**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 rr  Cell 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 source  Negative 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