Blood Clearing Study

Laboratory No. 454363

Intraluminal Protection System

InVision-Plus®

with Neutral Advantage Technology

1 mL per flush with 0.9% normal Saline-Only

RyMed Technologies, LLC

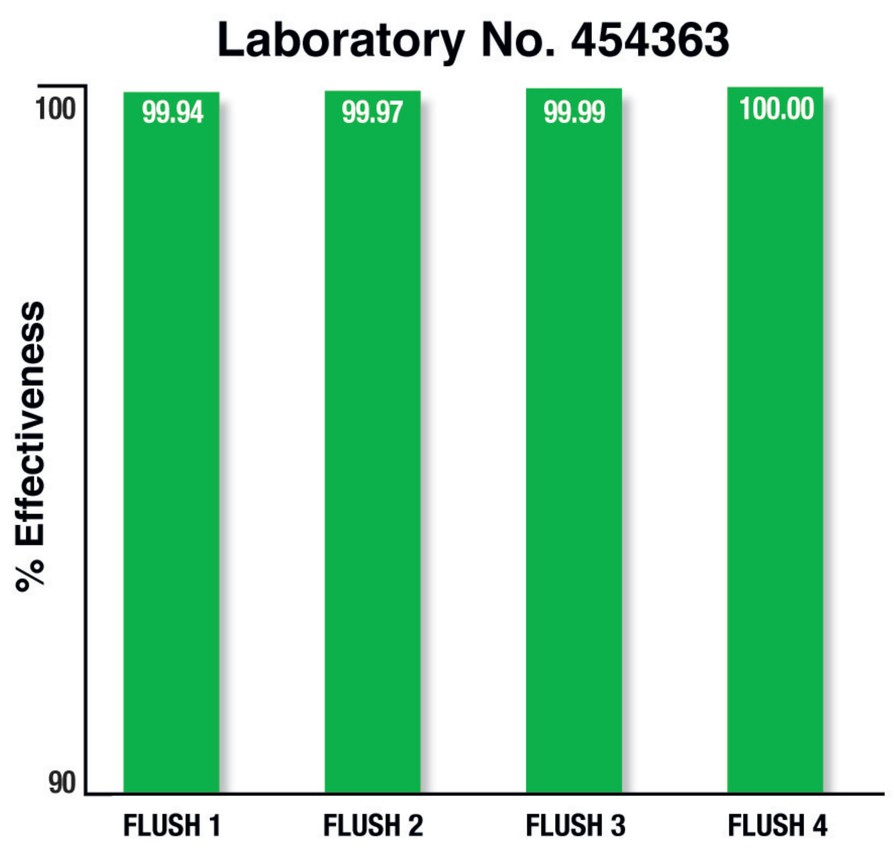
Blood Clearing Study for the InVision-Plus® with Neutral Advantage Technology

Nelson Laboratories, Inc. (Salt Lake City, UT), an independent laboratory facility, was contracted to conduct a blood clearing study on the **InVision-Plus® with Neutral Advantage Technology**, manufactured by RyMed Technologies, LLC.

OBJECTIVE: Effective clearing of blood and medications from needlefree I.V. connectors is a critical catheter care and maintenance practice. It has also been suggested that fluid pathway design within I.V. connectors can impact flushing success. The ability to effectively flush the I.V. connector's fluid pathway with 10 mL (per facility protocol) is important. This test procedure was designed to determine the flushing effectiveness of the **InVision-Plus®** using only a 1 mL 0.9% normal saline solution after blood exposure.

METHODS: Citrated human blood was used in this study. A hemoglobin standard curve was prepared by diluting the hemoglobin standard (0.80 mg/mL) with cyanmethemoglobin (CMR) to give solutions at concentrations of 0.80, 0.60, 0.40, 0.30, 0.20, 0.10, and 0.01 mg/mL. The solutions were allowed to stand at room temperature for >5 minutes, and the absorbance was measured on a spectrophotometer at 540 nm. A standard curve was performed with the optical density readings and concentrations of hemoglobin. To establish plasma hemoglobin determination, 4 mL of blood were centrifuged at 700-800 times g for 15 minutes. 1 mL of plasma was added to 1 mL of CMR and allowed to stand at room temperature for >15 minutes, then measured for absorbance at 540 nm on a spectrophotometer. The amount of hemoglobin present was determined from the standard curve and multiplied by a factor of 251 to account for the dilution. The procedure was performed in triplicate.

TEST PROCEDURE: Each device was exposed to human citrated blood by filling a 1 mL syringe with 1 mL of blood. The blood was injected through the device and the residual blood that escaped was collected in a test tube. The device was then flushed by filling a syringe with 1 mL of 0.9% saline, injecting saline through the device, and collecting the saline in the same test tube as the residual blood. The flushing procedure was repeated for a total of four times. Each time the flushed solution was collected in a separate test tube. A total of three devices were injected with blood and flushed. A baseline control was performed by filling a 1 mL syringe with 1 mL of blood and dispensing the blood into a test tube with 1 mL of 0.9% saline. Three baseline tubes were prepared. Once the flushing procedure was complete the collected samples were analyzed for the amount of hemoglobin present as described above.



RESULTS: The following chart summarizes the effectiveness of each consecutive 1 mL flush on the **InVision-Plus®** which has a priming volume of 0.027 mL.

CONCLUSION: After a 1 mL flush of 0.9% normal saline, the RyMed Technologies, LLC. **InVision-Plus® with Neutral Advantage Technology** (Catalog No. RYM-5001) was **99.94% cleared**, which corresponds to initial residual percent hemoglobin of 0.06%. The **InVision-Plus®** fluid pathway was **100% cleared** with only four 1mL flushes of 0.9% normal saline.

The complete study protocol and final report on file at RyMed Technologies, LLC.

RyMed TECHNOLOGIES, LLC