|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| WFBMC_color.jpg | | **Daily Quality Control using SCC**  BB.QC.1006.8 | **Dept:** | 324311 |
| **Dept Name** | Blood Bank |
| **Effective Date:** |  |
| **Revised Date:** |  |
| **Name & Title**: CLIA Laboratory Medical Director | | | **Contact:** | Julie Simmons/ Christina Warren |
| **Signature:** |  | | **Date:** |  |

**1. General Procedure Statement:**

**A.** **Purpose:** To ensure that routine reagents are in-date, show no visible evidence of contamination

or deterioration and react as expected with a positive and negative control.

**B.** **Responsible Department/Scope:**

i Procedure owner/Implementer: Julie H. Simmons

ii. Procedure prepared by: Carla Williams / Julie Simmons

iii. Who performs procedure: Department staff / management

**C. Definitions:**

QC: Quality Control

**D. Sections**:

.

I. Routine Rack for Daily QC

II. Special Rack for Daily QC

III. Preparation of Diluted Antisera for Quality Control

IV. Registration of Reagents

V. Entering New Lot number or Deleting Lot number of Reagents on Rack in SCC.

VI. Entering Rare Antisera Testing in SCC

VII. Entering Daily QC Results in SCC

VIII. Review of QC by Management or Designee

**E. Protocols**

1. Management review of QC is documented electronically in SCC using the Management>Blood Bank log>Release functionality.
2. Reports can be generated as needed during inspections to demonstrate review of QC.
3. Review (Release of QC in SCC) is performed by management or designee.

1. QC is performed daily.
2. Rare antisera (i.e. anti-E, -C, etc.) is performed on day of use.
3. Each daily rack is tested with the reagents within the specific daily rack. (i.e. Daily Rack 1 is tested with only the reagents within Daily Rack 1). Daily rack reagents should not be mixed when performing daily QC to assure all reagents within each rack are satisfactory.

