**Purpose:**

To describe the process of test result validation and LIS transfer utilizing the Blood Bank Instruments application of Sunquest from the Tango instrument to the LIS appropriate to institutional and government regulations and laws. This includes printing as well as export to Sunquest LIS.

**Policy**

Validation of test results can only be performed by authorized users who have been trained on the use of the instrument. The user is responsible for validating test results according to the instructions listed in this procedure. User that performs the validation must do so using their unique login information.

TANGO Results Acceptability Criteria

* Results transmitted from TANGO to LIS Interface must have a valid interpretation
* ABO/Rh test results must be ≥2+ reactivity. Reactions <2+ must be investigated by manual method prior to resulting or have historical investigation performed at HMC.
* Antibody Screen results with weak or inconclusive reactions must be evaluated and investigated prior to accepting results in Sunquest.

**Limitations and Precautions:**

* Do not keep data in the Daily Journal after validation, as this may cause errors in the software and ‘freeze’ the screen. Remember to export the data after validation and delete the information from the ‘Daily Journal’.
* The Tango does not grade for mixed field. Samples showing mixed field must be tested by tube method

**Procedure:**

|  |  |  |
| --- | --- | --- |
| **Step** | **Action** | **Related Documents** |
| **Review and Editing of Sample Results** | | |
| 1 | Touch the ‘Samples and Controls’ button on the Main Menu, then ‘Daily Journal. |  |
| 2 | Validate results:   * Check results visually. Check the camera strip well images for inappropriate items (e.g. dust, dirt, fibrin, small clots, and ambiguous reactions) which cannot always be clearly evaluated by the image analysis. * Affirm TANGO grade choice against Table A and/or Table B. * Affirm TANGO interpretation   + ABO/D testing   + Antibody Detection per Table C * If the assay results cover several pages or if several assays are available, scroll through the assays by using the arrow buttons or validate each assay by touching the ‘Validate’ button. * Enlarge by touching the image. | TANGO Infinity: Viewing the Daily Journal  Table A  Table B  Table C  ABO/D Typing by Tube Method |
| **Step** | **Action** | **Related Documents** |
| **Review and Editing of Sample Results (continued)** | | |
| 3 | Editing well results   * Touch the image to enlarge it. * Touch the preferred, more appropriate ‘Result’ button below the image. That result replaces the former result and is entered and displayed in the ‘Result’ field. * Touch ‘OK’ to confirm the manual change. The well will be flagged with the hand icon to indicate the result was modified. * Enter a comment in the ‘Remarks’ field to explain the change. | Table A  Table B  Table C |
| 4 | Edit assay result:   * Touch the button to open the edit box and make changes by selecting another interpretation. * Touch the return arrow button to confirm the change. The assay will be flagged with the hand icon to indicate the result was modified * Enter a comment in the ‘Remarks’ field to explain the change. |  |
| 5 | Discarding Assay Results   * Touch the ‘Discard’ button. * A security message is displayed. * Touch ‘OK’ to confirm discarding.   + - The results of the displayed assay are deleted in the Daily Journal and cannot be exported.     - The assay with the manually discarded assay result will automatically return to the ‘requested’ status in the ‘Daily Journal’.     - The strips of the discarded assay results appear dark. |  |
| **Validating Single Specimens** | | |
| 5 | Touch the ‘Validate’ button.   * The ‘Daily Journal-Strip Display’ dialog is displayed with the results of the first patient. |  |
| 6 | The validation can be done by:   * Validating the assay * Touch the ‘Validate’ button. This button is only available when all wells of the assay give allowed values and a result for the assay can be determined. * After the first assay is validated, the display moves to the next assay of the sample, if applicable. * Validating the result * Touch the ‘Validate Result’ button. This button is available only when all assays have been viewed and the overall result does not contain an error. * This button will validate all results for a single sample.   After the sample is validated, the sample data is stored automatically in the ‘Lab Journal’ for archiving. |  |
| 7 | If additional samples are not available for validation, the validation mode is closed and the ‘Daily Journal’ window is displayed. |  |
| 8 | To validate results for a different sample, select the sample arrow buttons until the desired sample result is displayed. |  |
| **Step** | **Action** | **Related Documents** |
| **Batch Validation** | | |
| 9 | Touch the ‘Batch Validation’ button.   * The ‘Batch Validation’ dialog is displayed. * Identical results for an assay are displayed simultaneously. * Up to 40 wells are displayed at one time. * An Image can be enlarged by touching that image. * The displayed result can be excluded from strip validation by selecting ‘Exclude from batch validation’ button, and must subsequently be cleared through normal validation following single specimen validation above. |  |
| 10 | Touch the ‘Validate’ button to validate all displayed results. The next assays will be displayed.   * When all samples have been validated, validation mode is closed and the ‘Daily Journal’ window is displayed. |  |
| **Export of Results and LIS Transfer** | | |
| 1 | Select the ‘Samples and Controls’ button on the Main Menu. |  |
| 2 | Select the ‘Daily Journal’ button.   * The ‘Daily Journal’ dialog will open. |  |
| 3 | Select the ‘Export’ button.   * The ‘Export’ dialog will open. |  |
| 4 | The format box lists the available export formats. After selection of a format, filters may be added or edited. The format must be selected first.   * LIS: Transfers selected data from the Daily Journal to the Laboratory Information System (LIS). * Daily Journal Summary Report: The selected data from the Daily Journal will be printed with the overall interpretation of test results. * Daily Journal Detail Report: The selected data from the Daily Journal will be printed, including well reaction results. * Daily Journal Control Report: Controls for the selected date are printed with the overall interpretation of results. * Daily Journal Control Detail Report: Controls for the selected date are printed, including well reaction results. |  |
| 5 | Select filters for the samples to be exported.   * Samples – This group box allows definition of the samples to be exported. * The results that are exported are determined by the combination of ‘Selected/All/Date’, ‘Type’ or ‘Status’. Only one of the ‘Selected/All/Date’ options can be selected at one time. * Selected: When this item is selected, only the samples highlighted in the ‘Daily Journal’ are exported. * All: When this item is selected, all samples in the ‘Daily Journal’ are exported. * Date: * Touch the button to open a selection dialog with the dates for which results exist. * Select the desired date and touch ‘OK’. * The selected date will appear in the button. Only results from this date are exported. |  |
| **Step** | **Action** | **Related Documents** |
| **Export of Results and LIS Transfer (continued)** | | |
| 6 | Select further filters for the samples to be exported:  Type   * Red and green dots: STAT and normal samples will be exported. * Blue dots: Control samples will be exported. This automatically defaults to control when printing the ‘Control Journal.’   Status   * + Test well icon: Ready: Sample has been processed successfully. Sample is not validated. Only samples that have been validated will be exported.   + Check mark: Validation samples. Only samples that have been validated will be exported   + Number: Indicates the number of samples that have been selected for export   + Progress: A progress bar indicates the amount of data that has already been exported |  |
| 7 | Once results have been verified in SQ, results can be deleted out of the daily journal.   * Select the data to be deleted in the Daily Journal and touch the ‘Delete’ button. * Touch ‘OK’ to delete the selected data   This may also be necessary if tests were requested on samples loaded on the TANGO but processing by the analyzer was incomplete | TANGO Infinity: Accepting and Clearing Results in SQ |
| 7 | To print reports, touch the ‘Export’ button. Patient and unit reports are not printed unless there is a discrepancy to resolve.   * Data is exported based on the selected filters. This report is shown in Adobe Reader * The report may be printed or stored as a PDF document * Printout: Select ‘Print’ from the ‘File’ menu of the Adobe Reader * PDF Document: Select ‘Save a Copy’ from the ‘File’ menu of Adobe Reader * If validated results have been chosen for exporting (printing or LIS transfer), a prompt is given to delete the information from the Daily Journal.   Touch ‘OK’ to delete the information from the Daily Journal. A record of the validated results will remain stored in the Lab Journal.   * To keep the number of entries in the Daily Journal small, deleting printed and exported samples is recommended. * To manually delete data from the Daily Journal   + Select the data to be deleted in the Daily Journal and touch the ‘Delete’ button.   + Touch ‘OK’ to delete the selected data.   + This may be necessary if tests were requested on samples loaded on the TANGO but processing by the analyzer was incomplete |  |

