 % Referee Consensus
DAT	95% Participant or 95 % Referee Consensus

iv. If due to lack of participant or referee consensus, the results are acceptable if they fall within the majority responses in the Participant Summary Report. Indicate acceptability next to the grade on the evaluation printout.
v. Document corrective action taken for any unacceptable results per SFOSOP-0269 NCAL Proficiency Testing Report Investigation and Corrective Action Policy.

d. Educational Challenge:

i. Compare the result to the majority of participants' responses in the Participant Summary Report. The results are acceptable if they fall within the majority responses. Indicate acceptability next to the grade on the evaluation printout.
ii. Document corrective action taken for any unacceptable results per SFOSOP-0269 NCAL Proficiency Testing Report Investigation and Corrective Action Policy.

e. For **ungraded analytes and educational challenge**, it is important to document the dates of reviews, initials or signatures of the reviewers, the concluded correct response or majority response (from the Participant Summary Report), and the acceptability written next to each ungraded result.
f. Supervisor or designee signs and dates the front page of the report after review.

3. After review by the supervisor, the CAP Evaluation report is submitted to the Transfusion Service Medical Director for approval.

4. **Corrective Action and CAP Exception Response:**
   a. Refer to SFOSOP-0269 NCAL Proficiency Testing Report Investigation and Corrective Action Policy.
   b. Complete and submit the appropriate response form to CAP.
   c. If the laboratory was instructed by the CAP to cease patient testing for an analyte or subspecialty due to repeat unsuccessful proficiency testing, the following records must be retained to demonstrate that no patient results were released until after the laboratory received approval from the CAP to resume patient testing:
      i. Records of communication notifying staff/physicians that testing is suspended for the required period of time OR
      ii. LIS report verifying that no patient results were reported for the affected analyte or subspecialty during the cease testing time frame OR
      iii. Patient reports indicating name and address of laboratory where testing was performed during the affected period OR
      iv. Send-out log to referral laboratory.

5. **Sharing Results with Staff:**

Staff is informed of the CAP evaluation results and any corrective action in monthly meetings.

J. **Records Retention**
1. Proficiency Testing records including packaging documents, instruction sheets, checklist, printed online forms, raw data, evaluation report and corrective action will be kept on site for a minimum of 2 years.
2. Records may be sent to CRD after the two years on site storage for the remainder retention time which totals 5 years for Transfusion Medicine.

IV. PROCEDURE NOTE(S)

1. When a test is put back into production (Intermittent Testing), proficiency testing or alternative assessment should be performed within 30 days prior to restarting patient testing.

V. REFERENCE

A. AABB, Standards for Transfusion Services and Blood Banks, current edition, Bethesda, MD.
B. Food and Drug Administration, Department of Health and Human Services. Title 42, Code of Federal Regulations, Part ***493 to end, Washington, DC: U.S. Government*** Printing Office, (revised annually).
C. Transfusion medicine checklist. College of American Pathologists, current version, Northfield, IL.
D. Transfusion medicine surveys supplement. College of American Pathologists, current annual supplement, Northfield, IL.

Associated Documents:

External Documents

SFOFCD-0202 QS - Proficiency Testing Forms
SFOSOP-0006 QS - NCAL Laboratory Proficiency Testing Policy
SFOSOP-0269 - NCAL Proficiency Testing Report Investigation and Corrective Action Policy
SFOFCD-0218 - NCAL Laboratory PT Exception Investigation and Corrective Action Form
SFOWI-1223 - NCAL Laboratory Testing Personnel Proficiency Testing Procedure

Associated Quality System Documents - None

Documents Generated:

Document Revision History:

Revision: 22	**Date Created:** 10/02/2005 **Date of Last Revision:** 01/17/2019	**Last Approval Date:** 03/24/2017

Document Author: Cara H Lim/CA/KAIPERM	**Document Manager:** Richard Chui/CA/KAIPERM

Reason for Change:

