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| **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:

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| **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.
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|  | 2 | Equipment out of control:

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| **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.
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| 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.
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| 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)
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| 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.
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|  | 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)
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|  | 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.
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|  | 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)
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| **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 |