**Purpose:**

To assure that quality control results are validated, printed, reviewed and archived in the appropriate manner. Quality control results that do not meet expected result are handled in an appropriate manner.

**Procedure:**

|  |  |  |
| --- | --- | --- |
| **Step** | **Action** | **Related Documents** |
| **Control Result Validation** |
| 1. | Select the control to be validated from the ‘Daily Journal’*Note: Control samples will be designated by a blue dot.* | Quality Control Testing and Review Schedule |
| 2. | Select the ‘Validate’ button. |  |
| 3. | Review the well images. | Validation and Export of Results |
| 4. | Results acceptable: Select the ‘Validate Results’ button Results unacceptable: Go to Invalid Controls *Note: Validated quality control results are stored in the ‘Control Archive’.* |  |
| 5. | Print Control results. |  |
| 6. | File Control Journal Report in the Tango Daily QC Reports notebook following CT Lead review. |  |
| **Invalid Controls** |
| 1. | The invalid control and affected sample(s) will be:* Flagged by a green question mark (?) in the flags column of the Daily Journal
* Quality Control (QC) icon at the bottom of the screen will flash red.
 |  |
| 2. | Document all investigatory and resolution steps on a TANGO problem log and QIM. | TANGO Problem LogQIM |
| 3. | Review the results from the failed controls. * The expected result of the QC sample and the actual results are shown in the Strip Display of the failed control.
* Discrepant values will be flagged in the flags field and marked with a red X in the results status field.
 | Validation and Export of Results |
| **Step** | **Action** | **Related Documents**  |
| **Invalid Controls** (continued) |
| 4. | Determine the cause of the failure:* Not due to Analyzer or Sample problem. For example, artifact in well
* Analyzer Problem
* Sample Problem
 |  |
| 5. | **QC failure is not due to the analyzer or reagent** (such as a small clot in the negative control well)* Visually examine control results
* QC result wells **can be interpreted** will require comments and QC reset.
* QC result wells **cannot be interpreted** will require invalidation, resolution and re-running controls.
* Reset control results
* Select the control from the Daily Journal and touch ‘Validate’.
* Enter a comment in the Remarks field regarding the probable cause of the QC failure. This entry activates the ‘Validate’ button.
* Select the ‘Validate’ button.
* Reset the failed QC status to ‘OK’ by touching the ‘Change Quality Status’ button in the Daily Journal window.
* Answer the question “Has the cause of the quality failure been removed?” with ‘OK’.
	+ The QC icon in the lower right hand corner of the screen will stop flashing red.
 |  |
| 6. | **Analyzer or Reagent Failure:*** Investigate Analyzer and/or Reagent problem
* Document all investigatory steps on a TANGO Problem Log
* Determine suitability of TANGO to proceed with patient / donor testing
	+ If suitable, Repeat QC run
	+ If TANGO cannot be returned to service:
		- Complete TANGO Problem log including Technical Support contact
		- Post Equipment Out Of Service Form on the TANGO PC
 | Equipment Out of ServiceQIM |
| 7. | **Control Sample problem*** Check QC samples for adequate volume
	+ Refill or replace as needed
* If controls continue to be aberrant:
	+ Antibody Detection: Open a new lot number and repeat
	+ ABD Testing: Select and test new patient samples
 |  |
| **Step** | **Action** | **Related Documents** |
| **Invalid Controls** (continued) |
| 8. | Invalidating an invalid control:* From the Daily Journal display, select the invalid control.
* Touch the ‘Validate’ button.
* In the Strip Display screen, review the assay results.
* Write a comment about the invalid control in the Remarks field
* Print screen results
* Select the ‘Invalidate’ button from the strip display screen to invalidate the result.
* Delete the invalid control from the Daily Journal window.
* Reset the invalid QC status to OK by selecting the ‘Change Quality Status’ button on the Daily Journal window.
 | Sending or Printing Tango Pictures |

**Referenced Documents:**

 TANGO User Guide, Version 3.3