**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.

**Procedure**

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| **Step** | **Action** | **Related Documents** |
| **General Statements:** | | |
| **A.** | * 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 |  |
| **B.** | * + - 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 |  |
| **C.** | * + - The following limitations and precautions apply: * 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. * Avoid samples with mixed field or questionable results. * Patient samples used for QC must return to room temperature prior to analysis if previously refrigerated. |  |
| **Control Definition:** | | |
| **A.** | * + - Select the ‘Samples/Controls’ button |  |
| **B.** | * + - Select the ‘Control Management’ button |  |
| **Step** | **Action** | **Related Documents** |
| **C.** | * + - To define a new control: * Select 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 |  |
| barcode label for that control.   * Enter the time interval for the run in hours, 24 hours. * Define the expected values by selecting 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’ window |  |
| **ABO/Rh Controls** | | |
| **A.** | * 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. | * Tango User Guide, Section 4.1 |
| **B.** | * 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. |  |
| **C.** | * + - 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. |  |
| **D.** | * + Place controls in a Control Rack (C) in the same manner that samples are placed in a rack. |  |
| **E.** | * + - 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 |  |
| **F.** | Start testing following Starting a Test Run SOP | * Starting a Test Run |
| **Antibody Screen Controls** | | |
| **A.** | * Two positive controls, Solidscreen II Control and Control B, 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. |  |
| **B.** | Solidscreen II Negative Control is available for testing on the TANGO. Alternately, a negative control may be selected from previously tested samples.   * Examine samples for acceptability, refer to limitations. * The sample selected as the negative control for the Solidscreen II assay should have previously produced clearly negative results on the TANGO. |  |
| **C.** | 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. | Tango User  Guide Section 4.2 |
| **D.** | 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. |  |
| **E.** | Place the positive and negative controls in a Control Rack (C) in the same manner that samples are placed in the rack. |  |
| **F.** | 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. |  |
| **G.** | Start testing following Starting a Test Run SOP | Starting a Test Run SOP |

**Referenced Documents:**

TANGO User Guide, Version 3.0.2