# Applicable Laboratory(s)):

[x]  North Carolina Baptist Hospital (NCBH)

[ ]  Lexington Medical Center (LMC)

[ ]  Davie Medical Center (DMC)

[ ]  Wilkes Medical Center (WMC)

[ ]  High Point Medical Center (HPMC)

[ ]  Westchester

[ ]  Clemmons

# Procedure Statement

The purpose of this procedure is to ensure that reagents perform as expected upon receipt of a new lot number of reagent red cells and antiserum.

# Scope

i. Procedure Owner/Implementer: Julie H. Simmons/Christina Warren

ii. Procedure Prepared by: Christina Warren

iii. Who Performs Procedure: Blood Bank Staff/management

# Definitions

1. Procedure: A process or method for accomplishing a specific task or objective.
2. WFBH Lab System: Wake Forest Baptist Lab System is a health system that includes Wake Forest Baptist Medical Center and all affiliated organizations including Wake Forest University Health Sciences (WFUHS), North Carolina Baptist Hospital (NCBH), Lexington Medical Center (LMC), Davie Medical Center (DMC), Wilkes Medical Center (WMC), High Point Medical Center (HPMC), Lab at Westchester and Lab at Clemmons.
3. AHG: Antihuman Globulin
4. CC cells: Coombs Control Cells (IgG coated red blood cells)
5. EC3b cells: Complement Control Cells (Complement coated red blood cells)
6. QCInt: QC interpretation field in SCC

# Sections

1. Receipt Testing of Anti-A,-B,-AB,-D, A1 cells, A2 cells, B cells
2. Receipt Testing of Anti-AHG (polyspecific) Anti-IgG, Anti-C3d , CC cells and EC3b cells
3. Receipt Testing of Enhancements (LISS, PEG, Albumin)
4. Receipt Testing of 0.8% Screening Cells
5. Receipt Testing of 2-5% Screening Cells
6. Entering Receipt Testing into SCC
7. Receipt Testing During Downtime
8. Receipt Testing of Ortho 0.8% Panel Cells

# Procedure

1. Receipt Testing of Anti-A, -B, -AB, -D, A1 cells, A2 cells, and B cells

Chemical Risk Assessment: None

Biological Risk Assessment: None

Protective Equipment: Lab coat, gloves

Supplies: Tubes

Reagents: Reagent/cell to be receipt tested and test cell/reagent

Equipment: Centrifuge

Specimen Requirements: None

| STEPS | INSTRUCTIONS | **CHANGE/****APPROVAL** |
| --- | --- | --- |
| 1.0 | **Label each 10x75 tube in the following manner for testing below:**

|  |  |  |
| --- | --- | --- |
| Reagent to be receipt tested | Positive and Negative | Label 10x75 tubes with: |
| Anti-D | D+D- |  <D SC1 <D SC3 |
| Anti-A | A+A- |  <A A  <A B |
| Anti-B | B+B- |  <B B <B A |
| Anti-A,B | AB+AB+AB- |  <AB A2 <AB B <AB O |
| A1 cells | A1+A1- |  A1<A A1<B |
| B cells | B+B- |  B<B B<A |
| A2 cells | A2+A2- |  A2<A A2<A1 |

1.1 * 1. The “<” sign designates antibody.

