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| **Handling of Failed Controls on the IH-500** | | | | | |
| **Purpose** | This procedure provides instructions to ensure that any quality control result performed on the IH-500 that does not meet the expected value is handled in an appropriate manner. | | | | |
| **Policy Statements** | * The quality control fails if a result for a QC sample obtained by the IH-500 differs from the defined target result. * Failed Controls and all samples processed after the failed control will be flagged in IH-Com. * Samples will continue to be indicated with a red QC flag until the issue has been resolve and acceptable QC run. | | | | |
| **Procedure** |  | | | | |
|  | **Step** | Action | | | |
|  | 1 | If QC fails, or has exceeded the pre-set time allotted for controls to be within limits, the “QC” tab in IH-Com will flash red. Select the “QC” tab to determine which reagents are affected.   1. Reagents affected will have a red flashing symbol beside them | | | |
|  | 2 | Select the “Results” tab to review the results of the failed control(s).   1. Hover over each reagent with the mouse for more detailed information. | | | |
|  | 3 | Determine the cause of the failure and fill out an Internal Occurrence form. | | | |
|  | 4 | For QC not OK results:   1. Compare results with claimed value on the Daily Journal Quality Controls report with the actual result. Note if control test failed is displayed. 2. Review values in the “required results” area of the “Control tests” view. 3. Review image of failed QC results. | | | |
|  | 5 | If the result(s) cannot be edited or editing is not appropriate, run the necessary control samples again or try new controls if necessary. Select “accept All’ then “Save”. The affected reagents will now have a green checkmark beside them and the “QC” tab will no longer flash red if repeated QC passes. | | | |
|  | 6 | Once QC is successful, print the Control Journal by selecting the “QC” tab and the “Print” button. | | | |
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| **References** | 1. IH-Com User Manual NA V1.2-02/2021, Chapter C, Section 4.8 and 4.10 | | | | |
| **Approval**  **Workflow** | Transfusion Service/Lab Director | | | | |
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| **Historical Record** | **Version** | | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | | S. Cassidy | 02/17/2023 | Initial Version |