**Purpose:**

This document describes how to perform quality control for ABO/Rh and antibody screen testing to ensure it is performed in an appropriate manner.

**Limitations and Precautions:**

* Samples and reagents derived from human or animal blood are potentially biohazardous and/or infectious. Use appropriate PPE when handling such materials.
* Control samples must be less than seven (7) days old.
* Control samples should not be clotted, hemolyzed, lipemic, or icteric.
* Control samples must have been previously tested, rejected or extra samples must be tested if used
* Avoid samples with mixed field or questionable results.
* Patient samples used for QC must return to room temperature prior to analysis if previously refrigerated.

**Procedure**

|  |  |  |
| --- | --- | --- |
| **Step** | **Action** | **Related Documents** |
| **General Statements:** |
|  | Quality Control Shall be performed:* + On each day of analyzer use
	+ When a reagent or plate lot number changes
	+ When a new lot of red cells or new preparation of Bromelin is placed on the system
	+ After service and/or repair of the analyzer
 |  |
|  | Required Materials include:* Sample Controls (EDTA Lavender or EDTA Pink Top)
* Control Barcode Labels
* Solidscreen II Control
* Solidscreen II Control B
* Solidscreen II Negative Control
* 12 x 75 mm Test Tubes or aliquot tubes
 |  |
| **Control Definition:** |
| 1 | Touch the ‘Samples and Controls’ button |  |
| 2 | Select the ‘Control Management’ button* Touch the ‘New’ button
* Enter the name of the control and barcode the product code for that control.
* Any given product code can be assigned to only one control.
* The product code is the first three digits of the control
* Enter the time interval for the run in hours, 24 hours.
* Define the expected values by touching the Target Value buttons and highlighting the expected result with the arrow keys. Select the ‘Enter’ key to select the expected result.
* Select the appropriate button to select the assays required for attaining the target values.
* Touch the ‘OK’ button. The new control will be displayed in the ‘Control Management’ dialog
 |  |
| **Step** | **Action** | **Related Documents**  |
| **Control Definition (continued):** |
| 3 | To edit a control:* In the ‘Control Management’ dialog, touch the control to be edited
* Touch the ‘Detail’ button
* Edit the information in the ‘Control Definition’ dialog
* Touch the ‘OK’ button to exit and return to the ‘Control Management’ dialog
 |  |
| **ABO/Rh Controls** |
| 1 | Controls may be selected from previously tested samples.* Examine samples for acceptability, refer to limitations.
* Samples selected as controls should give the appropriate reaction, positive or negative, with the target antisera/reagent. The reactivity should be clearly interpreted by the TANGO.
 |  |
| 2 | Control samples should be selected to verify both positive and negative reactions for every reagent.* An example of appropriate samples for ABO/Rh controls would be as follows:
	+ O neg and AB pos **or** A neg, B neg and O pos
	+ Other configurations as long as there is a positive and negative for each reagent.
 | Table A |
| 3 | Place the appropriate barcode label on samples to be used as controls.* Barcode labels are provided by Bio-Rad.
* Alternately, the control name (number) can be manually entered.
 |  |
| 4 | Place controls in a Control Rack (C) in the same manner that samples are placed in a rack, placing aliquot tubes only in positions with spacers. |  |
| 5 | After insertion of the Control Rack, the ‘Sample Loading’ window is displayed and the Sample ID’s of the controls are displayed, if barcode labels were used.* The Sample ID starts with a lower case c.
* If not using a barcode, input the sample ID manually
 |  |
| 6 | Start testing. It may be necessary to press “Request Manually’ for each control to be run, unless the controls are activated and due to run. | TANGO Infinity: Initializing Test Runs |
| **Antibody Screen Controls** |
| 1 | Two positive controls, Solidscreen II Control and Control B, and a Solidscreen II Negative Control are available for testing on the TANGO.* The Solidscreen II Controls are supplied as a ready to use reagent.
* Solidscreen II Control contains a dilute anti-D
* Solidscreen Control B contains a dilute anti-c and is used in conjunction with Solidscreen II Control to QC the 3 cell screening assay.
* Alternately, a negative control may be selected from a previously tested sample
* Examine samples for acceptability, refer to limitations.
* Sample should not be hemolyzed, lipemic, or icteric
* The sample selected as the negative control for the Solidscreen II assay should have previously produced clearly negative results on the TANGO.
 | Table A |
| **Step** | **Action** | **Related Documents**  |
| **Antibody Screen Controls (continued):** |
| 2 | Control samples should be selected to verify a minimum of one positive and one negative reaction with each screening cell of the antibody screen assay. |  |
| 3 | Aliquot a portion of each Solidscreen II control into a clean, properly labeled test tube.* When the Solidscreen II control aliquots are not in use, seal the tube and store at 2-8°C.
* The aliquot can be used until exhausted or until the expiration date on the original vial, whichever comes first.
 |  |
| 4 | Place the positive and negative controls in a Control Rack (C) in the same manner that samples are placed in the rack. |  |
| 5 | After insertion of the Control Rack, the ‘Sample Loading’ window is displayed and the Sample ID’s of the controls are displayed, if barcode labels were used.* The Sample ID starts with a lower case c.
* If not using a barcode, input the sample ID manually.
 |  |
| 6 | Begin testing. It may be necessary to press ‘Request Manually’ for each control to be run unless the controls are activated and due to run. | TANGO Infinity: Initializing Test Runs |

**Table A: Control Specimen Acceptability**

|  |  |  |
| --- | --- | --- |
| **Sample** | **TANGO assay** | **Expected Result** |
| ABO | ABO/D reverse/ABO Confirm | 2-4+ |
| Rh positive | ABO/D reverse/RhD Confirm | 2-4+ |
| Rh negative | ABO/D reverse/RhD Confirm | 0 |
| Solidscreen II control | Antibody Screen | 1-4+ |
| Solidscreen II Control B | Antibody Screen | 1-4+ |
| Solidscreen II negative control | Antibody Screen | 0 |

**Referenced Documents:**

TANGO Infinity System User Manual, Version 1.2.1