blank |  |
|  2.0 | **Add one (1) drop of well mixed 2-5% suspension of cells and one (1) drop of antisera to each appropriately labeled 10x75 tube being receipt tested.** *Refer to table below.*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Reagent to be receipt tested | Positive and Negative Control | Labeled 10x75 tubes | **Step 2.0**Add to tube 1 drop of antisera and 1 drop of cells | **Step 2.1** | **Step 2.2** | Expected Reactions |
| Anti-D | D+D- |  <D SC1 <D SC3 |  <D + SC1 <D + SC3 | **MIX EACH TUBE BEING TESTED** | **CENTRIFUGE AT I.S.** **REMOVE AND READ MACROSCOPICALLY**  | 3+ to 4+0 |
| Anti-A | A+A- |  <A A  <A B |  <A + A  <A + B | 3+ to 4+0 |
| Anti-B | B+B- |  <B B <B A |  <B + B <B + A | 3+ to 4+0 |
| Anti-A,B | AB+AB+AB- |  <AB A2 <AB B <AB O |  <AB + A2 <AB + B <AB+O | 3+ to 4+3+ to 4+0 |
| A1 cells | A1+A1- |  A1<A A1<B |  A1 + <A A1+ <B | 3+ to 4+0 |
| B cells | B+B- |  B<B B<A |  B + <B B + <A | 3+ to 4+0 |
| A2 cells | A2+A2- |  A2<A A2<A1 |  A2 + <A A2 + <A1 | 3+ to 4+0 |

2.3 The “<” sign designates antibody. 2.4 Enter results into SCC.  *Refer to Section VI: Entering Receipt Testing into SCC*2.5 During downtime, refer to Section VII: Receipt Testing During Downtime. |  |
| 3.0 | **Compare results obtained with expected results and take appropriate action.**

|  |  |
| --- | --- |
| **If results are acceptable:** | **If results are unacceptable:** |
| 1. Enter "S" in column "A/P" and select  ‘PASS’ for QCInt.2. Complete column 12 (Rec. testing  complete and acceptable) on  Reagent/Supply/Form/Label  Receiving log.3. Item may be released for use into  inventory.4. Initial on Daily QC checklist.  | 1. Repeat Testing.2. Record "U" in column "A/P" and ‘FAIL’  for QCInt.3. Complete and sign off on  Reagent/Supply/Form/Label  Receiving log that receipt testing is not  acceptable. 4. Quarantine item in the QC basket of Sera #5.5. Determine the current inventory of reagent.6. Alert management that the item(s) did **NOT** pass receipt testing, and current inventory of reagent.7. Submit a Quality Assurance Exception Report.8. Management will notify company. |

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1. Receipt Testing of Anti-AHG (polyspecific), Anti-IgG, -C3d, CC cells, and EC3b cells

Chemical Risk Assessment: None

Biological Risk Assessment: None

Protective Equipment: Lab coat, gloves

Supplies: Tubes

Reagents: Reagent/cell to be receipt tested and test cell/reagent

Equipment: Centrifuge

Specimen Requirements: None

| STEPS | INSTRUCTIONS | **CHANGE/****APPROVAL** |
| --- | --- | --- |
| 1.0 | **Label each 10x75 tube in the following manner for testing below:**

|  |  |  |
| --- | --- | --- |
| Reagent to be receipt tested | Positive and Negative | Label 10x75 tubes with: |
| Anti-AHG | AHG +AHG +AHG - | <AHG CC<AHG EC3b<AHG SC1 |
| Anti-IgG | IgG +IgG - |  <IgG CC  <IgG SC1 |
| Anti-C3d | C3d +C3d - |  <C3d EC3b <C3d SC1 |
| CC cells | CC+CC- |  CC <IgG  CC <C3d |
| EC3b cells | EC3b +EC3b - | EC3b <C3d EC3b <IgG  |

1.1  The “<” sign designates antibody.blank |  |
|  2.0 | **Add one (1) drop of well mixed 2-5% suspension of cells and one (1) drop of antisera to each appropriately labeled 10x75 tube being receipt tested.** *Refer to table below.*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Reagent to be receipt tested | Positive and Negative | Label 10x75 tubes with: | **Step 5.0**Add to tube 1 drop of antisera and 1 drop of cells | **Step 5.1** | **Step 5.2** | Expected Reactions |
| Anti-AHG | AHG +AHG +AHG - | <AHG CC<AHG EC3b<AHG SC1 | <AHG + CC<AHG + EC3b<AHG + SC1 | **MIX EACH TUBE BEING TESTED** | **CENTRIFUGE AT I.S.** **REMOVE AND READ MACROSCOPICALLY**  | 2+ to 4+2+ to 4+0 |
| Anti-IgG | IgG +IgG - |  <IgG CC  <IgG SC1 | <IgG + CC  <IgG + SC1 | 2+ to 4+0 |
| Anti-C3d | C3d +C3d - |  <C3d EC3b <C3d SC1 | <C3d + EC3b <C3d + SC1 | w+ to 1+0 |
| CC cells | CC+CC- |  CC <IgG  CC <C3d |  CC + <IgG  CC + <C3d | 2+ to 4+0 |
| EC3b cells | EC3b +EC3b - | EC3b <C3d EC3b <IgG  | EC3b + <C3d EC3b + <IgG  | w+ to 1+0 |

