

STANDARD OPERATING PROCEDURE

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APP'D:

VALIDATION PROTOCOL

- TRANS-VUE 10, Product No. 8210
- TRANS-VUE 8, Product No. 8208
- TRANS-VUE 6, Product No. 8206

Process to be validated – Temperature Measurement of Color Change in *TRANS-VUE 6* (TV 6), *TRANS-VUE 8* (TV 8), *TRANS-VUE 10* (TV 10).

References: William Laboratories, Inc. Product Sheet SAL/0100-4, Rev 0, 8/29/06.
American Association of Blood Banks Standards for Blood Banks and Transfusion Services, Reissue of Blood and Components. Package insert "*Handling/Use Instructions/Frequently Asked Questions (FAQs and Color change Interpretation Information*". Lot and Product specific Quality Assurance Documents.

Purpose of Validation – 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.

Installation Qualification (IQ)

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.
2. Equipment Design/Description
 - a. A refrigerator with temperature control between **1° to 6° C for TV 8 & TV 10**, and **1° to 3° C for TV 6**;
 - b. A validated shipping 'IGLOO' Brand style of container for 1 to 6 blood bags, or 1 to 16 blood bags.
 - c. Up to 6 simulated blood bags 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;
 - d. An electronic thermometer, such as a "DigiSense" ThermoLogR thermister electronic thermometer with a 'button' probe, or similar temperature measuring instrument that can be calibrated;
3. Sample Preparation
 - a. Store the *TRANS-VUE Device* with color-coded Temperature Indicator attached in a refrigerator at **1° to 6° C for TV 8 & TV 10**, and **1° to 3° C for TV 6** for a minimum of 24 hours prior to test.
 - b. Store 2 to 6 simulated blood bags in a refrigerator at **1° to 6° C for TV 8 & TV 10**, and **1° to 3° C for TV 6** for a minimum of 24 hours prior to test.;

- c. Store rigid coolant containers, and/or cold packs in same refrigerator at **1° to 6° C for TV 8 & TV 10**, and **1° to 3° C for TV 6** 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.
 - d. Load refrigerated coolant into validated container following the supplier's packing protocol.
 - e. Position 2 to 6 refrigerated blood bags in validated container following the supplier's packing protocol.
 - f. **Activate TRANS-VUE Device:**
 - i. Peel off the white foil lid from the color-coded, round label end to expose the white and red rounds;
 - ii. Fold the white round into the red round;
 - iii. Press firmly together by pressing only on the color-coded, round label.
 - g. Attach the button probe to the exposed portion of the media pillow opposite the Temperature Indicator using adhesive tape;
 - h. Place activated *TRANS-VUE* Device with electronic probe attached into validated container so that it is between temperature-sensitive items;
 - i. Connect probe to electronic thermometer
 - j. Position remaining cold packs on top of temperature-sensitive items and close top of transport container.
4. Observation parameters for determining the temperature of color change.
- a. The color change in the round white area is from white to a rose-red or red color.
 - b. The color change process from an all-white to and all-red color typically takes place over about 1° C.
 - c. The color change process may be described as progressive by observing in sequence:
 - i. Small, rose or red spots around the edges of the white area and/or within the white area;
 - ii. 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;
 - iii. The entire white area is rose-red to red indicating attainment of **6° C for TRANS-VUE 6, 8° C for TRANS-VUE 8**, and **10° C for TRANS-VUE 10**; a positive control is helpful for color comparison.
 - d. 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 **1° to 6° C for TV 8 & TV 10**, and **1° to 3° C for TV 6** refrigerator for a minimum of 24 hours prior to use;
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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