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| 1.0 | Principle | | | | | | |
|  | To check the alarm system of platelet incubators and to maintain the incubators in good working condition. | | | | | | |
| 2.0 | Scope and Related Policies | | | | | | |
|  | 2.1 | | The TML shall have a written procedure outlining actions to be taken when the temperature of a refrigerator, freezer or incubator for platelet storage exceeds the allowable temperature.9.1 | | | | |
|  | 2.2 | | Incubators for platelet storage shall be able to maintain a temperature throughout the cabinet within the range recommended by the supplier.9.1 | | | | |
|  |  | | 2.2.1 | The temperature of incubators for platelet storage shall have a temperature range between 20°C and 24°C.9.2 | | | |
|  |  | | 2.2.2 | Equipment for platelet storage shall maintain a constant gentle agitation of the platelet component(s). | | | |
|  | 2.3 | | Incubators for platelet storage shall have a system to monitor the temperature of the incubator continuously and to record the temperature at least every four hours. The recorded temperatures must be reviewed daily and the review documented.9.1 | | | | |
|  |  | | 2.3.1 | If platelets are not stored in a controlled environment, the ambient temperature in the area where the platelets are stored shall be checked and documented at least every four hours. The temperature must be within the range specified by the supplier or appropriate corrective action must be taken.9.1 The temperature range of the area should range between 20°C and 24°C. | | | |
|  | 2.4 | | Equipment used in the storage of blood products shall be maintained in a clean and orderly manner and shall have regular documented calibration and preventative maintenance. Records of maintenance, validation calibration, malfunction and repair must be kept during the working lifetime of the equipment plus five years.Records must document disposal of equipment. 9.1 | | | | |
|  | 2.5 | | Equipment used for blood product storage shall be connected to an emergency power supply. The system should be checked monthly to ensure an immediate switch to emergency power supply in the event of a power failure.9.1 | | | | |
|  | 2.6 | | TML shall have a written procedure outlining actions to be taken when the temperature of an incubator for platelet storage falls outside the allowable temperature range.9.1 | | | | |
|  | 2.7 | | All blood storage equipment needs to be validated prior to being placed into service (on receipt or following repair) to ensure it is functioning as intended.9.1 | | | | |
| 3.0 | Specimens – N/A | | | | | | |
| 4.0 | Materials | | | | | | |
|  | **Equipment:** Calibrated thermometers  For alarm probe testing:  Heating device (blow dryer)  Freezer packs  **Supplies:** Monthly and Biannual Maintenance Record (QCA.005F1)  Receipt Record (QCA.005F2)  Malfunction and Corrective Action Record (QCA.005F3) | | | | | | |
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| 5.0 | Quality Control | | | | | | |
|  | 5.1 | The alarm electrical circuits and back-up power supply must be checked and documented every month. | | | | | |
|  | 5.2 | Other semi-annual procedures shall include checking air circulation, door seals, cleaning inside and testing the alarm probes for upper and lower limits. | | | | | |
|  | 5.3 | TML shall have a written procedure outlining actions to be taken when the temperature of an incubator for platelet storage falls outside the allowable temperature range. | | | | | |
|  | 5.4 | Records of maintenance, validation calibration, malfunction and repair must be kept during the working lifetime of the equipment.9.1 | | | | | |
| 6.0 | Procedure | | | | | | |
| * 1. Monthly the following maintenance should be done on the platelet incubator. Follow the manufacturer’s directions for maintenance. These may be done by departments other than the laboratory (e.g. electrical, biomedical engineering, etc.) | | | | | | * + 1. Check the alarm for sound. Follow the manufacturer’s directions. If these are unavailable or do not describe how to test the alarm, perform the following steps. | * + - 1. Press the "alarm test" button. |
| * + - 1. If the alarm rings (and the light flashes, if applicable), record S (satisfactory) on form QCA.005F1. Some models have an alarm indicator light as well as an audible alarm. |