**2. Procedure:**

Chemical Risk Assessment: low

Biological Risk Assessment: low

Protective Equipment: Lab coat, gloves

Supplies: Gel cards, 10x75 tubes, pipets

Reagents: Anti-A, Anti-B, A1 cells, B cells, Anti-D, Screening Cells

Equipment: 37 C incubator, centrifuge

Specimen Requirements: NA

**I. Routine Rack for Daily QC**

| **STEPS** | **INSTRUCTIONS** | **CHANGE/**  **APPROVAL** |
| --- | --- | --- |
| **1.0** | **Obtain from Sera #5, each routine rack to be tested.**  1.1 Racks 1-6 are tested Monday-Friday.  1.2 Racks 1-4, are tested on weekends and holidays. |  |
| **2.0** | **Check each Routine rack for volume, integrity, expiration date of each reagent.**  2.1 Refer to Section III to add new lot numbers to rack. |  |
| **3.0** | **Go to SCC – Results >QC > Racks > Modify and compare all reagents in Rack 1 to information in SCC: Lot #, expiration date, introduction date - Routine Rack for Rack 1.**  *Refer to Attachment 2: Daily QC Procedure Flowchart.*  3.1 Select the correct Rack number from the drop down box and verify the site  information is correct.   1. DMCBR: Davie Medical Center Bermuda Run 2. WFBMC: Wake Forest Baptist Medical Center 3. WFLMC: Wake Forest Lexington Medical Center 4. HPMC: High Point Medical Center   3.2 Check all lot numbers, expiration dates, vial opened dates and initials should  correspond to the actual lot numbers, expiration dates and Introduction date (vial  opened dates) on the rack.  3.3 Remove any expired reagent from rack physically and in SCC.  3.4 Add any new reagent needed to the rack physically and in SCC.  *Refer to Section V: Entering New Lot number or Deleting Lot number of Reagents on Rack in SCC.*  3.5 For all information that does not match investigate problem, write a QA, and  submit to management.  3.6 Esc – End of view to go to next lot number. |  |
| **4.0** | **Repeat step 3.0 for all other routine racks to be tested for daily QC.** |  |
| **5.0** | **Label 10x75 tubes in the following manner for each routine rack.**   |  |  |  | | --- | --- | --- | | **Reagent to be tested** | **Rack #** | **Label tubes** | | Anti-A | 1 | 1A+ | |  |  | 1A- | | Anti-B | 1 | 1B+ | |  |  | 1B- | | Anti-D | 1 | 1D+ | |  |  | 1D- | |  |
| **6.0** | **Testing Protocol: Add reagents from the specified rack number on test tubes.**   |  |  | | --- | --- | | **Tube Labeled** | **Add one drop of:** | | A+ | Anti-A | | A- | Anti-A | | B+ | Anti-B | | B- | Anti-B | | D+ | Anti-D | | D- | Anti-D |   6.1 Example: Anti-A from Rack 1 to test tube 1. |  |
| **7.0** | **Add one drop of 3% red cells to each tube being tested. Test in the following manner for each routine rack.**   |  |  | | --- | --- | | **Tube Labeled** | **Add one drop of:** | | A+ | A1 cells | | A- | B cells | | B+ | B cells | | B- | A1 cells | | D+ | Screening cell 1 | | D- | Screening cell 3 |   7.1 If tube labeled Rack 1, then use cells from Rack 1.  7.2 Use screening cells from the rack being QC’d for positive and negative controls for  testing of Anti-D. |  |
| **8.0** | **Centrifuge all test tubes at the calibrated time and speed for immediate spin room temperature testing.**  8.1 Centrifuge all Anti-A, Anti-B, and Anti-D positive and negative controls for each  rack at the same time in the same centrifuge head. |  |
| **9.0** | **Read tubes immediately macroscopically with agglutination viewer.**  9.1 Enter results in SCC.  9.1 ***Refer to Section VII. Entering Daily QC Results in SCC*** |  |
| **10.0** | **Label 6 IgG gel cards as follows to designate appropriate Rack, Cell being tested and expected positive or negative reaction.**   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **Rack** | **Cell 1 +** | **Cell 1-** | **Cell 2+** | **Cell 2-** | **Cell 3+** | **Cell 3-** | | 1 | 1 1+ | 1 1- | 1 2+ | 1 2- | 1 3+ | 1 3- | | 2 | 2 1+ | 2 1- | 2 2+ | 2 2- | 2 3+ | 2 3- | | 3 | 3 1+ | 3 1- | 3 2+ | 3 2- | 3 3+ | 3 3- | | 4 | 4 1+ | 4 1- | 4 2+ | 4 2- | 4 3+ | 4 3- | | 5 | 5 1+ | 5 1- | 5 2+ | 5 2- | 5 3+ | 5 3- | | 6 | 6 1+ | 6 1- | 6 2+ | 6 2- | 6 3+ | 6 3- |   13.1 Racks 1-6 are tested Monday-Friday.  13.2 Racks 1-4 are tested on weekends and holidays.  13.3 Proceed with testing as for Gel Method.  *Refer to: BB.R.1004: ANTIBODY SCREEN – TUBE and GEL METHOD Indirect Antiglobulin Test* |  |
| **11.0** | **Add 50µL of each screening cell to the appropriately labeled well.**  12.1 If tubes labeled Rack 1, then use screening cells from Rack 1.  12.2 Continue in this manner until all screening cells from all racks to be tested have  been dispensed into appropriate labeled tubes. |  |
| **12.0** | **Add 25 µL of the following appropriately diluted antisera to the wells labeled 1+, 1-, 2+, 2-, 3+, 3- in the following manner:**   |  |  | | --- | --- | | **Screening Cell** | **Dilute Antisera** | | **Screening cell 1+** | **Anti-D** | | **Screening cell 1-** | **Anti-c** | | **Screening cell 2+** | **Anti-D** | | **Screening cell 2-** | **Anti-C\*** | | **Screening cell 3+** | **Anti-c** | | **Screening cell 3-** | **Anti-D** |   \*Anti-C will be undiluted and available in the special rack.  12.1 Dilute antisera is prepared by assigned tech as needed.  *Refer to Section III: Preparation of Diluted Antisera for Quality Control* |  |
| **13.0** | **Incubate all IgG gel cards for a minimum of 15±1 minute at 37°C ± 2°C (35-39°C).**  13.1 Maximum incubation time for gel testing is 40’. |  |
| **14.0** | **Spin gel cards in centrifuge at calibrated time and speed.** |  |
| **15.0** | **Read the front of each microtube macroscopically.**  *Refer to Routine: Grading of Positive and Negative Reactions.* |  |
| **16.0** | **Enter results in SCC.**  *Refer to Section VII. Entering Daily QC Results in SCC* |  |
| **17.0** | **Compare results with expected results.**  17.1 Select S (Satisfactory) or U (Unsatisfactory) under the A/P column.  17.2 Interpret the QC in column QCInt as PASS, FAIL or INVALID. |  |
| **18.0** | **Interpretation of results.**  *Refer to Attachment 4: Interpretation of Results.* |  |

