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|  | | **Daily Quality Control**  BB.QC.1006.7 | **Dept:** | 324311 |
| **Dept Name** | Blood Bank |
| **Effective Date:** | <12/2007 |
| **Revised Date:** | 1/31/19 |
| **Name & Title**: CLIA Laboratory Medical Director | | | **Contact:** | MR Jones/ JH Simmons |
| **Signature:** |  | | **Date:** |  |

****

1. **General Protocol Statement:**
   1. **Purpose:** To comply with regulatory requirements as stated by the American Association of Blood Banks (AABB) in their *Standards for Blood Banks and Transfusion Services,* and with standards set forth by the College of American Pathologists (CAP), quality control of reagents is required.
   2. **Responsible Department/Scope:** 
      1. Protocol owner/Implementer: Mary Rose Jones/Julie H. Simmons
      2. Protocol prepared by: C. Williams
      3. Who performs protocol: Department staff/management
   3. **Definitions:**

**QC:** Quality Control

LIS: Laboratory Information System

SCC: Soft Computer Blood Bank LIS

* 1. **Sections:**

1. Rack Storage

II. Frequency

III. Responsibility

IV. Lot Number Documentation

V. Visual Inspection

VI. Temperatures

VII. Cell Washer Levels

VIII. Pending Log

IX. QC Duties

X. Frequency of Additional QC Tasks

1. **Protocol: Daily Quality Control**
2. **RACK STORAGE**
   1. Reagent racks are stored in Sera #5 drawer, labeled *antisera racks and rare antisera in* *use.*
3. Reagents are to be stored according to the manufacturer’s storage temperature requirements.

|  |  |
| --- | --- |
| **Manufacturer** | **Storage Temperature** |
| Biorad | 2°C-8°C |
| Immucor | 1°C-10°C |
| Ortho | 2°C-8°C |
| Medion/Grifols | 2°C-8°C |
| Quotient | 2°C-8°C |
| Alba | 2°C-8°C |

1. Reagents must be refrigerated when not in use, unless otherwise specified by the manufacturer.
2. Daily reagents racks will be refrigerated at the end of each shift in Sera #5.
3. Racks that have been in use will be placed at the back of the shelf of Sera #5, so that the rack closest to the door will have been in storage the longest.
4. Each tech assigned to the crossmatch rotation will be responsible for ensuring that the rack they choose for testing has had quality control performed for the day.
5. **FREQUENCY**
6. Daily reagents racks and the special rack will be tested on day of use with a positive and negative control, in dated and not expired, passed QC, and documented in SCC Daily Racks/Special or on Daily QC reaction log sheet.

|  |  |
| --- | --- |
| **Day** | **Racks tested** |
| Monday-Friday | Racks 1-6, Specials |
| Saturday, Sunday, Holidays | Racks 1-4, Specials |

* 1. Daily Reagent Quality Control will be entered into SCC or during downtime recorded on Daily QC reaction log sheet, BB.Forms.1200.
  2. Reagents that are tested as part of daily quality control are receipt tested upon receipt, all other reagents (with the exception of panel cells and certain enhancements) are tested with a positive and negative control each day of use.
  3. Receipt testing is performed in SCC on the Receipt rack.

1. Rare antisera will be tested with a positive and negative control upon use, unless the

antisera has previously been tested within the last 24 hours.

* 1. Rare Antisera includes Anti-C, E, e, K, k, Fya, Fyb, Jka, Jkb, M, N, P, Lea, Leb, S, s.
  2. Quality Control for rare antisera will be entered into SCC on the Antigen rack or during downtime recorded on the RARE ANTISERA Quality Control Form, BB.Forms.1081.
  3. Rare antisera