2.1 The “<” sign designates antibody. *Refer to procedure (Routine): Grading Test Tube Reactions.* |  |
| 3.0 | **Hold all negative reactions in testing rack for 5 minutes room temperature.** |  |
| 4.0 | **Centrifuge negative reactions at the calibrated time and speed for immediate spin testing.**4.1 Read all negative reactions macroscopically and microscopically.4.2 Record results on the incoming reagents form. |  |
| 5.0 | **Add check cells to all negative tests.**5.1 To all tests with Anti-IgG and/or Anti-AHG, add 1 drop of Coombs Check Cells (CC).5.2 To all tests with Anti-C3d, add 1 drop of Complement Control Check Cells (EC3b)  and incubate 5 minutes at room temperature. |  |
| 6.0 | **Centrifuge all test tubes at the calibrated time and speed for immediate spin testing.** |  |
| 7.0 | **Enter results into SCC.** *Refer to Section VI: Entering Receipt Testing into SCC*7.1 During downtime, refer to Section VII: Receipt Testing During Downtime. |  |
| 8.0 | **Interpret results.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Reagent to be receipt tested | Positive and Negative | Label 10x75 tubes with: | Expected ReactionsAfter first centrifugation | Expected Results after 5 minute incubation of negatives | Expected Reactions after addition of CC (following centrifugation) |
| Anti-AHG | AHG +AHG +AHG - | <AHG CC<AHG EC3b<AHG SC1 | 2+ to 4+2+ to 4+0 | NTNT0 | NTNT2+ to 4+ |
| Anti-IgG | IgG +IgG - |  <IgG CC  <IgG SC1 | 2+ to 4+0 | NT0 | NT2+ to 4+ |
| Anti-C3d | C3d +C3d - |  <C3d EC3b <C3d SC1 | w+ to 1+0 | NT0 | NTw+ TO 1+ |
| CC cells | CC+CC- |  CC <IgG  CC <C3d | 2+ to 4+0 | NT0 | NT2+ to 4+ |
| EC3b cells | EC3b +EC3b - | EC3b <C3d EC3b <IgG  | w+ to 1+0 | NT0 | NTw+ TO 1+ |

8.1The “<” sign designates antibody. |  |
| 9.0 | **Compare results obtained with expected results and take appropriate action.**

|  |  |
| --- | --- |
| **If results are acceptable:** | **If results are unacceptable:** |
| 1. Enter "S" in column "A/P" and select  ‘PASS’ for QCInt.2. Complete column 12 (Rec. testing  complete and acceptable) on  Reagent/Supply/Form/Label  Receiving log.3. Item may be released for use into  inventory.4. Initial on Daily QC checklist.  | 1. Repeat Testing.2. Record "U" in column "A/P" and ‘FAIL’  for QCInt.3. Complete and sign off on  Reagent/Supply/Form/Label  Receiving log that receipt testing is not  acceptable. 4. Quarantine item in the QC basket of Sera #5.5. Determine the current inventory of reagent.6. Alert management that the item(s) did **NOT** pass receipt testing, and current inventory of reagent.7. Submit a Quality Assurance Exception Report.8. Management will notify company. |