II. Special Rack for Daily QC

Chemical Risk Assessment: low

Biological Risk Assessment: low

Protective Equipment: Lab coat, gloves

Supplies: 10x75 tubes, pipets

Reagents: Anti-A,B Anti-AHG, Anti-C3d, CCC, A1 cells, A2 cells, B cells, Anti-D, Gel Screening Cells, Ortho gel card, Buffered (Neutral) Gel card

Equipment: 37 C incubator, centrifuge, Ortho centrifuge

| **STEPS** | **INSTRUCTIONS** | **CHANGE/**  **APPROVAL** | |
| --- | --- | --- | --- |
| **1.0** | **Obtain the Special rack from Sera #5.**  1.1 The Special rack will be tested daily. |  |
| **2.0** | **Compare all reagents in Special rack to information in SCC Special Rack.**    2.1 All lot numbers, expiration dates and introduction (vial opened) dates should  correspond to the actual lot numbers, expiration dates and vial opened date on the  rack.  2.2 For all information that does not match investigate problem, write a QA, and  submit to management. |  |
| **3.0** | **Go to SCC – Results >QC > Racks > Modify and compare all reagents in Special Rack (SPEC) to information in SCC: Lot #, expiration date, introduction date - SPEC Rack.**  *Refer to Attachment 2: Daily QC Procedure Flowchart.*  3.1 Select the correct Rack (SPEC) from the drop down box and verify the site  information is correct.   1. DMCBR: Davie Medical Center Bermuda Run 2. WFBMC: Wake Forest Baptist Medical Center 3. WFLMC: Wake Forest Lexington Medical Center 4. HPMC: High Point Medical Center   3.2 Check all lot numbers, expiration dates, vial opened dates and initials should  correspond to the actual lot numbers, expiration dates and Introduction date  (vial opened dates) on the rack.  3.3 Remove any expired reagent from rack physically and in SCC.  3.4 Add any new reagent needed to the rack physically and in SCC.  *Refer to Section V: Entering New Lot number or Deleting Lot number of Reagents on Rack in SCC.*  3.5 For all information that does not match investigate problem, write a QA, and  submit to management.  3.6 Esc – End of view to go to next lot number. |  |
| **4.0** | **Label 7 10x75 tubes in the following manner for testing reagents in the the Special rack.**   |  |  | | --- | --- | | **Reagent to be tested** | **Label tubes** | | Anti-A,B | A,B +  A,B- | | Anti-AHG | AHG+; AHGC+  AHG- | | Anti-C3d | C3d+  C3d- | |  |
| **5.0** | **Add one drop of Anti-A,B to the tubes labeled A,B+, A,B-.** |  |
| **6.0** | **Add two drops of Polyspecific Anti-AHG to the tubes labeled AHG+, AHG-.** |  |
| **7.0** | **Add two drops of Anti-C3d to the tubes labeled C3d+, C3d-.** |  |
| **8.0** | **Add the cells to labeled antisera tubes in the following manner.**   |  |  | | --- | --- | | **Tube Labeled** | **Cells added** | | A,B +  A,B- | B cell\*  Screening cell 2 | | AHG+; AHGC+  AHG- | CC, CCC  Screening cell 1 | | C3d+  C3d- | EC3b cells  Screening cell 2 |   **\***From Rack 1 |  |
| **9.0** | **Centrifuge all test tubes from step 8 at the calibrated time and speed for immediate spin room temperature testing.** |  |
| **10.0** | **Read tubes macroscopically with agglutination viewer.**  10.1 Read all negative results with Polyspecific Anti-AHG, and Anti-C3d microscopically. |  |
| **11.0** | **Enter results in SCC.**  *Refer to Section VII. Entering Daily QC Results in SCC* |  |
| **12.0** | **Compare results with expected results.**  12.1 Select S (Satisfactory) or U (Unsatisfactory) under the A/P column.  12.2 Interpret the QC in column QCInt as PASS, FAIL or INVALID. |  |
| **13.0** | **Incubate all NEGATIVE reactions with Polyspecific Anti-AHG and Anti-C3d for 5 minutes at room temperature**    13.1 After 5 minute incubation at room temperature, spin tubes for calibrated  time and speed for AHG reactions,  13.2 Record results on the Daily Reagent Quality Control Worksheet with tubes  in hand according to workload organization policy.  13.3 To all NEGATIVE tubes with Anti-AHG add one drop of CC.  13.4 To all NEGATIVE tubes with Anti-C3d add one drop of Ec3b cells.  13.5 Spin tubes for calibrated time and speed for AHG reactions.  13.6 Repeat steps 11 and 12. |  |
