



RACCORDS & FLEXIBLES

## TEST RESULT CERTIFICATE

<b>Test Article</b>	Viewline Raw Material Tube
<b>Lot#</b>	DM275X028
<b>Study</b>	Direct Hemolysis – Rabbit Blood

**REFERENCE :** The essay conducted based on the following references.

Hemolysis – Rabbit Blood, Evaluation of Hemodialyzers and Dialysis Membranes DHEW publication # (NIH) 77-1294, Pp. 213, 1997.

The International Organisation of Standardisation (ISO) Biological Evaluation of Medical Devices Part 4 : Selection of Tests for Interactions, with Blood; ISO 10993-4, 1992.

Autian method described in ATTP-I, Material Sciences Toxicology Laboratories, University of Tennessee Center for the Health Sciences, Memphis, TN, April 18, 1977.

Veterinary Hematology, Schalm O.W., pp.51-53, 1965. Léa & Febiger, Philadelphia.

**PROCEDURE :** The test article, 5 gm, was added to a test vial containing 10mL USP 0.9% Sodium Chloride for Injection (NaCl). The test article was prepared in triplicate. The positive control (10mL UPS Sterile Water for injection) and negative control (10 mL NaCl) were prepared in triplicate. All tubes were incubated in a  $37 \pm 2^{\circ}\text{C}$  waterbath for 30 minutes. After the incubation period, 0.2 mL of fresh diluted rabbit blood was added to all vials. The rabbit blood was collected in tubes containing an anticoagulant (EDTA) and diluted in NaCl. All vials were incubated in a  $37 \pm 2^{\circ}\text{C}$  water bath for an additional 60 minutes. After incubation, the vials were centrifuged. The absorbance of each supernatant was determined at 545 nm. The percent hemolysis of the test article was determined.

**CRITERIA :** A test article with a percent hemolysis of 5% or less is considered non hemolytic.

**RESULTS :** The percent hemolysis of the test article was 0.20%.

**CONCLUSION :** The test article is considered non-hemolytic.

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