Manufactured by:
Temptime Corporation
116 The American Road
Morris Plains, NJ 07950

Suggested Validation Procedure for Safe-T-Vue® 10

1. Purpose:
To validate Safe-T-Vue 10 temperature indicators and assure proper use and handling of the indicators. Using this validation procedure, three temperatures are measured and recorded while observing the indicator's gradual change from white to red:

- When the white indicator first begins to show red spots
- When the indicator begins filling in with red
- When the indicator is completely red

2. Scope:
This procedure applies specifically to Safe-T-Vue 10 temperature indicators.
The measurement and interpretation of the temperature-related color change for Safe-T-Vue 10 consists of assuring a low enough starting temperature, use of temperature measuring instruments, and correct physical handling of the Safe-T-Vue 10.

3. Reference:
3.1. *Safe-T-Vue* Product Sheet
3.2. *American Association of Blood Banks* **Standards for Blood Banks and Transfusion Services**, Current Issue, Reissue of Blood and Components
3.3. Package insert "*Instructions & FAQs"*
3.4. Lot specific Quality Assurance Document received with Safe-T-Vue 10 shipment

4. Responsibilities:
4.1. Training to assure consistent handling and application of Safe-T-Vue Products.

5. Safety:
5.1. Use Personal Protective Equipment as required.

6. Attachments:
N/A

7. Materials / Equipment:
7.1. Cold Pack (use of cold pack is optional).
7.2. Refrigerator with temperature controlled between 1.0° and 4.0° C.
7.3. Bag of simulated blood product having approximately 350 cc capacity (or greater) filled with the appropriate volume of glycerol-water mixture to simulate blood mass and volume, or outdated blood.
7.4. Calibrated electronic temperature recorder with an immersion probe, or glass thermometer.
7.4.1. The temperature probe (or thermometer) is inserted into the bag and positioned so that it is in the approximate center of the blood bag liquid to assure temperature measurement of the 'core' temperature of the liquid mass.

8. Handling
8.1. Because the indicator is a temperature-sensitive device:

- Hold it by its outer edges.
- Do not hold or touch the temperature sensitive indicator area.

9. Validation Procedure

9.1. Preparation for Observation and Temperature Measurement

9.1.1. Store the following materials in refrigerator at least 24 hours prior to using:

- Cold Pack (optional)
- Safe-T-Vue Indicators (box of 50)
- Simulated blood product or outdated blood

9.1.2. To begin the validation, remove the simulated blood product (or outdated blood) from refrigerator.

9.1.3. Insert the temperature probe or thermometer in the blood product and position it so that it is in the approximate center of the blood bag liquid, to assure temperature measurement of the 'core' temperature of the liquid mass.

9.1.4. Remove one Safe-T-Vue 10 from refrigerator, taking care to handle by the edges.

9.1.5. Peel off the "Remove" label to expose the adhesive and attach Safe-T-Vue 10 directly to the blood bag where there is the greatest volume of liquid and immediately above the measurement probe.

9.2. Indicator Observation and Temperature Recording

9.2.1. Activate the indicator by stabilizing Safe-T-Vue 10 against the bag with fingertips, then peel off the top foil lid to expose the red and white rounds.

9.2.2. Fold the white round into the red round and press firmly to snap shut.

9.2.3. Observe the color change process and record the corresponding temperature* from an all-white color to an all red-color, which typically takes place over about 1° C.

- "Red Spots – Random" - Small, red spots around the edges of the white area and/or within the white area.
- "Red Filling In" - Areas of red spots coalescing into areas of red.
- "Completely Red" - The entire white area is red, indicating attainment of 10° C. A positive control is helpful for color comparison.

* If using an electronic temperature recorder for automated temperature recording, use the recorder functions to "mark" the temperature at each of the three observation points.

9.2.4. Repeat the validation process with two additional Safe-T-Vue 10 temperature indicators until satisfied that the process will consistently produce results meeting the specifications and quality characteristics of the product.

9.3. Data Collection and Management

9.3.1. Data may be collected on a data collection document, recording the following information:

- The calibration correction of the electronic probe/thermometer used;
- Visual change as described in 9.2.3 as "Red spots – Random", "Red Filling In", and "Completely Red" respectively in the spaces provided as shown on the following page.

9.4. Critical Process Variables

9.4.1. Refrigerator temperature range

9.4.2. Calibration of temperature-measuring instruments

9.4.3. Handling of samples

9.5. Conditions to be Monitored

9.5.1. Storage of Safe-T-Vue 10 in refrigerator so that 'warm air wash' from normal opening and closing of the door does not warm the indicators prior to use.

9.5.2. Training to assure consistent handling and application of Safe-T-Vue 10.

Suggested Format for Data Collection

LOT #_____; DATE REC'D_____; NUMBER OF BOXES REC'D_____

TESTED BOX ID_____

Safe-T-Vue Validation **Observations**	**Sample # 1** Temp. °C	**Sample # 2** Temp. °C	**Sample # 3** Temp. °C
Red Spots – Random			
Red Filling In			
Completely Red			