**Purpose:**

To ensure that sample results obtained from the TANGO are reviewed and validated appropriately.

**Limitations And Precautions:**

* For donor unit retype results that have a container designation, enter the container number in the ‘Remarks’ field of the Strip display prior to validation.
* Samples with positive antibody screens sometimes have an effect on a subsequent adjacent sample. See section E for investigation instructions.

**Procedure:**

|  |  |  |
| --- | --- | --- |
| **Step** | **Action** | **Related Documents**  |
| **A.** | Validation of Results (for Batch Validation, see section B) |  |
| 1. | Touch the ‘Samples/Controls’ button on the Main Menu, then ‘Daily Journal. |  |
| 2. | Touch the ‘Validate’ button. |  |
| 3. | A prompt will appear on the screen to enter a validator ID and password if the current login does not have the rights to validate. If this appears, enter validator user ID and password. Touch ‘OK’. |  |
| 4. | The ‘Daily Journal/Strip Display’ window is displayed with the results of the first patient. |  |
| 5. | Check results visually. If the assay results cover several pages or if several assays are available for one patient, scroll through the assays by using the arrow buttons or validate each assay by touching the ‘Validate’ button. * The image may be enlarged by touching the image.
 |  |
| 6. | Enlarge the image to edit the reaction strength. Confirm the change with ‘OK’. The well will be flagged that the result was modified manually.* The change can be explained by entering a comment in the ‘Remarks’ field.
 |  |
| 7. | The overall result can be edited by selecting the desired result button and editing the result.* Select the button to open the edit box and make changes by selecting another interpretation.
* Touch the back arrow button to confirm the change.
* The change must be explained by entering a comment in the ‘Remarks’ field.
 |  |
| 8. | 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.
 |  |
| 9. | If additional samples are not available for validation, the validation mode is closed and the ‘Daily Journal’ window is displayed. |  |
| 10. | To validate results for a different sample, select the sample arrow buttons until the desired patient sample result is displayed. |  |
| **B.** | Batch Validation |  |
| 1. | Touch the ‘Samples/Controls’ button on the Main Menu, then ‘Daily Journal’. |  |
| 2. | Touch the ‘Batch Validation’ button. |  |
| 3. | A prompt will appear on the screen to enter a validator ID and password if the current login does not have the rights to validate. If this appears, enter validator user ID and password. Touch ‘OK’. |  |
| 4. | 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 the ‘Exclude from batch validation’ button.
* Assays that are excluded from batch validation must subsequently be cleared through normal validation following section C above.
* Touch the ‘Validate’ button to validate all displayed results. The next assays will be displayed.
 |  |
| **C.** | When all samples have been validated, validation mode is closed and the ‘Daily Journal’ window is displayed. |  |
| **D.** | Invalidating Assay ResultsThe administrator has the ability to prevent validation of test results containing flags (see Chapter D 5.3). 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’s Guide, Version 3.0.3, Chapter D Part 5.3 |
| **1.** | 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.
 |  |
| **2.** | Push OK to confirm the invalid setting.* The results of the displayed test are considered invalid and the sample returns to 'requested' status.
* The strips of invalid test results appear dark.
 |  |
| **3.** | Either repeat sample testing on the Tango or send to the manual test bench for testing. |  |
| **E.** | In the unusual event that two or more samples pipette onto the TANGO Solidscreen II strip adjacent to each other have an antibody detected, carry-over must be investigated.* Test the subsequent sample(s) again on the TANGO either as the only/first sample of a test run, or after a negative control. If the results are negative, this sample(s) have been affected by the first positive sample and can be resulted as negative.
* Retest the first positive sample, followed by a negative control. If carry over was the problem, the first sample will retest as positive, and the negative control will also show a positive result.
 |  |

**Referenced Documents:**

TANGO User Guide, Version 3.0.2