

Safe-T-Vue® 10 • Product No. 7201

Quality Assurance: Safe-T-Vue® 10 Non-Reversible Blood Bag Temperature Indicator Product No. 7201
 PLEASE NOTE: ALL BOX OF 50 INFORMATION AND FOIL LID COPY FOR SAFE-T-VUE® 10 IS PRINTED IN BLACK.

Lot # **S10 120810**
 Expiration Date: **2012-12**

Non - Chemistry

Mark √ for "Accepted" and X for "Not Accepted."

| Box | Adh. Label | Foil Lid | Close Function | Fill Level |
|--------------|-------------|--------------|-----------------|--------------------|
| √ Copy | √ Copy | √ Copy | √ Formed | √ Acceptable |
| √ Tack | √ Tack | √ Position | √ Locked/Stable | Underfill |
| √ Clean | √ Color | √ Clean Peel | Hinge | Overfill |
| √ Box Damage | Tray | Disk | √ Elasticity | Color Label |
| | √ Edges | √ Appearance | | √ Color |
| | √ Color | √ Fit | | |

Test Protocol – Finished Goods Quality Assurance

Test performed on random sampling of finished product per ANSI ASQZ1.4-2003

Data from a "DigiSense" Thermister Electronic Thermometer, using a cold (start temperature 1° to 3° C) bag of simulated blood (10% glycerol-water) with thermometer probe positioned in center of blood bag. Agitation of blood bag necessary for collection of accurate temperature-color change data. Download detailed protocol, from www.williamlabs.com, QAP 0300-01 REV 0 "Receiving Inspection – Temperature Indicators".

Temperature Change and Corresponding Safe-T-Vue® Change

| Sample Set 1 | DATA | Sample Set 2 |
|--------------|------------------------------|--------------|
| 1 to 4 °C | <i>Starting Temperatures</i> | 1 to 4 °C |

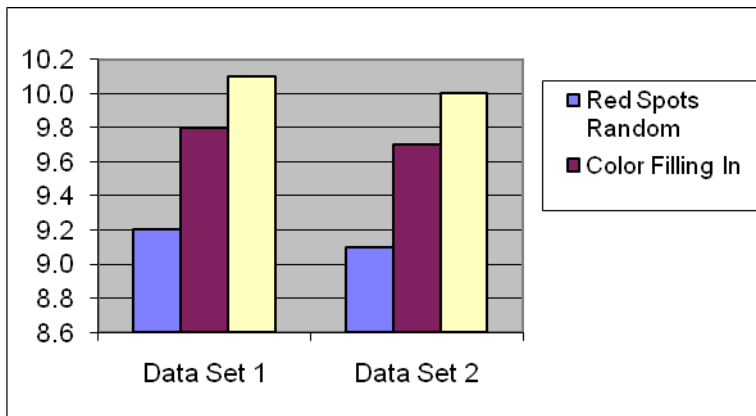
OBSERVATIONS

| Temperature | Condition |
|-------------|---------------------------------|
| 9.2 °C | Red Spots - Random WHITE CENTER |
| 9.8 °C | Red Filling In WHITE CENTER |
| 10.1 °C | Full Red Color RED CENTER |

| Temperature | Condition |
|-------------|---------------------------------|
| 9.1 °C | Red Spots – Random WHITE CENTER |
| 9.7 °C | Red Filling In WHITE CENTER |
| 10.0 °C | Full Red Color RED CENTER |

Temperature accuracy is +/-0.3°C.

Results of Testing: Red Spots - Random 9.2°C; Red Filling in White Center 9.8°C; Full Red Color at 10.1°C.



QUALITY ASSURANCE: APPROVED LOT # S10 120810 ; Edward N. Sharpless **January 06, 2011**

Laboratory Director Date