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Kaiser Permanente Medical Center, San Francisco
Northern California Region
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Work Instruction

Title:	**TC Daily Reagent Quality Control**	**WI Number** SFOWI-0031 **Revision:** 17
Department: Immunohematology **Area:** 2425 Geary Blvd SFO Hospital Lab	***Document is in the Final Approval Process. 2 - approvals are required***	
Type of Document: Work Instruction		**Review Period** - 340 **Days**

PURPOSE
To evaluate Blood Bank reagents to ensure the reagents are performing as expected. Factors, such as the duration of storage, severe change in temperature and contamination during usage may affect the integrity of blood bank reagents. Blood Bank reagents must be evaluated daily. New lot of reagent must demonstrate expected reactivity before they are placed into use.

REAGENTS:

A. Commercial Quality Control Kit (Ortho Confidence System)

1. **Ortho Confidence Antibody reagent**
   Weak Antibody - prepare appropriately diluted Ortho Confidence Antibody in 7% albumin, validated to react with screening cells between 1+ to 3+.
   a. Start with 1:10 dilution using 1 part Ortho Confidence Antibody reagent and 9 parts 7% albumin to make up 50ml total volume.
   b. Document on BF0006 Daily Reagent QC Worksheet.
   c. Test the weak antibody reagent with the screening cells using Gel and Provue. The acceptable reaction strength ranges from 1+ to 3+.
   d. May need titration to obtain the optimal dilution for 1+ to 3+ reactions.
   e. Label the container with the 'Diluted Weak Antibody' sticker:
      Date prepare:
      Lot #:
      Exp. Date: (One month from the preparation date or the original expiration date if it is sooner.)
      CLS initial:
      Dilution:
      Stored at 1-6 ^{0}C.

2. Confidence **Cell 1** (A_1B, rr cells)
3. Confidence **Cell 2** (O, R1r cells)

B. Reagents Listed on the Daily Reagents Lot# Worksheet (stored at 2^0 - 8^0C when not in use):

1. Anti-A
2. Anti-B
3. Anti-A,B
4. Anti-D
5. A_1 cells
6. A_2 cells
7. B cells
8. Screening cells I, II, III (0.8% Surgiscreen & 3% Surgiscreen)
9. Anti-IgG (monospecific AHG)
10. Anti-IgG, -C3d (polyspecific AHG)
11. Anti-C3b, -C3d
12. Check Cells (Coombs Control Cells)
13. Complement (C3) Control Cells
14. 22% Albumin
15. 7% Albumin
16. Ortho Confidence System (external QC materials)
17. PeG
18. LISS
19. Rh Control
20. IgG Gel Card
21. Blood Bank Saline
22. 0.8% and 3% Panels

EQUIPMENT

A. Daily Reagent QC Worksheets
B. 12x75 mm test tubes
C. Permanent marker
D. 37°C heat block
E. Serologic centrifuge
F. Cell washer
G. MTS incubator
H. MTS centrifuge
I. Pipettes

SPECIMEN

A. Routine Reagent Racks 1, 2, and 3:
Anti-A, Anti-B, Anti-A,B, Anti-D, A_1 cells, B cells, Check Cells.

B. Special Reagent Rack:
Anti-IgG,-C3d (poly AHG), Anti-IgG (mono AHG), Anti-C3b-C3d, PeG, LISS, Rh Control, 22% Albumin, C3 Control Cells, A_2 cells.

C. Antigen Typing sera rack.
D. 0.8% Panel Cells (Ortho Panel A, B, Untreated Panel C and Treated Panel C).
E. 3% Panel Cells (Immucor Panel 16 and Panel 20).

CONTROLS

A. Review daily QC and Maintenance records by supervisor or designee daily.
B. Review Check Point Temperature Log monthly by supervisor.
C. Review previous month's QC results by supervisor.
D. Review QC corrective action when they are out of acceptable limits by supervisor or

designee.