1. We can use rare expired antisera only if tested each time with a positive and negative control and documented.
2. The preference is to use rare indated antisera which will be tested as needed once per day with a positive and negative control and documented.
   1. Rare antisera rack is kept in labeled antisera rack on labeled shelf in Sera #5.
   2. Additional rare antisera stored in Sera #5.
   3. Frozen rare antisera is located in Freezer #12.
3. **RESPONSIBILITY**
4. Responsibility of performing daily quality control of reagents will be assigned to third shift.
   1. Although certain shifts and techs may be assigned to complete quality control duties, it is the responsibility of each tech obtaining a rack to ensure that the rack has had quality control performed in the last 24 hours.
   2. Duties and assignments are subject to change.
5. **LOT NUMBER DOCUMENTATION**
6. Lot numbers for all antisera racks and specials rack will be initially registered and checked in SCC.
   1. During downtime lot numbers can be recorded on the following logs and then checked daily against the log sheet– Routine Rack-Form-1201 and Misc-Form -1082.
7. **Any** reagent being put in a rack or taken out of a rack, due to **any** circumstance, must be recorded on the log sheet if new lot number.
8. The tech(s) performing QC each day, will verify that all lot numbers and expiration dates correspond to the information recorded on the log sheet.
   1. Lot numbers for all working reagents will be entered into SCC in either the Daily QC or Special QC racks.
9. During downtime they can be recorded on BB.Forms.1082 (Misc.):Routine (1201) and Special (1202), Daily Reagent QC Worksheet (1200).
10. **Any** reagent that is taken out of use, due to unexpected reactions, contamination, or any other abnormality should be documented on a QA and submit to management for follow-up.
11. **VISUAL INSPECTION**
12. All reagents will be inspected for normal appearance upon testing.

*Refer to Attachment 1: Criteria for Satisfactory and Unsatisfactory Appearance of Reagents.*

1. Documentation of satisfactory appearance or unsatisfactory appearance will be documented in SCC or during downtime on the Daily Reagent QC Form, (1200).
2. All reagents should be checked to make sure that an open date and initials are on the vial.
3. All reagents that fail visual inspection will be taken out of use and placed in quarantine. Wake Main: Basket located in Sera #5.
4. All vials of failed lot number will be taken out of use.
5. All reagents that fail visual inspection will have a QA written.
6. Assess current inventory levels.
7. Management should be told verbally about the problem and also the current inventory levels.
8. Management should also be informed via email.
9. Management will follow up with manufacturer for appropriate credits.
   1. Date opened and initials should be on all vials in use.
10. Information should correspond with information documented in SCC.
11. BLOOD INSPECTION

3.1 Blood shall have a visual inspection performed every 24 hours.

|  |  |  |
| --- | --- | --- |
| Product | Normal Appearance\* | Abnormal appearance\* |
| Red Blood Cells | * Segments appear to be the same color as primary bag contents * Closed and intact ports * No hemolysis | * Segments appearing lighter or darker in color than the primary bag contents * Purple color to the red cells * Clots * White particulate matter in the primary container * Supernatant fluid that is discolored from normal appearance * Gross lipemia * Foreign objects in the primary container or ports * Hemolysis * Open ports * Anything questionable |

*\*\*Refer to Protocols: Visual Inspection of Blood Products*

* 1. Blood will be checked in all locations to ensure that units are on the properly labeled shelf and stored in a manner of ascending expiration dates.

1. On shelves
2. Biofridges
3. Remote refrigerators
   1. The Short Dated Report should be run daily to get a list of units that are expiring and should be posted on the Crossmatch refrigerator.
4. Label All blood that is less than 5 days of expiration date with a short dated

sticker, BB.LABELS.1039

1. Pink flags are placed on short dated units when selected to a patient.
2. Verbally notify crossmatch tech and front desk tech of any units with less than 24

hours of expiration to ensure that the unit is properly allocated and issued.

3.4 All units that fail blood inspection will be placed on the quarantine shelf of Sera #5.

1. Corrective action must be taken and documented on a QA form.
2. Email management.
3. Refer to Protocol: Visual Inspection of Blood Products.
4. **TEMPERATURES**
5. Temperatures will be recorded on the Daily Temperature Recording and QC form,

BB.Forms.1026, every 24 hours.

1. Temperatures are taken from the digital readout on the instrument and also from the global sensors in the unit.
2. Corrective action must be taken for all results that are out of acceptable range.
3. QA will be written for all unacceptable results.
4. Management will be informed of all results and/or equipment that are out of range.
5. See table below for additional instructions.

