**Purpose**:

This procedure provides instructions for performing reagent QC for manual testing.

**Policy:**

* All antisera and cellular reagents are stored in a monitored refrigerator at 2-8°C.
* All reagents are used within their indicated expiration date.
* In use reagents are arranged in lettered racks for manual testing.
* Racks are rotated in alphabetical order ( A, B, C, A, etc.) for Daily Quality Control testing.
* One rack is used each day for Daily Quality Control testing.
* Each lot of reagents is tested before being placed into use.

|  |
| --- |
| **Reagents Requiring Daily QC Testing**  |
| **Routine Reagent Rack** * anti-A
* anti-B
* A1 cells
* B cells
* anti-D
* Screening Cells 1, 2, 3
* LISS
* anti-IgG
* antihuman globulin (AHG) control cells
 | **Direct Antiglobulin Reagent Rack*** Polyspecific antihuman globulin
* C3 Check Cells
* Anti-C3
* Albumin
 |
| **ABO Resolution Rack*** Anti-A,B
* Seraclone ABO + RH Control
* A2 Cells
 |

**Sources of Control Materials for Antibody Detection and ABO Reverse Testing:**

|  |  |  |
| --- | --- | --- |
| **Antibody QC** | **Source** | **Antibody** |
| **Primary** | Ortho Confidence QC Kit | Anti-A, -B, -D, -c |
| **Secondary** | BioRad Solid Screen II Control B | Anti-c |
|  | BioRad Solid Screen II Positive Control | Anti-D |
|  | TANGO QC Controls | Anti-A, -B |
| **Option requiring TS Manager Approval** | Patient source of antibody(ies) | Must react with all antibody detection cells |

**Sources of Control Materials for ABO and D Antigen Forward Testing:**

|  |  |  |
| --- | --- | --- |
| **Antigen QC** | **Source** | **Antibody** |
| **Primary** | Ortho Confidence QC Kit | Cell 1: A1B rrCell 2: O R1r |
| **Secondary** | TANGO QC Controls | Combination of types to test anti-A, -B, and –D reactivity and specificity |
| **Option requiring TS Manager Approval** | Other source of antigen(s) | Combination of types to test ABO and D antisera reactivity and specificity |

**Procedure:**

|  |  |  |
| --- | --- | --- |
|  | Action | Related Documents |
| **1** | * Examine reagents for color and appearance:
* In date
* Clear and no turbidity in antisera
* No Hemolysis in reagent red cells
* Reagent color has not changed
* Reagents and QC must meet criteria before testing is performed.
 |  |
| **2** | * Record testing date, lot number and expiration date of reagents.
 | * Daily Reagent QC Form
 |
| **3** | * Revise Daily QC Form as required for additional reagent QC:

Example: PEPG QC’d in addition to LISS QC | * Daily Reagent QC Form
 |
| **4** | * Label tubes as per in table 1
 | * Table 1
 |
| **5** | * Perform testing per applicable procedures for the test being controlled.
 |  |
| **6** | * Record Rack number and test result on Daily QC Form
 |  |
| **7** | * Interpret test results and evaluate for acceptability.
 | * Reading and Grading Tube Reactions
 |
| **8** | * Record Tech ID.
 |  |
| **9** | * Obtain 2nd Tech review
 |  |
| **10** | * Perform problem resolution for any unacceptable results as follows:
* Repeat testing on original bottle of reagent.
* If retest is unacceptable, test on a new lot number of same reagent.
* Quarantine unacceptable lots and notify TSL manager.
* Complete QIM to document.
* Repeat with the acceptable lot any patient testing performed with the quarantined lot since most recent acceptable QC on the quarantined lot.
* If there is any discrepancy, Correct Result per Amended Report Procedure.
* Notify Physician if critical result is corrected.
 | * Reagent Receipt and Discard
 |

**Table A: Tube Labeling:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Tube** | **Contains** | **Contents** | **Expected Results** | **Related Document** |
| ***1*** | Anti-A | Ortho Confidence Cell 1 (A1B Neg rr) or Acceptable QC source | **1-4+** | * ABO Rh Tube Method
 |
| ***2*** | Anti-B | **1-4+** |
| ***3*** | Anti-A,B | **1-4+** |
| ***4*** | Anti-A | Ortho Confidence Cell 2 (O Pos-R1r) or Acceptable QC source | **0** |
| ***5*** | Anti-B | **0** |
| ***6*** | Anti-A,B | **0** |
| ***7*** | Anti-D | **1-4** |
| ***8*** | Anti-D | Ortho Confidence Cell 1 (A1B Neg rr) or Acceptable QC source | **IS/IgG=0****CC=2-4+** |
| ***9*** | A1Cells | Ortho Confidence Antibody Reagent(Anti-A, Anti-B, diluted 1:3)or Acceptable QC source | **1-4+** |  |
| ***10*** | A2 Cells | **1-4+** |  |
| ***11*** | B Cells | **1-4+** |  |
| ***12*** | A1Cells | Seraclone | **0** |  |
| ***13*** | A2 Cells | **0** |
| ***14*** | B Cells | **0** |
| ***15*** | Coombs Control cells | AHG Poly  | **2-4+** | * DAT by Tube Method
 |
| ***16*** | Anti-C3 | **0** |
| ***17*** | Complement coated Control cells | AHG Poly  | **1-4+** |
| ***18*** | AHG IgG | **0** |
| ***19*** | Anti-C3 | **1-4** |
| POSITIVE ABS LISS | Positive Control: Ortho Confidence Antibody Reagent(Anti-A, Anti-B, Anti-c, Anti-D, diluted), or Acceptable QC sourceNegative Control: Seraclone | **37** | **IgG** | **CC** | * Antibody Screen by LISS Tube Method
 |
| ***20*** | SC I | **0-2** | **1-3** | **NT-4+** |
| ***21*** | SC II |
| ***22*** | SC III |
| Negative ABS LISS | **0** | **0** | **2-4+** |
| ***23*** | SC I |
| ***24*** | SC II |
| ***25*** | SC III |

**References:**

Standards for Blood Banks and Transfusion Services, Current Edition, Bethesda, MD: American Association of Blood Banks.

Roback J (ed). Technical Manual, 16th Edition. AABB Press, Bethesda, MD. 2008.

Current version of reagent manufacturer’s package insert instructions

CAP Accreditation Program, Transfusion Medicine Checklist, Current Version