E. Review QC Summary Log by Medical Director or designee monthly.

PROCEDURE

Note: The CLS performing the QC tasks is responsible to ensure that the QC results are within acceptable criteria/range.

A. **Prior to performing quality control, check Reagent Lot# and Expiration Date, and visually inspect reagents for acceptability.**

B. **Check Reagent Lot# and Expiration Date**

1. **Routine Reagent Racks 1, 2, 3, Special Reagent Rack and Ortho Confidence System**
   a. On the first of each month, start a new Daily Reagents Lot# worksheet.
      i. Record the Lot# and Expiration Dates on the worksheet.
      ii. Carefully transcribe the **Start Date** from the previous month's worksheet.
      iii. **Highlight** any **Expiry Date** that will **expire within the month**.
   b. Make sure that reagents in all the racks have the same lot number as recorded on the Daily Reagents Lot# worksheet.
   c. Make sure that reagents in all the racks are within their expiration dates and that the dates are correctly recorded on the Daily Reagents Lot# worksheet.
   d. Remove any expired reagent and place on the refrigerated Expired Reagent shelf.
   e. Remove expiring reagent and change to a new lot on the same day the reagent expires.
   f. Record the new lot number, expiration date and the start date on the Daily Reagents Lot# Worksheet when a new lot is placed in-use.
   g. For any reagent bottle that is less than half in volume, place another unopened bottle of the same lot# in its rack.
   h. Make sure the expiration date of the **Saline Cube at each station** and **Saline Bottles** is **1 month** from the open/start date unless the original expiration date is sooner.
   i. Make sure the expiration date of the **Ortho Confidence Diluted Weak Antibody** is **1 month** from the open/start date unless the original expiration date is sooner.

2. **Antigen Typing Sera Rack and Panel Cells**
   a. Make sure that antisera and panel cells are within their expiration dates. Remove any expired antiserum or panel and place on the refrigerated Expired Reagent shelf.
   b. Remove expiring antiserum/panel and change to a new lot on the same day the antiserum/panel expires.

C. **Visual Inspection of Reagents for Evidence of Deterioration/Contamination**

1. Visually inspect reagent cells for hemolysis (usually reddish brown in color) or contamination (greenish in color, lumpy or turbid).
2. Visually inspect reagent antisera for discoloration and contamination.
3. Visually inspect IgG gel cards for appropriate liquid level or contamination.
4. Visually inspect Saline in Bottles and Saline from each Saline Cube each day to

ensure that they are not discolored, turbid or show signs of bacterial/mold contamination.

5. Discard any unacceptable reagent/gel cards and replace with new bottle/gel card.

D. **Daily Reagent Quality Control**

1. QC one of the three reagent racks each day and QC the next rack the following day.
2. **New Reagent Lot Confirmation of Acceptability**
   a. Before a new lot of reagent is placed in use, the expected reactivity must be checked against the old reagent lot.
   b. If the same lot of Ortho Confidence System was used to test the old reagent lot, the new reagent lot is acceptable if the reactivity is the same or within +/- 1 of the old lot.
   c. If a new lot of Ortho Confidence System is started concurrently with a new reagent lot, the old reagent lot must be tested concurrently with the new reagent lot using the new QC material. The new reagent lot is acceptable if the reactivity is the same or within +/- 1 of the old lot.
3. The specificity and reactivity of antisera and reagent cells are tested and verified as follows:
   a. Anti-A, and anti-B and anti-A,B are each tested against Confidence **Cell 1**, using the ABO Grouping procedure.
   b. Anti-D is tested against Confidence **Cell 1** and **Cell 2** separately, using the Rho(D) Typing procedure. **Cell 1** is tested using Weak D procedure, with **anti-IgG,-C3d (poly AHG)** and **C3 Control cells**.
   c. Rh control is tested against **Check cells**, using the Rho(D) Typing procedure.
   d. Saline is tested against **C3 Control cells** and **as Negative Control in the Indirect Antiglobulin test.**
   e. Anti-C3b, C3d is tested against **C3 Control cells**.
   f. Reverse grouping cells, A1 cells and B cells are each tested against the **Confidence Antibody Reagent**, using the ABO Grouping procedure.
   g. Antibody screening cells I, II, III are each tested against **Confidence Antibody Reagent**, using the antibody screen **PeG/Anti-IgG** procedure for **SC I and SC II** and **LISS/anti-IgG,-C3d (poly AHG)** for **SC III**.
   h. 0.8% antibody screening cells I, II, III are tested against **Confidence Weak Antibody Reagent**, and **a previously tested Negative ABSC patient** using the manual gel antibody screen procedure.
3. Label test tubes and perform QC as follows:

