**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.

**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:**

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| **Review and Editing of Sample Results** | | |
| **Step** | **Action** | **Related Documents** |
| 1 | Touch the ‘Samples/Controls’ button on the Main Menu, then ‘Daily Journal. |  |
| 2 | Validate results:   * Check results visually. * 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. | Table A  Table B  Table C  ABO/D Typing by Tube Method |
| 3 | Edit the reaction strength   * Enlarge the image * Confirm the change with ‘OK’. The well will be flagged that the result was modified manually. * Explain any changes in the ‘Remarks’ field. |  |
| 4 | Edit the result:   * Select the desired result button * Select the button to open the edit box and make changes by selecting another interpretation. * Touch the back arrow button to confirm the change. * Enter explanation as a comment in the ‘Remarks’ field. |  |
| **Step** | **Action** | **Related Documents** |
| **Validating Single Specimens** | | |
| 5 | Touch the ‘Validate’ button.   * The ‘Daily Journal/Strip Display’ window 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. * After each assay of the sample is validated, the sample is considered validated and the data is stored automatically in the ‘Lab Journal’ for archiving. * 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. |  |
| **Batch Validation** | | |
| 9 | Touch the ‘Batch Validation’ button.   * The ‘Batch Validation’ window 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. |  |

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| **Step** | **Action** | **Related Documents** |
| **Invalidating Assay Results** | | |
| 11 | The administrator has the ability to prevent validation of test results containing flags. (An assay which cannot be validated because of this setting has to be invalidated. Results from an individual assay can also be invalidated based on visual review (small clots, fibrin, etc.) | Tango User manual, section D 6.3 or F |
| 12 | Push the 'Invalid' button in the 'Daily Journal | Strip display' window to set the results of the displayed test to invalid.   * The results will be saved with the repeat test results. * The 'invalidated' results will not be compared to the previous results or subsequent tests. * A security message will be displayed |  |
| 13 | Push OK to confirm the invalid setting.   * The results of the displayed test are considered invalid and the sample returns to 'requested' status. * The results of invalid test results appear dark. |  |
| 14 | Either repeat sample testing on the Tango or send to the manual test bench for testing. |  |
| **Export of Results and LIS Transfer** | | |
| 1 | Select the ‘Samples/Controls’ button on the Main Menu. |  |
| 2 | Select the ‘Daily Journal’ button.   * The ‘Daily Journal’ window will open. |  |
| 3 | Select the ‘Export’ button.   * The ‘Export’ window 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.   * Journal: The selected data from the Daily Journal will be printed in a list * Report: The selected individual results of the Daily Journal are printed * LIS: Data is sent to the Laboratory Information System * Journal Control: Controls for the selected date are printed |  |
| 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: * Select the button to open a selection window 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 + orange + green dots: Emergency, express 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: Sample is not validated. Only samples that have been validated will be exported.   + Check mark: Validation samples |  |
| 7 | The system will display the number of samples that have been selected for export. |  |
| 8 | Select the ‘Export’ button.   * Data is exported based on the selected filters. * If validated results have been chosen for exporting (printing or LIS transfer), a prompt is given to delete the information from the Daily Journal. * Note: If both printed report and LIS transfer is desired, complete the LIS transfer first, then the Report as you will be prompted to delete after printing.   Select ‘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 |  |
| 9 | If the ‘Daily Journal’ Sample Report is printed, place the corresponding accession label of the sample to the left of the sample results.   * Be mindful not to cover any test results or comments * The ‘Daily Journal’ Sample Report can now be used to verify sample results transmitted to the LIS. |  |
| 10 | Verify tech ID on the Daily Journal Sample report.   * File in box on TANGO table. * Daily sample reports are filed after midnight in the laboratory filing cabinet. |  |

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

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| **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, invalidate 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**

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| --- | --- |
| **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, invalidate 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**

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| --- | --- | --- |
| 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** |

**Referenced Documents:**

Tango Optimo User’s Guide Version 3.3

Supplement to Tango Optimo User’s Guide Version 3.0.3