| **14.0** | **Label 6 10x75 tubes for as follows to designate appropriate Rack, Cell being tested and expected positive or negative reaction.**   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **Rack** | **Cell 1 +** | **Cell 1-** | **Cell 2+** | **Cell 2-** | **Cell 3+** | **Cell 3-** | | SP | SP 1+ | SP 1- | SP 2+ | SP 2- | SP 3+ | SP 3- |   13.3 Proceed with testing as for Tube Method, Indirect Antiglobulin Testing.  *Refer to: BB.R.1004: ANTIBODY SCREEN – TUBE and GEL METHOD Indirect Antiglobulin Test* |  |
| **15.0** | **Add two drops of the following appropriately diluted antisera to the tubes labeled 1+, 1-, 2+, 2-, 3+, 3- in the following manner:**   |  |  | | --- | --- | | **Screening Cell** | **Dilute Antisera** | | **Screening cell 1+** | **Anti-D** | | **Screening cell 1-** | **Anti-c** | | **Screening cell 2+** | **Anti-D** | | **Screening cell 2-** | **Anti-C\*** | | **Screening cell 3+** | **Anti-c** | | **Screening cell 3-** | **Anti-D** |   \*Anti-C will be undiluted and available in the special rack.  11.1 Dilute antisera is prepared by assigned tech as needed. |  |
| **16.0** | **Add 1 drop of each screening cell to the appropriately labeled tube.** |  |
| **17.0** | **Add 2 drops of PeG to each tube.** |  |
| **18.0** | **Incubate all tubes for a minimum of 15±1 minute at 37°C ± 2°C (35-39°C).**  18.1 Maximum incubation time for PeG/tube testing is 30 minutes. |  |
| **19.0** | **Remove tubes from the incubator and observe for hemolysis.** |  |
| **20.0** | **Wash tubes in cell washer or by hand 3-4 times.** |  |
| **21.0** | **Add 2 drops Anti-IgG to each tube, mix.** |  |
| **22.0** | **Centrifuge all test tubes at the calibrated time and speed for Antiglobulin testing.** |  |
| **23.0** | **Read tubes immediately macroscopically with agglutination viewer.**  22.1 Questionable reactions may be observed microscopically. |  |
| **24.0** | **Enter results in SCC.**  *Refer to Section VII. Entering Daily QC Results in SCC* |  |
| **25.0** | **Compare results with expected results.**  25.1 Select S (Satisfactory) or U (Unsatisfactory) under the A/P column.  25.2 Interpret the QC in column QCInt as PASS, FAIL or INVALID. |  |
| **26.0** | **Interpretation of results.**  *Refer to Attachment 4: Interpretation of Results.* |  |
| **27.0** | **Read the front of each microtube macroscopically.**  *Refer to Routine: Grading of Positive and Negative Reactions.* |  |
| **28.0** | **Enter results in SCC.**  *Refer to Section VII. Entering Daily QC Results in SCC* |  |
| **29.0** | **Compare results with expected results.**  29.1 Select S (Satisfactory) or U (Unsatisfactory) under the A/P column.  29.2 Interpret the QC in column QCInt as PASS, FAIL or INVALID. |  |
| **30.0** | **Interpretation of results.**  *Refer to Attachment 4: Interpretation of Results.* |  |
| **31.0** | **Label 1 Buffered (Neutral) gel card as follows to designate Special Rack QC, Cell being tested and expected positive or negative reaction.**   |  |  | | --- | --- | | **Special Rack QC** | | | **A1 Cell +** | **Cell 1-** | |  |
| **32.0** | **Add 50µL of each cell to the appropriate labeled well.**  32.1 A1 cell – prepare 0.8% cell suspension  32.2 Screening cell |  |
| **33.0** | **Add 25µL of Anti-A,B to the appropriate labeled well in the following manner:**   |  |  |  | | --- | --- | --- | | **Antisera** | **Positive control** | **Negative Control** | | **Anti-A,B** | **A1 cell** | **Screening Cell 1** | |  |
| **34.0** | **Spin gel cards in centrifuge at calibrated time and speed.** |  |
| **35.0** | **Read the front of each microtube macroscopically.**  *Refer to Routine: Grading of Positive and Negative Reactions.* |  |
| **36.0** | **Enter results in SCC.**  *Refer to Section VII. Entering Daily QC Results in SCC* |  |
| **37.0** | **Compare results with expected results.**  37.1 Select S (Satisfactory) or U (Unsatisfactory) under the A/P column.  37.2 Interpret the QC in column QCInt as PASS, FAIL or INVALID. |  |
| **38.0** | **Interpretation of results.**  *Refer to Attachment 4: Interpretation of Results.* |  |