Table for Daily Reagent QC

Tube #	Antisera or Antibody	Cells	Expected Reaction	Purpose
1	1 drop Anti-A	1 drop **Cell 1** A_1B, D-negative	3+ - 4+	Verify anti-A reactivity
2	1 drop Anti-B	1 drop **Cell 1** A_1B, D-negative	3+- 4+	Verify anti-B reactivity
3	1 drop Anti-A,B	1 drop **Cell 1** A_1B, D-negative	3+ - 4+	Verify Anti-A,B reactivity
4	1 drop Anti-D		IS: 0 37: 0 anti-IgG,-C3d	Verify anti-IgG,-C3d (poly AHG) and negative control for anti-D and Saline Cube at **Cell**

		1 drop **Cell 1** A_1B, D-negative	(poly AHG): 0 C3 Control cell (Incubate 5 mins): W+ - 2+	**Washer 1**. Verify C3 Control cells reactivity and potency of anti-C3 in anti-IgG,-C3d (poly AHG).
5	1 drop Anti-D	1 drop **Cell 1** A_1B, D-negative	IS: 0 37: 0 anti-IgG,-C3d (poly AHG): 0 C3 Control cell (Incubate 5 mins): W+ - 2+	Verify anti-IgG,-C3d (poly AHG) and negative control for anti-D and Saline Cube at **Cell Washer 3**. Verify C3 Control cells reactivity and potency of anti-C3 in anti-IgG,-C3d (poly AHG).
6	1 drop Anti –D	1 drop **Cell 2** O D-positive	2+ - 4+	Verify anti-D potency
7	1 drop Rh Control	1 drop **Check cells**	IS: 0	Verify Rh Control and Check cells reactivity
8	1 drop Saline	1 drop **C3 Control cells**	IS: 0	Verify Saline and C3 Control cells reactivity
9	1 drop of anti-C3b, C3d	1 drop **C3 Control cells**	2+ - 4+	Verify potency of anti-C3b, C3d and C3 Control cells reactivity
10	1 drop Confidence Antibody Reagent	1 drop A_1 Cells	2+ - 4+	Verify A_1 cells reactivity
11	1 drop Confidence Antibody Reagent	1 drop B Cells	2+ - 4+	Verify B cells reactivity
12	2 drops Confidence Antibody Reagent	1 drop SC I 2 drops PeG 2 drops anti-IgG	1+ - 3+	Verify Screening Cells I reactivity and positive control for anti-IgG Verify PeG and and positive control for anti-IgG
13	2 drops Confidence Antibody Reagent	1 drop SC II 2 drops PeG 2 drops anti-IgG	1+ - 3+	Verify Screening Cells II reactivity and positive control for anti-IgG Verify PeG and and positive control for anti-IgG
14	2 drops Confidence Antibody Reagent	1 drop SC III 2 drops LISS 2 drops anti-IgG,-C3d (poly AHG)	1+ - 3+	Verify Screening Cells III reactivity. Verify LISS and positive control for anti-IgG,-C3d (poly AHG)
IgG Gel Card	25ul Confidence Weak Antibody Reagent	50ul 0.8% SC I	1+ - 3+	Verify Screening Cells I, IgG Gel card reactivity
IgG Gel Card	25ul Confidence Weak Antibody Reagent	50ul 0.8% SC II	1+ - 3+	Verify Screening Cells II, IgG Gel card reactivity
IgG Gel Card	25ul Confidence Weak Antibody Reagent	50ul 0.8% SC III	1+ - 3+	Verify Screening Cells III, IgG Gel card reactivity
IgG Gel Card	25ul Previously tested ABSC negative patient's	50ul 0.8% SC I, SC II, SC III each into respective	IAT = 0	Negative Control to verify IgG Gel card and Screening Cells.

