|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Out of Control Plan** | | | | | |
| **Purpose** | This procedure provides instructions for actions to take if reagent quality control results or daily equipment function checks do not conform to established limits. | | | | |
| **Policy Statements** | * Any daily reagent quality control testing that does not meet the established parameters as defined in [TS. 18.2 Performing Daily Reagent Quality Control](http://khan.childrensmn.org/Manuals/Lab/SOP/TS/OperCon/202407.pdf) must be investigated and resolved prior to patient testing with the implicated reagents. * Any daily equipment function check that does not fall within established limits according to [TS 18.3 Performing Daily equipment Function Verification](http://khan.childrensmn.org/Manuals/Lab/SOP/TS/OperCon/202408.pdf) must be investigated and resolved or backup equipment shall be used. * Follow-up investigation of reagent or equipment failures and malfunctions shall include an assessment of the effect on patient safety related to patient testing results and/or blood and blood component selection and preparation processes. * Corrective action will be documented on TSQPf 07.10.01 Internal Occurrence Form | | | | |
| **Procedure** |  | | | | |
|  | **Step** | Action | | | |
|  | 1 | Reagent out-of-control:   |  |  | | --- | --- | | **If** | **Then** | | Reagent appears turbid, hemolyzed, clumped or has expired | Replace with new reagent and repeat testing. | | Reagent appears OK | Repeat testing with same reagent. | | Gel card appears abnormal or has expired | Replace with new gel card or lot number and repeat testing. | | Testing is still out-of-control after repeat testing | * Use alternative test method if available. (E.g. tube vs. gel testing)   or   * Refer testing to other Children’s campus or blood center reference lab. * Quarantine or discard implicated reagents. | | | | |
|  | 2 | Equipment out of control:   |  |  | | --- | --- | | **If** | **Then** | | Temperature is out of control | * Check that the equipment or storage device is on. * Check thermometer integrity, replace thermometer as needed. * Adjust equipment temperature setting as needed allowing temperature to stabilize before taking an additional reading. | | Other type of function verification failures | * Repeat function verification assessment * Refer to equipment manual for troubleshooting options. * Refer to TS Equipment Section for additional equipment maintenance options. | | Equipment function out of control | * Use backup equipment (refer to Equipment section) or alternative testing methods.   or   * Refer testing or blood product preparation to other Children’s campus or blood center. * Remove implicated equipment from service.   + Send mailbox to staff about removal of equipment from service   + Place [TSja 18.5.1 Equipment Removed from Service](http://khan.childrensmn.org/Manuals/Lab/SOP/TS/Res/JobA/206041.pdf) on piece of equipment. * Notify Children’s BioMed as needed for repairs or equipment decommission. * Document equipment malfunction on the [TSf 17.10.3 Equipment Maintenance Service Record](http://khan.childrensmn.org/Manuals/Lab/SOP/TS/Res/Sysf/199566.pdf) | | Low level Alarm Activated on Liquid nitrogen freezer | * Security will call Blood bank for a low level alarm has been activated. * Monitor temp on the nitrogen freezer. * Place work order through St. Croix for facilities to replace nitrogen tank. Note that it is an urgent request but can wait for dayshift. | | | | |
|  | 3 | Assess if any previously tested samples require retesting or if any blood products (issued or in inventory) may be affected.   * Notify the transfusion service technical specialist or pathologist if needing assistance in this assessment. * Complete a Safety Learning Report if erroneous testing results or non-conforming products were released. * Document on [TSf 17.10.3 Equipment Maintenance Service Record](http://khan.childrensmn.org/Manuals/Lab/SOP/TS/Res/Sysf/199566.pdf) | | | |
|  | 4 | Leave notification for the transfusion service technical specialist if:   * Unable to resolve the issue. * Large volumes of reagent require quarantine or disposal. (Include reagent name, lot number, expiration date, amount) * Equipment is taken out of service. | | | |
|  | 5 | Re-validate equipment per technical specialist instructions prior to use.   * Document on [TSf 17.10.3 Equipment Maintenance Service Record](http://khan.childrensmn.org/Manuals/Lab/SOP/TS/Res/Sysf/199566.pdf) | | | |
|  |  | | | | |
| **References** | AABB Standards for Blood Banks and Transfusion Service, current edition | | | | |
| **Approval**  **Workflow** | Transfusion Service/Laboratory Director | | | | |
|  |  | | | | |
| **Historical Record** | **Version** | | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | | J Wenzel | 12/28/2009 | Initial Version |
| 2 | | J Wenzel | 4/10/2012 | CMS format |
|  | 3 | | S. Cassidy | 8/20/13 | Added-steps to ensure equipment is removed from service, documentation on equipment maintenance service log and step 5. |
|  | 4 | | S. Cassidy | 5/1/2016 | Added steps for low level alarm activation for nitrogen freezer. |
|  | 5 | | S. Cassidy | 2/24/2020 | Added policy statement where to recorded corrective action |