**Table A: ABD Forward and Reverse Reaction Definitions**

|  |  |
| --- | --- |
| **ABO and D: ABD Forward and Reverse Reactions** | |
| **TANGO Grade** | **Appearance** |
| **4+** | A single agglutinate. No free RBCs detected. |
| **3+** | Strong reaction. A number of large agglutinates |
| **2+** | Large agglutinates in a sea of smaller clumps, no free RBCs. |
| **1+** | Many small agglutinates with a lot of free cells |
| **+/-** | Weak granularity in the RBC suspension. Images that receive a +/- on the TANGO will have “?” for the overall interpretation |
| **0** | An even RBC suspension. No agglutinates detected. |

No TANGO Grade: If present, Validate to keep record and test by manual method

|  |  |
| --- | --- |
| **H** | Hemolysis may be detected as a clear, red background behind agglutination |
| **MF** | Scattered, free cells behind the agglutination |

**Table B: Solidscreen Reaction Definitions**

|  |  |
| --- | --- |
| **Antibody Detection: Solidscreen Reactions** | |
| **TANGO Grade** | **Appearance** |
| **4+** | Homogenous layer of cells across the bottom of the well. |
| **3+** | Homogenous layer of cells across the bottom, with some settling of the cells toward the center of the well. |
| **2+** | A layer of cells adhering to the bottom of the well, distinct settling of unattached cells toward center of well. |
| **1+** | Some cells adhering to bottom of well, distinct settling of approximately 50% of the ells in the center of the well. |
| **+/-** | Cell button forming in the center of the well, some cells adhering to well bottom |
| **0** | No reaction: compact cell button |

No TANGO Grade: If present, Validate to keep record and test by manual method

|  |  |
| --- | --- |
| **H** | Hemolysis may be detected as a clear, red background behind agglutination |
| **MF** | Scattered, free cells behind the agglutination |

**Table C: Interpretation of Antibody Detection Testing**

|  |  |  |
| --- | --- | --- |
| Consult the following table to interpret the antibody screen results. | | |
| **If the IAT results show** | **Then** | **Report Antibody screen as** |
| no cell button | Antibodies were not present or wereundetected. | Negative |
| Hemolysis or layer of cells (any strength) | An antibody is present.  Proceed to antibody identification procedure. | Positive |

**References**

TANGO Infinity System User Manual, Version 1.2.1