1.1

|  |  |
| --- | --- |
| **If** | **Then** |
| **Out of acceptable range** | * Document in the maintenance log * Take corrective action as needed, consult equipment manuals, call biomedical personnel * Inform management/designee * Post message (DO NOT USE with Date/Initials) on equipment. * Remove non working equipment from service * Follow-up should include recalibration as needed. |
| **Problem Continues** | * For refrigerators, freezers, and platelet incubators it may be necessary to move products to a unit that is in an acceptable range. * Manually take temps of all storage units that are not hooked up to the REES every 4 hours. * Use charts for the equipment that has a chart recorder. |
| **No back up equipment available** | * Return products to supplier |

1. **CELL WASHER LEVELS**
2. Cell washer levels will be tested weekly on all operational cell washers.
3. If volume is not in acceptable range, adjust dial in back of cell washer until cell washer is within range.
4. If volume does not test within acceptable range, remove from service and call biomedical engineering.
5. **PENDING TESTS REPORT**

1.0 Pending Tests Report will be done at the end of every shift by assigned tech.

|  |  |
| --- | --- |
| **Shift** | **Rotation assigned to Pending Tests Report** |
| 1st | XM2 |
| 2nd | XM2 |
| 3rd | CP |

1. All tests not resulted, should have a result in the LIS or given instructions to follow up by next shift.
2. Outreach samples should be investigated if not received on date of collection. Call Beverly Smith, 6-6867.
3. All samples not received in a timely manner should be investigated.
4. Any additional follow up instructions should be documented in the communication notebook and management made aware.
5. **QC DUTIES PERFORMED MONDAY- FRIDAY(excluding holidays)**

1.0 TRANSFUSION REACTIONS

a) Transfusion log will be checked to ensure that all tests have been resulted.

b) Any pending tests, should be checked for completion (i.e. DATs, gram stain, cultures).

1. Check for pathologist comments and signature.
2. Check for approval for more products.
3. Check for completion of suspected adverse transfusion reaction investigation form, BB.FORMS.1096.
4. Results all pending tests in SCC and/or follow up with management and/or medical director for completion.

2.0 EXPIRED PRODUCTS

1. The expiration summary report prints nightly, see QC: Unit Status/Disposition in SCC.
   * + - All units need to have a final disposition in the computer.
       - Units that are expired will be placed on the quarantine shelf of Sera #5 and discarded by third shift. Credit may be due for some products. Ex. Platelets received up to 36 hours before expiration.
       - Products with quality issues, such as ABO/discrepancies, positive DATS, and/or failure of visual inspection may need to be returned to the supplier and credit will be due from the manufacturer. These will be recorded and handled on the Unacceptable Unit Disposition log.
       - Follow up on all units that repeatedly show up on expired products. If resolution cannot be completed by third shift document on QA and forward to management.

3.0 RECEIPT TESTING

1. Receipt testing will be routinely performed on Monday-Fridays as time permits and

may be performed on weekends when necessary.

* + - Items requiring receipt testing will **not** be released into inventory until receipt

testing is completed and acceptable.

* + - Receipt testing will be signed off on the Rgt/Supply/Form/Label Receiving log, BB.FORMS.1083.
* Receipt testing reactions will be documented in SCC in the Receipt Rack.
* Once receipt testing is completed and acceptable, the reagent must be modified in SCC to document receipt testing is acceptable.
* See table below for items requiring receipt testing.

| **Items requiring receipt testing** | **Items that do NOT require receipt testing** |
| --- | --- |
| Anti-A | Blood Group Antisera(with the exception of Anti-A, -B, -AB, -D) |
| Anti-B | Panel Cells |
| Anti-D | Enzyme solutions |
| Anti-AB | Elution kits |
| Antiglobulin coombs(polyspecific, IgG, C3d) | Chloroquine |
| Reverse Cells(A1, A2, B) | NEO/ECHO reagents |
| Screening cells(0.8% and 2-5%) | Gel Cards |
| Labels | Anti-C, Anti-c |
| Forms | Anti-E, -e |
| C3d cells | Anti-Fya, -Fyb |
| Coombs Check Cells | Anti-Jka, -Jkb |
| LISS | Anti-S, -s |
| PEG | Anti-Lea, -Leb |
| Albumin | Anti-M, -N |
|  | Anti-P1 |
|  | Anti-Cw |
|  | Anti-Kpa |
|  | Anti-Kpb |
|  | Anti-Jsa |
|  | Anti-K, -k |
|  | \*\*any other rare antisera |
|  | Salines |
|  | A1 lectin |
|  |  |

1. FREQUENCY OF ADDITIONAL QC TASKS

1.0 Quarterly, Semi-annual, annual QC tasks are assigned by management.

2.0 Weekly tasks are performed by assigned QC tech on day designated on QC

checklist, BB.FORMS.1025.