 |  |

1. Receipt Testing of Enhancements (LISS, PEG, Albumin)

Chemical Risk Assessment: None

Biological Risk Assessment: None

Protective Equipment: Lab coat, gloves

Supplies: Tubes

Reagents: Reagent/cell to be receipt tested and test cell/reagent

Equipment: Centrifuge

Specimen Requirements: None

| STEPS | INSTRUCTIONS | **CHANGE/****APPROVAL** |
| --- | --- | --- |
| 1.0 | **Label 2 10x75 tubes as follows:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Reagent to be receipt tested | Positive and Negative | Label 10x75 tubes with: | **Step 5.0**Add to tube 2 drops of dilute antisera and 1 drop of cells | **Step 5.1**Add 2 drops of enhancement being tested to each tube |
| LISS or Albumin | SC1+SC1 - | <D SC1<c SC1 | <D + SC1<c + SC1 | **MIX EACH TUBE BEING TESTED and INCUBATE** ***15 MINUTES* AT 37 C** |
| PEG | SC1 +SC1 - | <D SC1<c SC1 | <D + SC1<c + SC1 |

1.1 The “<” sign designates antibody.*Note: Dilute anti-D and Anti-c are prepared as needed by the tech assigned to QC.*1. *Dilute antisera are stored in a reagent refrigerator.*
 |  |
| 2.0 | **LISS and ALBUMIN**

|  |  |  |  |
| --- | --- | --- | --- |
| Reagent to be receipt tested | Positive and Negative | Label 10x75 tubes with: | After 37C Incubation:4.1  |
| **LISS or Albumin** | SC1+SC1 - | <D SC1<c SC1 | Spin tubes at calibrated time and speed for immediate spin testing and record reactions on the receipt testing of incoming reagents form.Refer to routine procedure: *Grading Test Tube Reactions.* |
| **PEG** | SC1 +SC1 - | <D SC1<c SC1 | Check tubes for hemolysis, DO NOT spin tubes after 37˚C incubation.a) Hemolysis should be  documented on receipt  testing form, using slight, moderate, or  marked as grades.b) No hemolysis should be noted on receipt  testing form as NH(no hemolysis). |

2.1 The “<” sign designates antibody.  |  |
| 3.0 | **Wash cells 4 times with blood bank saline.**3.1 Cells may be washed in cell washer or washed by hand at calibrated time and speed for washing cells.1. After washing cells, in either cell washer or manually, ensure that all tubes decant completely.
 |  |
| 4.0 | **Add two drops of Anti-IgG to dry cell button and spin at calibrated time and speed for AHG reactions.** |  |
| 5.0 | **Resuspend and read macroscopically for agglutination.** |  |
| 6.0 | **Record reactions on the receipt testing of incoming reagents form.** |  |
| 7.0 | **Confirm all negative tests by adding one drop of Coomb’s check cells.** |  |
| 8.0 | **Spin tubes at calibrated time and speed for immediate spin testing.** |  |
| 9.0 | **Enter reactions into SCC.** *Refer to Section VI: Entering Receipt Testing into SCC*9.1 During downtime, refer to Section VII: Receipt Testing During Downtime. |  |
| 10.0 | **Interpret results:**10.1 Acceptable Results:

|  |  |  |
| --- | --- | --- |
| **Screening Cell 1 with** | **Anti-c** | **Anti-D** |
| **37˚** | **IgG** | **CC** | **37˚** | **IgG** | **CC** |
| **LISS/ALBUMIN** | **Neg.** | **Neg.** | **2-4+** | **1-3+** | **1-3+** | **NA** |
| **PEG** | **NH** | **Neg.** | **2-4+** | **NH** | **1-3+** | **NA** |

 **CC=Check Cells ND=Not Done NA=Not Applicable Neg.=Negative** |  |
| 11.0 | **Interpretation of results:**

|  |  |
| --- | --- |
| **If results are acceptable:** | **If results are unacceptable:** |
| 1. Enter "S" in column "A/P" and select  ‘PASS’ for QCInt.2. Complete column 12 (Rec. testing  complete and acceptable) on  Reagent/Supply/Form/Label  Receiving log.3. Item may be released for use into  inventory.4. Initial on Daily QC checklist.  | 1. Repeat Testing.2. Record "U" in column "A/P" and ‘FAIL’  for QCInt.3. Complete and sign off on  Reagent/Supply/Form/Label  Receiving log that receipt testing is not  acceptable. 4. Quarantine item in the QC basket 5. Determine the current inventory of  reagent.6. Alert management that the item(s) did **NOT** pass receipt testing, and current inventory of reagent.7. Submit a Quality Assurance Exception  Report.8. Management will notify company. |