	plasma into each of 3 microtubes	microtube		

4. Record reactions as the test results are being read on the Daily QC Reagent Worksheet.
5. Make sure that all results are within acceptable criteria/range.

E. **Unacceptable Quality Control Results**

1. **Patient test results or blood products affected by the unacceptable QC results should not be released until after the failure has been investigated and corrected.**
2. Circle all unacceptable results. Notify supervisor or designee immediately.
3. **Perform immediate corrective action:**
   a. Repeat QC. If the failed QC was due to technical error e.g. adding the wrong reagent, no further investigation is necessary after repeating the test(s) with acceptable results.
   b. If the results are still unacceptable, repeat QC using a new vial or a new lot of reagent(s).
   c. Quarantine reagents which give the unacceptable QC results. Put the reagent(s) in a Biohazard bag labeled 'Quarantine' and place on the refrigerated Quarantine shelf.
   d. Quarantine blood products that are affected by the unacceptable QC results. Place the blood product on the refrigerated Quarantine shelf.
   e. Remove equipment/device which caused the QC failure from service, e.g. pipette, centrifuge, cell washer, 37^{0}C incubator and etc. Complete and place BF0022 'Instrument Not in Service' form on equipment. Request repair service.
   f. Perform look-back of previously reported patient/unit test results and repeat test(s) that may have been affected by the unacceptable QC.
   g. Notify Medical Director or designee immediately if patient safety has been impacted.
   h. Document unacceptable reagent(s)/equipment on a Variance Log including the corrective action taken.
   i. Communicate the problem to other CLS via Communication Log and email.

PROCEDURE NOTES

A. **PeG, LISS, and anti-Human globulin** are:
   1. QC'ed by performing antibody screening test.

B. **IgG Gel ABSC:**
   1. a patient sample with negative antibody screen is used as negative control
   2. supervisor or designee reviews positive and negative control results in Gel card.

C. **Refrigerate daily reagents when not in use** at 2-8 $^{\circ}$C. Store saline at 15-30 $^{\circ}$C.

D. **Manufacturer instructions and Kit components:**
   1. **reagents' manufacturer instructions are followed** for patient and QC testing.
   2. **components of a reagent kit are used within the kit lot** unless otherwise specified by the manufacturer's.

E. **Infrequently used reagents**:
   1. quality control must be performed to ensure that their performance is acceptable on the day of use.

F. **Antibody Screening cells**
   1. only one set of 3% and 0.8% antibody screening cells is in use at a time.

G. **Rare reagents** (other than anti-A, anti-B, anti-A,B and anti-D):
   1. are unique antisera that are difficult to obtain due to a nation wide temporary manufacturing shortage
   2. may be used beyond their expiration date if appropriate positive and negative controls are run each day of use and react as expected.

H. **The reactivity for A_1 cells, B cells, anti-A, and anti-B:**
   1. is checked whenever the reagent is used, by the forward and reverse grouping results that agree consistently.

I. **Anti-IgG (mono AHG), anti-IgG,-C3d (poly AHG) or anti-C3** (use C3 Control cells):
   1. are performing as expected when positive reaction is obtained after Check cells have been added to negative direct or indirect antiglobulin test.

REFERENCE

A. Ortho reagent inserts, current edition.
B. Immucor reagent inserts, current edition.
C. AABB, Standards for Blood Bank and Transfusion Services, current edition, Bethesda, MD.
D. AABB Technical Manual, current edition.