3.0 See table below for QC tasks and frequencies.

QC Tasks and Frequency

|  |  |
| --- | --- |
| **Task** | **Frequency** |
| Calibrate/Clean automatic pipettors  Lubricate Helmer plasma basket assembly lift-out rail.  Sorvall function testing and bleaching  Clean coolers  Clean and disinfect eyewash  Change glycerol  Check IBM/Cobe RBC detector  Fire Drill  Clean Refrigerators  Clean outside of all freezers | QUARTERLY |
| Calibrate Scale  Check filter on TSCD | SEMI ANNUAL |
| Serofuge Calibration  Alarm Activation/Sensors | ANNUAL |
| Prepare Dilute Antisera  Helmer bath clean/drain  Verify REES  Clean Grifols dispenser  Clean Sorvalls  Scrape freezers  Run eyewash  Inventory reagents, storeroom, outside vendors  Clean Forma plasma water bath  Inventory reconciliation | WEEKLY |
| CP inventory  Print Shop inventory | MONTHLY |
| Cooler Validation | BIENNIAL |

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

All procedures must be reviewed as stated in the document change 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:**

**QC:** Daily Quality Control using SCC

QC: Unit Status/ Disposition SCC

**5. References**: NA

**6. Attachments**: NA

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

See Document Change Control

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| **Document Change Control Page 1 of 2** | | | | | | | | | | | | | | | | | | |
| **Title:**  **Daily Quality Control using SCC** | | | | | | | | | | | | | | | | | | |
| Previous title: Daily Quality Control | | | | | | | | | | | | | | | | | | |
| Written date | | | | |  | | | | Written by: | | | |  | | | | | |
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| Effective date in use | | | | | <12/2007 | | | | In use by | | | | See archived record | | | | | |
| **Revisions** | | | | | | | | | | | | | | | | | | |
| Revised Date | By | | | MD  Date | | By | | MD  Date | | By | | Review Date | | | By | | Effective Date | By |
| 8/20/14 | CW | | | 2/5/15 | | GP | | 2/17/15 | | EF | | 2/17/15 | | | JHS | | 3/1/15 | JHS |
| Validate Date | By | | | Revisions: Put into standard format. All racks are QCd on days used. | | | | | | | | | | | | | | |
| 1/28/15 | MRJ | | |
| Revised Date | | By | | MD  Date | | By | | MD  Date | | By | | Review Date | | | By | | Effective Date | By |
| 5/20/15 | | BT | | 2/5/14 | | GP | | 5/22/15 | | EF | | 5/22/15 | | | JHS | | 5/28/15 | JHS |
| Validate Date | | By | | Revisions: Changed Routine Rack testing to PEG. Removed anti-IgG, CC and PEG from Special rack and added to Routine Rack. Removed gel cells from Routine Rack and added to special Rack. Corrected form names, Edited forms to reflect rack changes. Added Section III: Prep of Diluted Antisera for QC | | | | | | | | | | | | | | |
| 5/22/15 | | SMA | |
| Revised Date | | By | | MD  Date | | By | | MD  Date | | By | | Review Date | | | By | | Effective Date | By |
| 7/7/16 | | JHS | |  | |  | | 7/29/16 | | Ef | | 7/21/16 | | | MRJ | | 8/6/16 | jhs |
| Validate Date | | By | | Revisions: Added Lexington QC. Added sections on SCC. Paper documentation is done during downtime. | | | | | | | | | | | | | | |
| 7/21/16 | | MRJ | |
| Revised Date | | By | | MD  Date | | By | | MD  Date | | By | | Review Date | | | By | | Effective Date | By |
| 6/6/18 | | mjones | |  | |  | |  | |  | |  | | |  | |  |  |
| Validate Date | | By | | Revisions:  Section II frequency – 1.0 clarified QC must be daily, pass QC, indated, and documented  Step 2.3 clarified the use of rare antisera  Step 3.2 clarified that blood must be inspected in all locations stored  Section IX step 2 clarifed some units may be returnable for credit if expired eg. Plts less than 36 hrs left  Section X updated tasks | | | | | | | | | | | | | | |
| 6/6/18 | | jclark | |
| Locations | | |  | | | | Out of Use: Date: | | | |  | | | By | |  | | |
|  | | | | Reason | |  | | | | | | | | | |