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1. Receipt Testing of 0.8% Screening Cells

Chemical Risk Assessment: None

Biological Risk Assessment: None

Protective Equipment: Lab coat, gloves

Supplies: Tubes

Reagents: Reagent/cell to be receipt tested and test cell/reagent

Equipment: Centrifuge

Specimen Requirements: None

| STEPS | INSTRUCTIONS | **CHANGE/****APPROVAL** |
| --- | --- | --- |
| 1.0 | **Label a gel card SC1+, SC1-, SC2+, SC2-, SC3+, SC3-.** |  |
| 2.0 | **Remove the foil seal from the card.**2.1 Gel card should be room temperature (18.-25.C).2.2 Leave unused wells covered with foil packaging or parafilm. |  |
| 3.0 | **Use an appropriate pipette to add 50 microliters of each screening cell to the appropriate well.** |  |
| 4.0 | **Use an appropriate pipette to add 25 microliters of antisera to each tube in the following manner:**4.1

|  |  |
| --- | --- |
| **Item to be receipt tested** | **Tested with:** |
| **Positive control** | **Negative control** |
| **Screening cell 1** | **Dilute Anti-D** | **Dilute Anti-c** |
| **Screening cell 2** | **Dilute Anti-D** | **Anti-C** |
| **Screening cell 3** | **Dilute Anti-c** | **Dilute Anti-D** |

4.2 Dilute anti-D and Anti-c are prepared as needed by the tech assigned to QC. a) Dilute antisera are stored in a reagent refrigerator. |  |
| 5.0 | **Incubate at 37.C for 15 minutes in DG Therm incubator.** |  |
| 6.0 | **Centrifuge the gel card at the pre-set conditions (10 minutes) of the manufacturer.** |  |
| 7.0 | **Read the front and back side of each microwell macroscopically, grade and enter results in SCC.***Refer to Section VI: Entering Receipt Testing into SCC*7.1 If either side is positive, the reaction is considered to be positive. 7.2 Cards may be viewed for up to one week if microwells are properly sealed  with tape or parafilm.7.3 During downtime, record reactions on the receipt testing of incoming reagents  form. |  |
| 8.0 | **Interpret results:**8.1 Acceptable results:

|  |  |
| --- | --- |
| **Item to be receipt tested** | **Tested with:****Antisera** |
| **Anti-c** | **Anti-D** | **Anti-C** |
| **Screening Cell 1** | Negative | 1-3+ | Not done |
| **Screening Cell 2** | Not done | 1-3+ | negative |
| **Screening Cell 3** | 1-3+ | Negative | Not done |

 |  |
| 9.0 | **Interpretation of results:**

|  |  |
| --- | --- |
| **If results are acceptable:** | **If results are unacceptable:** |
| 1. Enter "S" in column "A/P" and select  ‘PASS’ for QCInt.2. Complete column 12 (Rec. testing  complete and acceptable) on  Reagent/Supply/Form/Label  Receiving log.3. Item may be released for use into  inventory.4. Initial on Daily QC checklist.  | 1. Repeat Testing.2. Record "U" in column "A/P" and ‘FAIL’  for QCInt.3. Complete and sign off on  Reagent/Supply/Form/Label  Receiving log that receipt testing is not  acceptable. 4. Quarantine item in the QC basket of Sera #5.5. Determine the current inventory of reagent.6. Alert management that the item(s) did **NOT** pass receipt testing, and current inventory of reagent.7. Submit a Quality Assurance Exception Report.8. Management will notify company. |