1. Preparation of Diluted Antisera for Quality Control

| **STEPS** | **INSTRUCTIONS** | **CHANGE/**  **APPROVAL** |
| --- | --- | --- |
| **1.0** | **Titer selected antisera.**  *Refer to Specials: Titrations* |  |
| **2.0** | **Test diluted antisera in gel and/or tube with a heterozygous antigen positive cell if possible.**  *Refer to Specials: Titrations*  2.1Use anti-D for Screen cells 1 and 2.  2.2 Use anti-c for Screen cell 3.  2.3 Document reactions on Preparation of Diluted Antisera for Daily QC form.  *Refer to Attachment 5: BB.FORMS.2079 Preparation of Diluted Antisera for Daily QC.* |  |
| **3.0** | **Select a dilution that results in a 1-3+ reaction.**  3.1 Separate dilutions are needed for gel (0.8%) and tube (2-4%) testing. |  |
| **4.0** | **Aliquot by filling 12 x 75 tubes equally and cap tubes.** |  |
| **5.0** | **Label reagent aliquots with the following:**   * Initials * Date Prepared * Dilution * Lot# of antisera * Expiration Date (1 year from preparation date) * Concentration use: 0.8% or 2-4% |  |
| **5.0** | **Store diluted antisera in Freezer 11 in appropriately labeled tube.** |  |
| **6.0** | **NOTE: WB CorQC Samples that have been removed from use may be utilized to aliquot for anti-c and anti-D.**  6.1 Obtain WBCorQC (1) for anti-c and WBCorQC (2) for anti-D from the  student refrigerator.  6.2 Centrifuged and remove the supernatant (plasma).  6.3 Tested in gel and/or tube.  6.4 Determine if acceptable results are obtained.  6.5 If results are acceptable, then this may be used for anti-c and anti-D instead  of diluting. *Refer to Steps 4-6 for aliquoting, labeling and storage.*  6.6 If unacceptable results are obtained, prepare diluted antisera. Refer to Steps 1-6. |  |

IV. Registration of Reagents for Quality Control.

| **STEPS** | **INSTRUCTIONS** | **CHANGE/**  **APPROVAL** |
| --- | --- | --- |
| **1.0** | **Go Results > Quality Control > Reagents> Registration.**   * 1. Select the reagent from the drop down box at the Type field.   2. Leave Kit field blank for single reagents or Check Kit for products that come together (Ex. Screening Cells, Panels, Fetal Screen Kit).   3. Enter the lot number of the kit or first vial if the same lot number.   4. Enter the manufacturer. (F2 to bring up list when in the manufacturer box.)  1. Click in manufacturer box and select from drop down. 2. Alternatively can press F2 while in box to bring up list to select).    1. Enter the expiration date of the reagent (kit).    2. Check Pkg insert reviewed IF insert has been reviewed. 3. Enter correct Date/Time of insert review    1. Check receipt criteria met IF receipt testing has been performed and acceptable. 4. Enter correct Date/Time of receipt testing. 5. If receipt testing is not yet performed, do not check.   *Refer to Receipt testing.*   * 1. If Pkg insert reviewed and receipt criteria met, then OK to use should default to checked with date and time.   2. Enter a comment if desired by click in the Comment field.   3. Click F12 to accept when all data has been entered.   4. Proceed to table below depending on single reagent or kit.  |  |  | | --- | --- | | **Delivery of Single Reagent** | **Delivery of Kit**  **(Screening cells, Panels, Fetal Screen)** | | 1. System displays “Save data for delivered reagent? (Yes/No). Click Yes 2. Click Quit to return to the Results Menu. 3. Click Quit to return to the Main Menu. | 1. Enter the lot number of each vial in the kit under vial lot number. 2. Click the drop down and select the correct reagent type. Delete the default if needed to select the correct reagent.   **NOTE: It defaults the kit code in the reagent field. It MUST be changed to the correct individual vial code.)**   1. Continue entering all reagents in the kit. 2. Click F12 when all data has been entered. 3. System displays “Save data for delivered reagent? (Yes/No). Click Yes 4. Click Quit to return to the Results Menu. 5. Click Quit to return to the Main Menu. | |  |
| **2.0** | **Proceed to next Section to add reagent to a rack or open a reagent or kit.** |  |