Reviews: Record date/initials

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| Date | Initials | Date | Initials | Date | Initials | Date | Initials |
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| **Document Change Control Page 2 of 2** | | | | | | | | | | | | | | | | | | |
| **Title:**  **Daily Quality Control using SCC** | | | | | | | | | | | | | | | | | | |
| Previous title: Daily Quality Control | | | | | | | | | | | | | | | | | | |
| Written date | | | | |  | | | | Written by: | | | |  | | | | | |
| Validation date | | | | |  | | | | Validation by | | | |  | | | | | |
| Reviewed date | | | | |  | | | | Reviewed by | | | |  | | | | | |
| Approved date | | | | |  | | | | Approved by | | | |  | | | | | |
| Approved date | | | | |  | | | | Approved by | | | |  | | | | | |
| Effective date in use | | | | | <12/2007 | | | | In use by | | | | See archived record | | | | | |
| **Revisions** | | | | | | | | | | | | | | | | | | |
| Revised Date | By | | | MD  Date | | By | | MD  Date | | By | | Review Date | | | By | | Effective Date | By |
| 1/30/19 | JHS | | |  | |  | |  | |  | |  | | |  | |  |  |
| Validate Date | By | | | Revisions: Cell washers volume are checked weekly not daily. Added Grifols storage temp. Unacceptable Unit Disposition log is used for unacceptable units. A1 lectin is not receipt tested. | | | | | | | | | | | | | | |
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| Revised Date | | By | | MD  Date | | By | | MD  Date | | By | | Review Date | | | By | | Effective Date | By |
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| Locations | | |  | | | | Out of Use: Date: | | | |  | | | By | |  | | |
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Reviews: Record date/initials

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| 11/13/17 | jhs |  |  |  |  |  |  |
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Attachment 1: Criteria for Satisfactory and Unsatisfactory Appearance of Reagents

| **Reagent** | **Satisfactory Appearance** | **Unsatisfactory Appearance\*\*see Section IV** |
| --- | --- | --- |
| **Antisera** | * Clear/No turbidity * No particulate matter * Not expired | * Cloudy * Particulate matter * Anything questionable? |
| **Reagent**  **Red Cells** | * Hemolysis grade <7 * Not expired | * Hemolysis grade >7 * Expired * Discoloration * Bacterial contamination-red cells will be dark purple to black in color * Anything questionable |
| **Gel cards** | * Foil intact * No bubbles in gel * Not expired | * If cards show signs of drying out * Discoloration * Bubbles * Crystals * Seal not intact |
| **Eluate Kit** | * Clear/No turbidity * No particulate matter * Buffering solution is blue * Not expired | * Cloudy * Particulate matter * Anything questionable? * Buffering solution is not blue |
| **Grifols Diluent** | * Clear/No turbidity * No particulate matter * Not expired | * Cloudy * Particulate matter * Anything questionable? |
| **Saline Cubes** | * Clear/No turbidity * No particulate matter * Not expired | * cloudy * turbidity * particulate matter |
| **Radsures** | * NOT clearly shown on radsure prior to irradiation * NOT should not be visible on radsure after irradiation * Stored in dark place, preferably between 0°C-6C° but in circumstances where it is difficult to refrigerate indicators after each use, the indicators may remain at room temperature for up to 30 days * Not expired | * “NOT” not clearly visible on radsure prior to irradiation * “NOT” visible on radsure after irradiation. * NOT stored according to manufacturer’s instructions |
| **RadControls** | * Red visible before irradiation and black visible after irradiation * Stored in dark place * Not expired | * Black before irradiation * Red after irradiation |
| **0.7% Delglycing Saline** | * Clear/No turbidity * No particulate matter * Not expired | * Cloudy * Particulate matter * Anything questionable? |
| **Saline bottles** | * Clear/No turbidity * No particulate matter * Not expired | * Cloudy * Particulate matter * Anything questionable? |
| **Working Wash Solution** | * Clear/No turbidity * No particulate matter * Not expired | * Cloudy * Particulate matter * Anything questionable? |
| **8.5% Saline for deglycing segments** | * Clear/No turbidity * No particulate matter * Not expired | * Cloudy * Particulate matter * Anything questionable? |