PROCEDURE

Title: Quality Control for the Tube System

Procedure #: 2015BLOODBANK63

Institution: Highlands Regional Medical Center

Address: 3600 Highlands Avenue, Sebring Florida 33870

Prepared by: Anita Smith Date: 6/5/2015

Title: Laboratory Administrative Director

Accepted by: _____ Date: 6-5-15

Title: Laboratory Medical Director

Date Patient Testing Implemented: _____11/1/2008_____

Review of procedure every two years

Reviewed by: _____ Date: _____

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Discontinued testing date: _____

Highlands Regional MEDICAL CENTER

Policy Name: DAILY QC FOR TUBE TEST SYSTEM **Department:** Blood Bank

Departmental Review: **Policy #:**

INITIATE DATE	**DATE REVIEWED/REVISED**	**PAGE** 1 of 5
11/2008	02/2012, 05/2014, 11/2014	

PURPOSE:
Daily quality control (QC) in the Blood Bank is performed to confirm the reliability of the test system. The test system includes reagents, procedures, and equipment.

POLICY:
The Blood Bank quality control of reagents and equipment is performed daily by rotating technologists. Any confirmed deviation from the expected result must be investigated and brought to the attention of the Blood Bank supervisor. Patient test results will not be reported when controls do not yield acceptable results.

REAGENTS:
- corQC control kit
- anti-A antisera
- anti-B antisera
- Rh control reagent
- anti-D antisera
- anti-human globulin (monoclonal)
- anti-human globulin (polyspecific, IgG,-C3d)
- C3b,C3d reagent
- N-Hance reagent
- PeG reagent
- Complement Check Cells
- Coombs control Check cells
- A1 and B reagent red cells
- Grp O screening reagent red blood cells (Panocsreen I,II,III)
- 0.9% buffered saline
- 37°C incubator
- automatic cell washer(optional)
- 10 x 75 mm test tubes

NOTE: Check reagents for clarity and absence of hemolysis. A hazy appearance is an indicator of contamination. Hemolysis is an indication of reagent deterioration. If both are observed in any of the reagents a new batch of reagents should be opened and used.

PROCEDURE:

1. **Blood Grouping System QC**
   - Label tubes as A,B,D,DC,A1C,BC
   - Dispense a drop of reagent to the appropriate labeled tubes (anti-A to tube A, anti-B to tube B, anti-D to tube D, Rh control to tube DC, A1 cells to tube labeled A1C and B cells to tube BC).
   - Label a tube as AD or BD and dispense a drop of reference red blood cell (either A1 or B). Add a drop of the anti-D. This will be for the NEGATIVE QC.
   - Centrifuge the tubes and observe for agglutination.
   - All tubes will give a positive reaction from 2+ to 4+ except for the Rh control and AD/BD tubes).
   - Incubate the AD/BD tubes for 15 minutes at 37°C.
   - Wash 3 times and add anti-IgG.
   - Centrifuge and observe for agglutination. Add a drop of the check cells to confirm if the reaction is a true negative.
   - The reaction should range from 1+ to 4+

2. **Antibody Detection**
   - Label three sets of tubes as I, II and III(9 tubes in all)
   - Dispense a drop of each Panoscreen cells to the appropriately labeled tubes (screen cell I to tube I screen cell II to tube II and screen cell III to tube III)
   - To one set of tubes add a drop of 0.9% buffered saline. Incubate at 37°C for 15 minutes.
   - To the second and third set add a drop of the corQC antisera.
   - Add a drop of N-Hance reagent to the second set. Incubate at 37°C for 15 minutes.
   - Add a drop of PeG reagent to the third set. Incubate at 37°C for 15 minutes.
   - After incubation wash all three sets of tubes 3 times.
   - Add a drop of the IgG reagent to the second set of tubes and Poly IgG to the third set of tubes.
   - To the first set of tubes, add a drop of anti-IgG to tube I, PolyIgG to tube 2 and C3b,C3d to tube III.
   - Centrifuge all tubes.

- Agglutination should be present on the second and third set of tubes (tubes with enhancement added). Reactivity should range from 1+ to 3+
- No agglutination observed for the first set of tubes (only saline added).
- For the negative tubes, add check cells to tubes I and II and complement check cells to tube III. Agglutination should present and reaction should be between 1+ and 4+.

TUBE	REAGENT	QC REAGENT	EXPECTED REACTIONS	
1	Anti-A	corQC cells	2+ - 4+ (IS)	Reactivity of anti-A,-B,-D reagents
2	Anti-B	corQC cells		
3	Anti-D	corQC cells		
4	Rh Control	corQC cells	0 (IS)	Performance of control reagent
5	Anti-D	A1 or B cells	0/0 (IS/IAT)	Specificity of anti-D
6	A1 cells	corQC antisera	2+ - 4+ (IS)	Reactivity of reagent
7	B cells	corQC antisera		
8	SCI/N-HANCE	corQC antisera	1+ - 3+ (IAT)	Reactivity of red cells Performance of potentiators
9	SCII/N-HANCE	corQC antisera		
10	SCIII/N-HANCE	corQC antisera		
11	SC1/PeG	corQC antisera		
12	SCII/PeG	corQC antisera		
13	SCIII/PeG	corQC antisera		
14	SCI	0.9% buffered saline	0 (IAT)	Specificity of anti-IgG
15	SCII	0.9% buffered saline		Specificity of anti-IgG,-C3d
16	SCIII	0.9% buffered saline		Specificity of anti-C3b,-C3d
17	ANTI-IgG	Coombs control Check cells	1+ - 4+ (IS)	Reactivity of Anti-Human Globulin
18	ANTI-IgG,-CEd	Coombs control Check cells		
19	ANTI-C3b,-C3d	Complement Check Cells		

IS = Immediate Spin IAT = Indirect antiglobulin test SC = screening cells

REPORTING RESULTS:

Reactivity of each test should be entered in the Daily QC Worksheet in SoftBank. Reaction will range from 1+ to 4+. Appearance and performance are noted as it is a part of the daily quality control.

PROCEDURE NOTES:

If expected test results are observed, procedures are being performed accurately, and reagents and equipment are performing properly. If unexpected results are observed, the problem may be due to improper test performance, faulty equipment, reagent contamination or deterioration. The source of the problem should be determined before test results are reported.

Since commercially prepared blood grouping reagents and reagent red blood cells must meet FDA specificity requirements, extensive daily specificity testing by blood bank laboratories is redundant. The essential property to be confirmed by each laboratory is reagent reactivity.

REFERENCES:

- Brecher, Mark E., technical Manual of the American Association of Blood Banks, 14th ed., Bethesda, MD: american Association of Blood Banks, 2002
- SoftBank II, Version 25.1 User's manual, Palm Harbor, FL, SCC
- Package insert: Immucor corQC, 12/09, Immucor Inc, 3130 Gateway Drive, P.O. Box 5625, Norcoss, GA
- Package insert: Panoscreen I, II and III, Immucor Inc, 3130 Gateway Drive, P.O. Box 5625, Norcoss, GA
- AABB Technical Manual (15thedition) 2005

Highlands Regional MEDICAL CENTER

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Departmental Review: **Policy #:**

INITIATE DATE 11/2008

DATE REVIEWED/REVISED 02/2012, 05/2014, 11/2014

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	5-29-15		

Initial Implementation Date: _____

Reviewed by: _____ Date: 11.14.14
Department Supervisor

Reviewed by: Angela Lawston Date: 11/17/14
Department Adm. Director

Reviewed by: NA Date: _____
Department Chief Technologist

Reviewed and Approved by: _____ Date: 11/18/14
Department Medical Director