Associated Documents:

External Documents

SFOWI-0082 Performing ABO Grouping & Investigating ABO Grouping Discrepancies
SFOWI-0084 Rho(D) Typing
SFOWI-0087 Antibody Detection Method
Associated Quality System Documents - None

Documents Generated:

Document Revision History:

Revision: 17	**Date Created:** 09/12/2005 **Date of Last Revision:** 10/09/2018	**Last Approval Date:** 01/31/2017

Document Author: Cara H Lim/CA/KAIPERM	

Reason for Change:

Revision:	Sec/Para Changed	Change Made:	Date
1	N/A	Initial Issue of Document	
2	Reagent	Expiration of diluted weak antibody is one month from preparation.	11/12/06
2	Table	To tube 4, add AHG and C3 control cells.	11/12/06
2	Procedure notes	Only one set of antibody screening cells, 3% and 0.8%, is in use.	11/12/06
3	Approver	New Lab Director	1/7/07
4	Approver	New Lab Director	7/27/07

5	Procedure notes	rare reagents (other than anti-A, anti-B, anti-A,B and anti-D)	9/30/07
6	Procedure	Describe visual inspection; change acceptable range of antibody screen to 1 - 3+.	1/28/2010
7	Procedure Approver	Change albumin to Rh Control; parallel test weak antibody; Change lab director.	6/1/2011
8	Procedure	Add F-4, Test saline against C3 control cells.	11/26/11
9	Reagent A.1; procedure notes table	Weak Ab dilution 1:20 removed; added saline control QC	12/5/11
10	Approver	New Lab Director	1/17/13
11	Procedure C, D, N. Procedure E & G.	New. Revised.	2/7/13
11	Reagents.A.1. Procedure Note(s).H. Quality Controls B. Procedure.	Added instructions for preparation of Weak Antibody. Added definition of rare reagents. New. Added Note.	2/26/13
12	Approver Procedure Note Procedure Note H. Procedure Note D.	New BB Medical Director. Reformatted. Added that expired panel cells must be Ag typed to confirm reactivity. Added that manufacturer instructions are followed.	11/8/13
13	Reagents B.10 Procedure H.5 and Table #8	New. Added anti-C3b, C3d. New. Added quality control for checking potency of anti-C3b, C3d.	4/2/14
14	Specimen Table for Daily Reagent QC Procedure Procedure B. Unacceptable QC Results Associated Documents	Added Special Reagent Rack, Antigen Typing sera rack, 0.8% Panel Cells, and 3% Panel Cells. Changed the Expected Reaction for tube#8 from >0 to 2+ - 4+. Changed the Expected Reaction for tube#4 C3 Control Cells from >0 to W+ - 2+. Revised and reformatted into sections. Revised. Added to start a new Daily Reagent Lot# WKST first of each month and highlight any expiry date that will expire within the month. Revised Corrective Actions to include more detailed instructions, look-back of blood products and removal of faulty equipment. Added SFOWI-0082, SFOWI-0084 and SFOWI-0087.	4/21/15
15	Procedure B. Procedure D.2. Table for Daily Reagent QC Procedure Notes H. Reagents A.1.f.	Added to check expiration date of the external QC materials, Ortho Confidence System. New. Added instructions for New Reagent Lot Confirmation. Added 'Verify PeG and and positive control for anti-IgG' to Tube 11 & 12. Deleted Use of Expired Panel Cells. Moved I to H. Deleted parallel testing of the commercial QC material as it is unnecessary.	9/9/15 9/22/15
16	Approver	New CLIA Director.	1/19/17
17	Procedure B.h. & i. Procedure D.3.d. & h. & Table for Daily Reagent QC	Specified to make sure the expiration of Saline and Ortho Confidence Diluted Weak Antibody is 1 month from start/open date unless original expiration is sooner. Added to QC Saline as Negative Ctrl in Indirect Antiglobulin test (weak D tests in duplicates - Tube 4 uses CW1, Tube 5 uses CW 2). Added Negative Control for Gel ABSC as per long standing practice.	10/5/18

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