**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:**

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| --- | --- | --- | --- |
| **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 Log  QIM | |
| 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 Service  QIM | |
| 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