

Product Validation Procedure	Products: Trans-Vue™ 10 [Cat. #8210-XXX] Trans-Vue™ 8 [Cat. #8208-XXX] Trans-Vue™ 6 [Cat. #8206-XXX]
Transport Cooler Temperature Monitor Refrigerator Temperature Monitor	Manufacturer: William Laboratories, Inc. Enfield, CT 06082 800.767.7643 www.williamlabs.com
Ref: William Laboratories SOP QAP/0104 REV 02	Page 1 of 4

1.0 Purpose. To assure a consistent method of measuring and interpreting color-related temperature change in TV 6, TV 8, and TV 10 when used as a temperature-monitoring device.

2.0 Scope

This procedure applies specifically to TRANS-VUE 10, TRANS-VUE 8, and TRANS-VUE 6 temperature indicators.

3.0 Related Documents

- 3.1. *American Association of Blood Banks Standards for Blood Banks and Transfusion Services, Reissue of Blood and Components.*
- 3.2. Package insert “*Handling/Use Instructions/Frequently Asked Questions (FAQs and Color change Interpretation Information*”.
- 3.3. William Laboratories’ CD ***Instructional & Training Videos*** for Safe-T-Vue and Trans-Vue Nonreversible Temperature Indicators

4.0 Installation Qualification (IQ)

4.1. Process Description – The measurement and interpretation of the temperature-related color change for TV Devices is a simple procedure consisting of assuring starting temperatures, use of a validated shipping container, use of temperature measuring instruments, and the correct physical handling of *TRANS-VUE* Temperature Indicators and Devices.

4.2. Equipment Design/Description

4.2.1. A refrigerator with temperature control:

4.2.1.1. Between 1° to 4° C for TV 8 & TV 10,

4.2.1.2. Between 1° to 3° C for TV 6;

4.2.2. A validated shipping container for 1 to 6 blood bags, a predetermined number of blood bags.

4.2.3. Up to the maximum predetermined number of simulated blood bags (or out of date blood units) consisting of a common, flexible plastic blood bag filled with the appropriate volume of glycerol-water mixture (approx. 10% by wt. glycerol) to simulate blood mass and volume;

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Ref: William Laboratories SOP QAP/0104 REV 02	Page 2 of 4

4.2.4. An electronic thermometer, or a **TEMPERATURE DATA LOGGER INFO TO BE ENTERED HERE** with a ‘button’ probe, or similar temperature measuring instrument that can be calibrated;

5.0 Preparation for Temperature Measurement: Sample Preparation

- 5.1. Store the *TRANS-VUE* Device with color-coded Temperature Indicator attached in a refrigerator for a minimum of 24 hours prior to test.
 - 5.1.1. 1° to 4° C for TV 8 & TV 10
 - 5.1.2. 1° to 3° C for TV 6
- 5.2. Store a predetermined number of simulated blood bags in a refrigerator for a minimum of 24 hours prior to test.
 - 5.2.1. 1° to 4° C for TV 8 & TV 10
 - 5.2.2. 1° to 3° C for TV 6
- 5.3. Store rigid coolant containers, and/or cold packs in same refrigerator at for a minimum of 24 hours prior to test. NOTE: Wet ice may be substituted for coolant containers or cold packs if the transport container has been validated using wet ice.
 - 5.3.1. 1° to 4° C for TV 8 & TV 10
 - 5.3.2. 1° to 3° C for TV 6
- 5.4. Load refrigerated coolant into validated container following the supplier’s packing protocol.
- 5.5. Position the predetermined number of refrigerated blood bags in validated container following the supplier’s packing protocol.
- 5.6. Activate procedure for *TRANS-VUE* Device:
 - 5.6.1. Peel off the white foil lid from the color-coded, round label end to expose the white and red rounds;
 - 5.6.2. Fold the white round into the red round;
 - 5.6.3. Press firmly together by pressing only on the color-coded, round label.
- 5.7. Attach the button probe to the exposed portion of the media pillow opposite the Temperature Indicator using adhesive tape;
- 5.8. Place activated *TRANS-VUE* Device with electronic probe attached into validated container so that it is between temperature-sensitive items;

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Ref: William Laboratories SOP QAP/0104 REV 02	Page 3 of 4

5.9. Connect probe to electronic thermometer

5.10. Position remaining cold packs on top of temperature-sensitive items and close top of transport container.

6.0 Temperature Measurement

6.1. Observation parameters for determining the temperature of color change.

6.1.1. The color change in the round white area is from white to a rose-red or red color.

6.1.2. The color change process from an all-white to and all-red color typically takes place over about 1° C.

6.1.3. The color change process may be described as progressive by observing in sequence:

6.1.3.1. Small, rose or red spots around the edges of the white area and/or within the white area;

6.1.3.2. Areas of rose or red spots coalescing into areas of rose-red to red color; bag positioned so that it is in the approximate center of the liquid in the bag;

6.1.3.3. The entire white area is rose-red to red indicating attainment of

6.1.3.3.1. 6° C for TRANS-VUE 6, 8° C for TRANS-VUE 8

6.1.3.3.2. 10° C for TRANS-VUE 10;

NOTE: A positive control is helpful for color comparison.

6.1.4. Repeat process with one or more TV Devices until satisfied that the process will consistently produce results meeting the specifications and quality characteristics of the product.

Critical Process Variables

1. Refrigerator temperature range;
2. Calibration of temperature-measuring instruments
3. Handling of and Activation of samples

Conditions to be Monitored

1. Storage of TRANS-VUE Device with Non-Activated Temperature Indicator attached in a refrigerator for a minimum of 24 hours prior to use.
 - a. 1° to 4° C for TV 8 & TV 10, and

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Ref: William Laboratories SOP QAP/0104 REV 02	Page 4 of 4

- b. 1° to 3° C for TV 6;
- 2. Storage of simulated blood bags and coolant blocks and cold packs at 1° to 3° C for a minimum of 24 hours prior to use.
- 3. Training to assure consistent preparation and handling of items used in the validation.

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