Revision:	Sec/Para Changed	Change Made:	Date
1	N/A	Initial Issue of Document	
2	Approver	New Lab Director	11/27/06
3	Approver	New Lab Director	6/1/07
3	Procedure	Enter CAP samples in RILIS using the assigned CAP patients	7/1/07
4	Procedure	Submit CAP result on-line	7/14/07
5	Procedure A-4-e-(C)	Enter PFGCodesSet SampleRYYYY as the donor red cell number.	11/30/07
6	Procedure	Assign new MR# to each CAP sample	03/08/08
7	Procedure	Reviews of PT should be completed within one month.	02/28/09
8	Procedure C Approver	Changed Patient Registration instructions for PT Samples in Millennium. Added CAP PT Instruction form. Added all results should be entered in LIS unless prohibited by the system. Added use of Supplemental worksheets and antigrams. Changed Blood Bank to Transfusion Service. Added filing of completed PT paperwork. Changed Medical Director.	5/11/11
9	Quality Control Procedure A Procedure A.2 Procedure A.3 Procedure A.4 Procedure B.7 Procedure B.15 Procedure D.2, 3 Procedure D.5.d	Added that the supervisor and ALAD are responsible to ensure that the lab participates in all CLIA regulated tests. Changed 'subscribes' to 'is enrolled in' and added 'for all required CAP surveys'. Changed to instruct employee to time stamp, store kit appropriately and inform a supervisor upon receipt of survey. Added 'acceptability', 'via email or phone call'. Added supervisory review of the Kit Instructions for revision. Added instruction to attach revised specimen or testing Kit Instructions. Added signatures for attestation statement. ***Added 'promptly' and 'documented'.*** Changed 'did not submit an appropriate method code' to 'did not complete the result form correctly'.	10/12/11
10	Procedure Notes	PT within 30 days prior to restart intermittent testing .	12/4/2011
11	Procedure C.2 Procedure C.3 Procedure C.4, 5, 6, 7, 8	Added that PT will be alternated on instruments. Deleted instructions for entering/ordering PT samples in RILIS Millennium. Deleted instructions pertaining to RILIS Millennium.	1/26/2012
12	Procedure C.3 Procedure C.4 Procedure C.6 Procedure C.14 Procedure D.6 Procedure D.7 Associated Documents	Changed manual MRNs assignment to 'TBD' for J-A, J-B and J-C Surveys as these kits include EXM Surveys. Added table for DIN assignment. Added instructions to request PT MRNs from RILIS prior to receiving J-A, J-B and J-C survey kits. Added to include StageNC access instructions in email to CLS. Added instructions to print a copy of the submitted results form. Added the use of PT Investigation Report form for unsatisfactory PT results. Added instructions to complete the CAP Laboratory Accreditation Program Exception Response form. Added the PT Instructions forms and PT Investigation Report form.	2/8/2012
13	Whole document Procedure	Revised to incorporate elements required by Regional Lab LQC. New sections created for new instructions.	6/5/12
14	Whole document Whole document Whole document Procedure F.2	Changed StageNC to Millennium. Deleted J-B for Millennium results entry. Revised to align with Regional LQC PT investigation and corrective action policy. Changed last name convention for J-A and J-B from CAPXXXX to SFOCAP in accordance with RILIS Central's policy.	12/21/12
15	Approver	New Lab Director.	5/16/13
16	Approver Procedure G.1 Procedure E.e	New BB Medical Director. Added or sooner when specified by CAP. New. Added instructions for donor cells handling.	9/9/13
17	Procedure J.	Added evaluation report and corrective action. Changed to 2 years on-site storage. Added that records may be sent to	11/8/13

		CRD after 2 years for 5 years total retention time.	
18	Whole document Associated Documents	Changed Chain of Custody Checklist to Tracking Form per NCAL standardized PT policies and documents. Added titles of associated policies, procedures and forms.	4/30/14
19	Procedure E.3.a Procedure F.1.d.ii Procedure F.1.d.iv	Changed from within 10 days to the same or next business day to inform CAP of unacceptable survey materials. Added in-lab due date to reflect current practice. Added Millennium Quick Reference binder for LIS instructions.	6/13/14
20	Procedure E.3.e.i Procedure E.3.e.ii Procedure G.6.b. Whole document Procedure I.2.c. and d Procedure I.3 Procedure 4 Approver	Added instructions to label vial/tube containing donor cells per current practice. Added instructions on how to enter donor cells in LIS for JAT-A and JAT-C surveys. Added CLS responsibility to accurately identify PT samples. Deleted J survey and EXM survey which were cancelled per LQC's recommendation and replaced by addition of EXM2 to JAT surveys. Revised determination of result acceptability for ungraded analytes and educational challenge. Revised review process for evaluation report. Revised Exception Response instructions to refer to NCAL Regional policy. New CLIA Director.	8/31/16 10/25/16 12/5/16
21	Procedure G.3 Procedure I.4.c	Revised CAP Common Checklist requirement COM.01900 Rev.08/17/2016 specifically prohibits acceptance of PT samples from another laboratory for testing. New CAP Common Checklist requirement COM.01950 Rev.08/17/2016 requires certain records retention to demonstrate cessation of patient testing due to repeat PT failures.	3/14/17
22	Procedure F.1.b Procedure F.1.d.iii.	Change ProVue to Analyzer. Revised in-lab due date for EXM2.	1/1/19

Notification List:

Approvals:

First Approver's Signature

Name: Maria F Serrano/CA/KAIPERM
Title: Transfusion Service Medical Director

Second Approver's Signature

Name: Eric Suba/CA/KAIPERM
Title: Chief of Pathology; CLIA Director

Document History Section