**SOP**
Cooler Validation Procedure for 2 units

**Suggestion:**
**View the Instructional Videos on www.zebra.com/valasuresupport.**

Maintaining the appropriate temperature during the transport and storage of Whole Blood, Red Blood Cells, and Plasma, is required to ensure their integrity and meet compliance requirements. This validation procedure should be utilized to ensure that units are maintained in their containers for a time period designated to meet the 4 hour minimum compliance time and a realistic and practical time period for the institution.

**1. Purpose**

1.1. This validation procedure is to ensure that the container used for transport or storage of blood products will maintain the products at less than \_\_\_\_ ºC for \_\_\_\_ hours.

1.1.1. Cooler validation is to be repeated every \_\_\_\_ months and before the initial use of each cooler being used for blood products.

1.1.2. This validation is to be used when transporting or storing up to \_\_\_\_ units of \_\_\_\_\_\_\_ (*insert the specific blood product here*).

**2. Equipment Needed**

2.1. Transport Cooler

2.2. Temperature Recorder (Note: Calibration to a NIST traceable standard is required annually)

2.3. Temperature Recorder software

2.4. Expired units of blood product or similar units containing glycerol-water solution (see recommendations at https://temptimecorp.com/2018/03/17/simulated-blood-products-10-glycerol-in-water-may-not-be-one-size-fits-all/).

2.5. Freezer Packs, Cold Packs or Wet Ice (with a Wet Ice barrier between blood product and Wet Ice when Wet Ice is used).

2.6. Container to place the units of blood or simulated blood product within cooler.

**3. Definitions**

3.1. Unit - expired units of packed red blood cells, other blood products or simulated units using glycerol-water solution.

3.2. Start time - the time when the cooler validation begins, which is the time the “START/MARK” button is pushed on the temperature recorder.

**4. Personnel**

4.1. Facility to determine.

**5. Attachments**

5.1. Validation Log for Transport Containers.

5.2. Packing guidelines for blood supplied by cooler manufacturer or facility guidelines.

5.3. Cooler label template.

**6. References**

6.1. American Association of Blood Banks, Technical Manual ‘Tech Man’

6.2. American Association of Blood Banks, Standards for Blood Banks ‘Standards’

6.3. FDA 21CFR 600.15(a)

**7. Procedure**

7.1. Prepare Temperature Recorder

7.1.1. Install software for temperature recorder onto computer.

7.1.2. Plug cradle into USB port on computer

7.1.3. Dock the temperature recorder in the cradle.

7.1.4. Configure the recorder for the following:

 Degrees C

 Recording Intervals (every 5 minutes is suggested)

 High/low temperature

7.2. Pack the uniquely identified cooler following cooler manufacturer’s or facility guidelines.

7.2.1. Place cold packs or wet ice and freezer packs in the cooler according to guidelines.

7.2.2. Remove units of blood from the refrigerator. NOTE: Ensure the temperature recorders have been configured. (See 7.1)

7.2.3. Place 2 units into container, with the temperature recorder positioned between the units.

7.2.4. Fill the remaining space above the units with cold packs or bagged crushed ice (using a barrier to prevent direct contact with blood product when using crushed ice).

 7.2.5. Close the cooler lid.

7.3. Simulate the removal of the blood products.
NOTE: This is an optional step to be determined by individual facility.

7.3.1 Open the cooler and remove one unit \_\_\_\_ minutes after the “start” time to simulate the removal of one unit of blood product. NOTE: Make sure the final unit in the cooler is one with a temperature recorder in contact with it.

7.4. Completion of Validation

7.4.1. Stop Validation \_\_\_\_ hours after the “start” time.

7.5. Review of data.

 7.5.1. Manually complete the Validation Log Sheet.

7.5.2. Place temperature recorder back in the cradle (attached to computer) and download the data from the temperature recorders.

 7.5.3. Print out and attach the data to the Validation Log Sheet.

 7.5.4. Place completed cooler validation label on validated cooler.

7.5.5. If cooler has failed the validation, inspect cooler packing, cooler integrity and compare to a cooler that has passed the validation. If appropriate, repeat the validation attempt or take the cooler out of service. Document actions taken on the validation log.

7.5.6. Follow the facility procedure for coolers not passing the validation by failing to maintain temperature less then \_\_\_\_ºC over a \_\_\_\_ hour time period.

7.6 Hibernate temperature recorder (to preserve battery life)

 7.6.1 While recorder is still in the cradle and software is open, select “LogTag” from top menu.

 7.6.2 Scroll down to select “Hibernate”.

7.6.3 Remove the recorder and store until next use.

Validation Procedure Reviewed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date Reviewed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_