| * + - 1. If the alarm is malfunctioning, record N (not satisfactory) on QCA.005F1. Notify supervisor and check and record the temperature manually every 4 hours until the alarm is repaired. |
| * + 1. Check the back-up power supply according to the manufacturer’s instructions. If these are unavailable or if testing is done as a part of the back-up power supply of the hospital (if the electrical outlet is connected to an emergency power supply) proceed to step 6.1.3. | * + - 1. Disconnect the platelet agitator from the power supply and then remove the back-up power supply (if there is a separate one) to activate the audible alarm. |
| * + - 1. When the back-up power supply is disconnected, there should be a visual or audible sign. Record S (satisfactory) on QCA.005F1. |
| * + - 1. If the back-up power supply is not functional, document N (not satisfactory) on QCA.005F1. Notify supervisor and record the temperature of the platelet incubator should be recorded every 4 hours until the back-up power can be restored. |
| * + 1. Every six months check the temperature sensors for low and high temperatures according to the manufacturer’s instructions. If these are not available or not described, the following procedure should be performed. | * + - 1. Remove platelets from the incubator and place in alternate storage. |
| * + - 1. Warm the platelet incubator with a heating device (e.g., blow dryer) until the alarm sounds and check the temperature indicated on the temperature recorder. |
| * + - 1. Record the temperature on the digital or continuous temperature recorder on QCA.005F1 (for semi-annual check) or on QCA.005F2 (for upon receipt or after repair).   The alarm should have sounded at 24°C. Adjust the set point to 24°C and repeat testing if the alarm did not sound at 24°C. |
| * + - 1. Stop heating the incubator; open the door(s) and note the temperature on the digital or continuous temperature recorder at which the alarm stops ringing (it should stop ringing at 24°C). |
| * + - 1. Place several freezer packs to cool the temperature of the incubator. Close the door and wait until the alarm sounds. |
| * + - 1. When the alarm sounds, check the temperature on the digital or continuous temperature recorder.   Record the temperature on form QCA.005F1.  The alarm should have sounded at 20°C.  Adjust the set point to 20°C and repeat testing if the alarm did not sound at 20°C. |
| * + - 1. Remove the freezer packs; close the door(s) and note the temperature on the digital or continuous temperature recorder at which the alarm stops ringing (it should stop ringing at 20°C). |
| * + - 1. Record the date the alarm probe was checked on form QCA.005F1. |
| * + 1. Check the motion alarm indicator if the incubator has one. Follow the manufacturer’s instructions. Turn off the agitator. The motion sensor should indicate that the agitator is not moving. If the sensor indicates no motion, record S (satisfactory) on QCA.005F1. If there is no indication, record N (not satisfactory) and initiate a maintenance request (or contact the manufacturer if warranty applies). | |
| * + 1. Clean the interior and exterior of the cabinet with a disinfectant solution (e.g., Presept, glutaraldhyde, etc.). Record Y (yes) on QCA.005F1 when completed. | |
| * + 1. Clean the dust from mechanical parts (a vacuum works best, if available). | |
| * + 1. Check that there is proper air circulation (fan is working, no obstacles preventing efficient air flow). Record Y (yes) on QCA.005F1 when completed. | |
| * + 1. Check that the door seals tightly (adjust gasket as necessary). Record Y (yes) on QCA.005F1 when completed. | |
| * + 1. Record the date and initial the appropriate area on form QCA.005F1. | |
| * + 1. Record all corrective actions on QCA.005F1. Keep a copy of documentation of the work performed, including work done by the maintenance department or servicing. | |
| * + 1. Report any abnormalities found with the platelet incubator to the supervisor. | |
| * 1. Following recommendations from the service provider that equipment has been repaired or prior to putting into service (following validation), before storing products: | | | | | | * + 1. Check the temperature of the platelet incubator. | * + - 1. Place one thermometer on the bottom shelf and another one on the top shelf (if applicable). |