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| 10.0 | **Place antigram in antigram notebook.** |  |

1. Receipt Testing of 2-5% Screening Cells

Chemical Risk Assessment: None

Biological Risk Assessment: None

Protective Equipment: Lab coat, gloves

Supplies: Tubes

Reagents: Reagent/cell to be receipt tested and test cell/reagent

Equipment: Centrifuge

Specimen Requirements: None

| STEPS | INSTRUCTIONS | **CHANGE/****APPROVAL** |
| --- | --- | --- |
| 1.0 | **Label 6 10x75 tubes as follows: SC1 +, SC1-, SC2+, SC2-, SC3+, SC3-.** |  |
| 2.0 | **Add two drops of antisera to each tube in the following manner:**2.1

|  |  |
| --- | --- |
| **Item to be receipt tested** | **Tested with:** |
| **Positive control** | **Negative control** |
| **Screening cell 1** | **Dilute Anti-D** | **Dilute Anti-c** |
| **Screening cell 2** | **Dilute Anti-D** | **Anti-C** |
| **Screening cell 3** | **Dilute Anti-c** | **Dilute Anti-D** |

2.2 Dilute anti-D and Anti-c are prepared as needed by the tech assigned to QC. a) Dilute antisera are stored in a reagent refrigerator. |  |
|  3.0 | **Add one drop of 2-5% screening cell to the corresponding test tube.** |  |
| 4.0 | **Add two drops of PEG enhancement to each test tube.** |  |
| 5.0 | **Incubate all tubes for 15 minutes at 37∙C.** |  |
| 6.0 | **Remove from incubator and observe for hemolysis..***6.1 Go to routine procedure: Grading Test Tube Reactions.* |  |
| 7.0 | **Wash cells 4 times with blood bank saline.**7.1 Cells may be washed in cell washer or washed by hand at calibrated time and  speed for washing cells.1. After washing cells, in either cell washer or manually, ensure that all tubes

decant completely. |  |
| 8.0 | **Add two drops of Anti-IgG to dry cell button and spin at calibrated time and speed for AHG reactions.** |  |
| 9.0 | **Resuspend and read macroscopically for agglutination.** |  |
| 10.0 | **Confirm all negative tests by adding one drop of Coomb’s check cells** |  |
| 11.0 | **Spin tubes at calibrated time and speed for immediate spin testing.** |  |
| 12.0 | **Enter results in to SCC.** *Refer to Section VI: Entering Receipt Testing into SCC*12.1 During downtime, refer to Section VII: Receipt Testing During Downtime. |  |
| 13.0 | **Interpret results:****13.1 Acceptable Results:**

|  |  |
| --- | --- |
| **Item to be receipt tested** | **Tested with:****ANTISERA** |
| **Anti-c** | **Anti-D** | **Anti-C** |
| **37.** | **IgG** | **CC** | **37.** | **IgG** | **CC** | **37.** | **IgG** | **CC** |
| **Screening Cell 1** | **Neg.** | **Neg.** | **2-4+** | **1-4+** | **1-4+** | **NA** | **ND** | **ND** | **ND** |
| **Screening Cell 2** | **ND** | **ND** | **ND** | **1-4+** | **1-4+** | **NA** | **Neg.** | **Neg.** | **2-4+** |
| **Screening Cell 3** | **1-4+** | **1-4+** | **NA** | **Neg.** | **Neg.** | **2-4+** | **ND** | **ND** | **ND** |
|  |  |  |  |  |  |  |  |  |  |

 **CC=Check Cells ND=Not Done NA=Not Applicable Neg.=Negative** |  |
| 14. 0 | **Interpretation of results:**

|  |  |
| --- | --- |
| **If results are acceptable:** | **If results are unacceptable:** |
| 1. Enter "S" in column "A/P" and select ‘PASS’ for QCInt.2. Complete column 12 (Rec. testing complete and  acceptable) on  Reagent/Supply/Form/Label  Receiving log.3. Item may be released for use into inventory.4. Initial on Daily QC checklist.  | 1. Repeat Testing.2. Record "U" in column "A/P" and ‘FAIL’  for QCInt.3. Complete and sign off on  Reagent/Supply/Form/Label  Receiving log that receipt testing is not  acceptable. 4. Quarantine item in the QC basket.5. Determine the current inventory of reagent.6. Alert management that the item(s) did **NOT** pass receipt testing, and current inventory of reagent.7. Submit a Quality Assurance Exception Report.8. Management will notify company. |

