**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.
* Reagent QC is performed day of use, expiring at 2359 on day of testing.

|  |  |
| --- | --- |
| **QC Testing performed Daily** | **QC Testing performed Day of Use** |
| **Routine Reagent Rack** * anti-A
* anti-B
* A1 cells
* B cells
* anti-D
* Screening Cells 1, 2, 3
* LISS (various sources)
* anti-IgG
* antihuman globulin (AHG) control cells
 | **Direct Antiglobulin Reagent Rack*** Anti-C3
 |
| **ABO Resolution Rack*** A2 Cells
 |
| **Other*** PEG
* Ortho anti-IgG
 |
| **Direct Antiglobulin Reagent Rack*** Polyspecific antihuman globulin
* C3 Check Cells
* Albumin
 |
| **ABO Resolution Rack*** Anti-A,B
* Seraclone ABO + RH Control
 |

**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** | Bio-Rad Solid Screen II Control B | Anti-c |
|  | Bio-Rad 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:**

|  |  |  |
| --- | --- | --- |
| Step | Action | Related Documents |
| 1 | Examine reagents:* 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 on the Daily Manual Testing QC form:* Rack ID
* Testing date
* Lot number and expiration date
 | Daily Manual Testing QC Form |
| 3 | Check box(es) for rack/reagent being QCed:* Daily QC: Rack followed by Rack designation (A, B, or C)
* PEG
* DAT Rack
* Ortho IgG
* New Lot \_\_\_\_\_\_\_\_\_\_\_\_\_ (record reagent name)
* Additional Lot \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (record reagent name)
 |
| 4 | Label tubes as per Table A | Table A |
| 5 | Perform testing per applicable procedures for the test being controlled. |  |
| 6 | Record test result and Tech ID performing testing. |  |
| 7 | Evaluate for acceptability. | Reading and Grading Tube Reactions |
| 8 | Record Appearance and Performance acceptability by circling “Y” or “N” |  |
| Step | Action | Related Documents |
| 9 | 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 Process |
| 10 | Obtain 2nd Tech review for acceptability (“Y” or “N”). |  |
| 11 | Post form in TSL for use during testing date.* MLS Lead/MLS2 review will be performed in a timely manner.
 |  |

**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 | **2-4+** | ABO Rh Tube Method |
| ***2*** | Anti-B | **2-4+** |
| ***3*** | Anti-A,B | **2-4+** |
| ***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 | **2-4** |
| ***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 | **2-4+** |
| ***10\**** | A2 Cells | **2-4+** |
| ***11*** | B Cells | **2-4+** |
| ***12*** | A1Cells | Seraclone | **0** |
| ***13\**** | A2 Cells | **0** |
| ***14*** | B Cells | **0** |
| ***15*** | IgG coated cells | AHG Poly  | **2-4+** | DAT by Tube Method |
| ***16\**** | Anti-C3 | **0** |
| ***17*** | Conf cell 1 | AHG Poly  | **0** |
| ***18*** | ComplementCoated cells | AHG Poly | **1-4+** |
| ***19\**** | Anti-C3 | **1-4** |

\* Testing performed day of use

**Table A: Tube Labeling (continued)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Tube** | **Contains** | **Contents** | **Expected Results** | **Related Document** |
| POSITIVE ABS LISS/PEG | Positive Control: Ortho Confidence Antibody Reagent(Anti-A, Anti-B, Anti-c, Anti-D, diluted), or Acceptable QC source | **IS/37** | **IgG** | **CC** | Antibody Screen by LISS Tube MethodAntibody Screen by PEG Tube IAT Method |
| ***20*** | SC I | **0-2+** | **1-4** | **NT-4+** |
| ***21*** | SC II |
| ***22*** | SC III |
| Negative ABS LISS/PEG | Negative Control: Albumin | **0** | **0** | **2-4+** |
| ***23*** | SC I |
| ***24*** | SC II |
| ***25*** | SC III |

**References:**

AABB Standards for Blood Banks and Transfusion Services, Current Edition

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