1. New Lot number or Deleting Lot number of Reagents on Rack in SCC.

| **STEPS** | **INSTRUCTIONS** | **CHANGE/**  **APPROVAL** |
| --- | --- | --- |
| **1.0** | **Open any new reagent that is added to the QC Racks.**  1.1Click Results > Quality Control> Reagents> Open.  1.2 Delete data in Type field if needed.  1.3 See below and refer to Attachment 1: Opening Reagents.   |  |  | | --- | --- | | Single Reagent | Reagent Kit | | Click the drop down arrow and select reagent to be opened. | Click the drop down arrow and select one of the vials in the kit that is to be opened. | | Enter the lot number of the reagent  F12 to accept | Enter the lot number of the kit  F12 to accept. | | Edit the open date and time if needed. Click F12 to accept. | Edit the open date and time if needed. Click F12 to accept. | |  | The system will display all reagents in the kit. Edit the open date and time if needed. Click F12 to accept. | | Answer Yes to “Save data for opened reagent?” Reagent is opened | Answer Yes to “Save data for opened reagent?” All reagents in kit are opened. | | Click Quit to exit to the QC Menu. | Click Quit to exit to the QC Menu. | |  |
| **2.0** | **Go Results > Quality Control > Racks> Modify.**   * 1. Select Rack number that needs to have reagent added or deleted.  |  |  |  | | --- | --- | --- | | **Delete** | **Add** | **Change** | | 1. Highlight row of reagent to delete. 2. Click F6 to remove. 3. F12 to Accept. | 1. Go to first empty row number. 2. Select reagent under type column from drop down. 3. Select lot number. 4. Select vial number if a lot or 0 if not. 5. Select vial lot number. 6. Verify date defaults in correctly for open date or edit. 7. Verify expiration date. 8. F12 to accept. | 1. Delete the lot number 2. Click F2 while in the lot number box. 3. List of lot numbers comes up. 4. Select the current one or key into that box. | |  |
| **3.0** | **Edit reagent at the end of Use.**  *Refer to Attachment 3: Edit End of Use Flowchart.*   * 1. Click Results> Quality Control>Reagents>End of use.   2. Select Type of reagent from drop down box.   3. Enter Lot number of reagent.   4. F12 to accept.   5. Review information.   6. F12 to accept.   7. Enter end of Use date if different from default.  1. End of use date defaults to current date.   h. F12 to accept and Yes to save. |  |

1. Entering Rare Antisera QC Testing in SCC

| **STEPS** | **INSTRUCTIONS** | **CHANGE/**  **APPROVAL** |
| --- | --- | --- |
| **1.0** | **Go to Results> QC>Results>Edit.**   * 1. Select AGat Rack #, F12 to accept and Enter to Select. |  |
| **2.0** | **Click F5 to enter the reagent and control information.**  2.1   |  |  | | --- | --- | | **Reag row (Reagent)** | **Contr row (Control)** | | 1. Enter the Type of Antisera from the drop down box, i.e. FyA for Anti-Fya. 2. Select the antisera lot number 3. Select Vial # if applicable. 4. Select Test from drop down box.  * QC Negative Test * QC Positive Test | 1. Enter the reagent the antisera is being tested against, i.e. p1 for cell#1 of panel. 2. Enter the Lot# of the cell and Vial #. |   2.2 Click F12 to Accept.  2.3 Enter results of QC Test and select if S (Satisfactory) or U (Unsatisfactory).  2.4 *Refer to Attachment 4: Interpretation of Results.*  2.5 F12 to accept entry and Yes to accept results.  2.6 Investigate any discrepancies identified at review. |  |