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| 14.0 | **Place antigram in antigram notebook.** |  |

1. Entering Receipt Testing in SCC

| **STEPS** | **INSTRUCTIONS** | **CHANGE/****APPROVAL** |
| --- | --- | --- |
| **1.0** | **Go to Results>QC>Reagents>Modify.*** 1. Enter Lot number and F12 to accept.
	2. Place check mark in box by Receipt criteria met as you begin testing.
1. OK to use will be checked.
	1. Go to Results>QC>Reagents>Open.
	2. Enter Lot number and F12 to accept.
	3. F12 to open reagent so that it will be available to select in SCC to perform the receipt testing.
 |  |
| **2.0**  | **Go to Results> QC>Results>Edit.** * 1. Select RECPT at Rack #, F12 to accept and Enter to Select.
	2. Answer Yes if “There are no unfinished or valid QC tests. Add new QC test?” appears.
 |  |
| **3.0** | **Click F5 to enter the reagent and control information.**3.1

|  |  |
| --- | --- |
| **Reag row (Reagent)** | **Contr row (Control)** |
| 1. Enter the Type of Reagent 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 #.
 |

3.2 Click F12 to Accept. 3.3 Enter results of QC Test and select if S (Satisfactory) or U (Unsatisfactory). *Refer to Attachment 4: Interpretation of Results.* 3.4 F12 to accept entry and Yes to accept results. 3.5 Investigate any discrepancies identified at review.3.6 If receipt testing is unsatisfactory:a. Go to Results>QC>Reagents>Modify.b. Enter Lot # and F12.c. Uncheck receipt criteria met so that reagent is not OK to use.  |  |
| **3.0** | **Management will review in SCC.** |  |

1. Receipt Testing During Downtime

Chemical Risk Assessment: None

Biological Risk Assessment: None

Protective Equipment: Lab coat, gloves

Supplies: Tubes

Reagents: Reagent/cell to be receipt tested and test cell/reagent

Equipment: Centrifuge

Specimen Requirements: None

| **STEPS** | **INSTRUCTIONS** | **CHANGE/****APPROVAL** |
| --- | --- | --- |
| **1.0**  | **Obtain the appropriate form for the reagent that is to be receipt tested from the Forms Drawer or master forms book.** **1.1**

|  |  |
| --- | --- |
| **Reagents** | **Form Used During Downtime** |
| Anti-A,-B,-AB,-D, A1 cells, A2 cells, B cells | *BB.FORMS.5000* *Receipt Testing of Anti-A,-B,-AB,-D, A1 cells, A2 cells, B cells* |
| Anti-AHG (polyspecific) Anti-IgG, Anti-C3d , CC cells and EC3b cells | *BB.FORMS.5030:* *Receipt Testing of* Anti-AHG (polyspecific), Anti-IgG, Anti-C3d , CC cells and EC3b cells |
| LISS, PEG, Albumin, 0.8% Screening Cells,2-5% Screening Cells | *BB.FORMS.5040:* *Receipt Testing of Screening Cells (2-5%, 0.8%), LISS,**PEG, Albumin form* |

