**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**

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| **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**

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| **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