| * + - 1. Read and record the temperature for 24 – 72 hours on both thermometers and on the recorder. Record the temperatures on QCA.005F2. See Procedural Notes 8.1 and 8.2. |
| * + 1. Test the alarm for sound for 24 – 72 hours. See step 6.1.1.   Record S (satisfactory) or N (not satisfactory) on QCA.005F2. | |
| * + 1. Test the alarm sensor for low and high temperatures. See step 6.1.3. Record the high and low temperatures on QCA.005F2. | |
| * + 1. Ensure specific instructions in case of equipment malfunction are posted on the incubator. | |
| * 1. Immediate Corrective Action for Alarm Sounding on Platelet Incubator | | | | | | * + 1. Silence the alarm. | |
| * + 1. Read and record the temperature of the continuous recording device and internal thermometer. | |
| * + 1. Determine the cause for the alarm: door ajar or incubator malfunction.  |  |  | | --- | --- | | ***If*** | ***Then*** | | A door was ajar | proceed to step 6.3.4 | | The door was closed completely | a malfunction is the cause for the alarm. Proceed to step 6.3.5. | | |
| * + 1. If the temperature of the platelet incubator is between 20°C and 24°C and a door was ajar: | * + - 1. Close the door and minimize entry. |
| * + - 1. Set a timer for 15 minutes. |
| * + - 1. Check the temperature after 15 minutes. |
| * + - 1. If the temperature remains between 20°C and 24°C, record the date and immediate action taken on QCA.005F3. |
| * + 1. Malfunction instructions: | * + - 1. Remove all platelets and place in backup incubator. |
| * + - 1. If an interim platelet incubator is not available, remove the agitator from the incubator and store at room temperature. |
| * + - 1. Read and record the temperature every 4 hours using a calibrated thermometer placed on the agitator, unless a continuous room temperature monitoring device is available for the area. |
| * + - 1. Call maintenance immediately after ascertaining the safety of the platelets. |
| * + - 1. If there is an off-site alarm that did not alert someone, determine why there was no response. |
| * + - 1. Record the malfunction and corrective action on form QCA.005F3. |
| **7.0** | Reporting | | | | | | |
|  | 7.1 | | A supervisor must review the results of maintenance and any action taken. Corrective action should be documented, if taken. See Procedural Notes 8.3. | | | | |
|  | 7.2 | | This review must be documented. | | | | |
| 8.0 | Procedural Notes | | | | | | |
|  | 8.1 | | If the three temperatures are not within 1°C, the recorder must be adjusted. | | | | |
|  | 8.2 | | When the temperature readings of the two thermometers agree within 1°C, only one thermometer may be used. | | | | |
|  | 8.3 | | Maintenance of equipment may be documented on a computer system, if applicable. | | | | |
|  | 8.4 | | Equipment should be validated when received and following repair prior to being placed into service. Validation should follow an established protocol and must be documented. Validation includes the following: | | | | |
|  |  | | 8.4.1 | | Installation – checks that electrical and special requirements set out by the manufacturer are met. | | |
|  |  | | 8.4.2 | | Operational – shows that the equipment functions as intended with respect to temperature range, alarm, temperature monitoring, and shelving. | | |
|  |  | | 8.4.3 | | Performance – demonstrates that the equipment performs as expected using the established facility processes. | | |
| 9.0 | References | | | | | | |
|  | 9.1 | | Standards for Hospital Transfusion Services Version 3 – February 2011. Canadian Society for Transfusion Medicine, 3.2.3.1, 3.2.4.1, 3.2.1.5, 3.2.4.2, 5.1.2.14, 5.1.2.15, 3.1.2, 3.1.6, Appendix A | | | | |
|  | 9.2 | | Kavemeier KG, Ziebell LW, ed. Quality control: a component of process control in blood banking and transfusion medicine. Bethesda MD: American Association of Blood Banks, 1999. | | | | |
|  | 9.3 | | Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: American Association of Blood Banks, 2011, 272-274, 967. | | | | |
|  | 9.4 | | IQMH Requirements and Guidance Information. Version 6.0, December 2013 (IV) | | | | |

**10.0 Revision History**

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| **Revision Date** | **Summary of Revision** |
| September 1, 2015 | * Revised name of manual * Revised and numbered section 2.0 * Added section 2.2.2 * Revised section 6.0 * Updated list of references to include most recent editions |