 |  |
| **2.0** | **Record the following from the vial to be receipt tested: manufacturer, lot number, and expiration date on the appropriate form.** 2.1 Record your initials in the tech column. |  |
| **3.0** | **Record rack number from the reagent rack that will be used to receipt test item, your initials and date tested on form.**  |  |
| **4.0** | **Proceed to testing reagents in appropriate section:**1. Receipt Testing of Anti-A,-B,-AB,-D, A1 cells, A2 cells, B cells
2. Receipt Testing of Anti-AHG (polyspecific) Anti-IgG, Anti-C3d , CC cells and EC3b cells
3. Receipt Testing of Enhancements (LISS, PEG, Albumin)
4. Receipt Testing of 0.8% Screening Cells
5. Receipt Testing of 2-5% Screening Cells
 |  |
| **5.0** | **Compare results obtained with expected results and take appropriate action.**

|  |  |
| --- | --- |
| **If results are acceptable:** | **If results are unacceptable:** |
| 1. Enter "S" in column "A/P" and  select ‘PASS’ for QCInt.2. Complete column 12 (Rec.  testing complete and acceptable)  on Reagent/Supply/Form/Label  Receiving log.3. Item may be released for use  into inventory.4. Initial on Daily QC checklist.  | 1. Repeat Testing.2. Record "U" in column "A/P" and ‘FAIL’  for QCInt.3. Complete and sign off on  Reagent/Supply/Form/Label  Receiving log that receipt testing is not  acceptable. 4. Quarantine item in the QC basket.5. Determine the current inventory of reagent.6. Alert management that the item(s) did **NOT** pass receipt testing, and current inventory of reagent.7. Submit a Quality Assurance Exception Report.8. Management will notify company. |

 |  |
| **6.0** | **Forward completed form for management review.** |  |

1. Receipt Testing of 0.8% Ortho Panel Cells

# Protocol

1. Ortho Clinical Diagnostics quality assurance states that Ortho 0.8% Panel Cells be tested periodically with weak reacting antibodies.
2. Each in-date panel cell set will be tested upon opening and as requested by management after reviewing antibody workups and expected reactivity of panel cells.
3. Multiple sets of 0.8% Panel A and B, and one set of Panel C is on standing order and utilized for patient testing
4. Panel cells will be marked with a number when they are received. (Example: multiple sets of Panel A should be labeled: A-1, A-2, A-3, etc.)
5. Performing testing on these panels as they are opened will ensure proper reactivity at different time intervals during the shelf life of the panels.
6. All expired panels utilized for patient testing will undergo testing to ensure reactivity of antigens tested per SOP.

# Procedure

Chemical Risk Assessment: None

Biological Risk Assessment: None

Protective Equipment: Lab coat, gloves

Supplies: Tubes

Reagents: Reagent/cell to be receipt tested and test cell/reagent, Panel QC antisera

Equipment: Centrifuge, Vision

Specimen Requirements: None

| STEPS | INSTRUCTIONS | **CHANGE/****APPROVAL** |
| --- | --- | --- |
| 1.0 | **Obtain 0.8% panel in need of testing and sample labeled “QC Panel”*** 1. “QC Panel” contains weakly reacting anti-D and anti-c
 |  |
| 2.0 | **Testing can be automated using Ortho Vision analyzers or manually using Ortho Workstations**

|  |  |
| --- | --- |
| Ortho Vision | Manual |
| * + Select “create order”
	+ San “QC Panel” barcode
	+ Select Panel (A, B, C or C Ficin) to be tested
	+ Load well mixed red cell reagent panel
	+ Print Ortho Vision panel results
 | * + Carefully label a gel card with Panel Cell (A, B, C or C Ficin), vial number, and QC.
	+ Pipette panel cells per SOP
	+ Pipette “QC Panel” sample into each well per SOP
	+ Incubate for 15 min at 37°C
	+ Spin card for 10 min per SOP in Ortho Workstation centrifuge
	+ Document reactions on proper antigram
 |

 |  |
| 3.0 | **Document that testing is complete on appropriate sticker on panel cell holder.** |  |
| 4.0 | Turn in Vision printouts and appropriate antigram or manual results to management for review. 4.1 Ensure paperwork turned into management is labeled with date/time and Panel name (example: Panel A-3).  |  |

# 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.

# Related procedures/policies

# Attachments/Linked documents (title 21)

# Revision Dates: Review Change Summary as represented in Title 21.