1. Entering Daily QC Results in SCC

| **STEPS** | **INSTRUCTIONS** | **CHANGE/**  **APPROVAL** |
| --- | --- | --- |
| **1.0** | **Go to SCC and Click Results > QC -Results – Edit: Select Rack#: F12: Enter to select under function.**  1.1 Result screen should open. |  |
| **2.0** | **Enter results in SCC computer BEFORE discarding test tubes.**  2.1 Go to procedure BB.R.1018: *Grading Test Tube Reactions.*  2.2 Enter result under QC test.  2.3 Select S (Satisfactory) or U (Unsatisfactory) under the A/P column.  2.4 Interpret the QC in column QCInt as PASS, FAIL or INVALID. |  |
| **3.0** | **F12 to accept and Answer Yes to Accept.** |  |
| **4.0** | **Repeat Steps 1-3 for Each Rack tested.**   |  |  | | --- | --- | | **Wake – Main Campus** | **Lexington** | | **DLY1 – DLY6** | **DAILX** | | **Antigen** |  | | **Special** |  | |  |

1. Review of QC by Management or Designee

| **STEPS** | **INSTRUCTIONS** | **CHANGE/**  **APPROVAL** |
| --- | --- | --- |
| **1.0** | **Go to Management>Blood Bank Log>Release.**  1.1 Select Q for QC if it does not default into Test type. |  |
| **2.0** | **Highlight each Daily Rack under Test.**  2.1 Click F9 to see result view.   * 1. Enter if correct Daily Rack.   2. Verify that all results are in a status of completed.   3. View any comments if present.   4. Verify that QC test result is correct and S for Satisfactory.   2.6 Investigate any QC result that is not correct or resulted as U for Unsatisfactory.   * 1. Verify that the QC Int is PASS if the result is correct.   2. Investigate any discrepancies identified at review.   3. Esc-End of view to return to other racks. |  |
| **3.0** | **Repeat Step 2.1 to 2.9 for Each Rack in use.**   |  |  | | --- | --- | | **Wake – Main Campus** | **Lexington** | | **DLY1 – DLY6** | **DAILX** | | **Antigen** |  | | **Special** |  | |  |
| **4.0** | **Place a check in the Order # row by each rack that has been reviewed.** |  |
| **5.0** | **F12 to accept and Answer Yes to Accept.** |  |
| **6.0** | **View the file and** |  |

**3. Review/Revised/implemented:**

All procedures must be reviewed according to Document Control protocol.

All new procedures and procedures that have major revisions must be signed by the

CLIA Director.

All reviewed procedures and procedures with minor revisions can be signed by the

designated section medical Director or designee

**4. Related Procedures: NA**

**5. References**:

Code of Federal Regulations, 606.65(b)(c), 606.160 (b)(5)(i) and (ii), revised periodically

Standards for Blood Banks and Transfusion Services, American Association of Blood Banks, revised periodically.

**6. Attachments**:

Attachment 1: Opening Reagents

Attachment 2: Daily QC Procedure

Attachment 3: Edit End of Use Date FlowChart

Attachment 4: Interpretation of Results

Attachment 5: BB.FORMS.2079 Preparation of Diluted Antisera for Daily QC

**7. Revised/Reviewed Dates and Signatures:**

See Document Change Control

ATTACHMENT 1: Opening Reagents Flowchart



ATTACHMENT 2: DAILY QC FLOWCHART

ATTACHMENT 3: EDIT END OF USE DATE FLOWCHART

Attachment 4: Interpretation of Results

|  |  |
| --- | --- |
| **If results are acceptable:** | **If results are unacceptable:** |
| 1. Select "S" in column "A/P".  2. Interpret QCInt as PASS.  3. Rack may be released for use. | 1. Repeat Testing.  2. Select "U" in column "A/P".  3. Interpret QCInt as FAIL.  4. Quarantine item.  5. Determine the current inventory of reagent.  6. Alert management that the item(s) did **NOT** pass QC,  and current inventory of reagent.  7. Submit a Quality Assurance Exception Report.  8. Management will follow-up. |