Hemolysis Testing Report for the NovaCath™ Integrated IV Catheter System

INTRODUCTION
The NovaCath Integrated IV Catheter System is a closed IV catheter system with a unique internal 180° fluid path turn. An in vitro procedure was designed to evaluate potential hemolytic properties of the NovaCath fluid path using a simulated blood sampling protocol.

Hemolytic index was calculated for the NovaCath system as well as a control IV catheter system, consisting of a ProtectIV® catheter connected to a standard extension set. Testing was conducted by Nelson Laboratories, a leading independent medical device testing lab, based in Salt Lake City, Utah.

METHODS
A 500 mL unit of citrated human blood was suspended above the table top and connected to a standard blood administration set, flow-control clamp (CAIR clamp), female luer lock coupler, and a puncturable membrane. The NovaCath system (n=5) was inserted into the puncturable membrane and connected to a Vacutainer® luer adaptor. Three 5 mL aliquots of blood were collected through the system into non-additive Vacutainer tubes. This blood collection method was repeated for the control system (n=5). Both catheter systems were 20G with 1” catheters.

Plasma free hemoglobin and total blood hemoglobin were determined for each collected sample by reading the optical density at 540 nm on a spectrophotometer and comparing it to a standard curve, as outlined in ASTM F756-08. The hemolytic index (percent hemolysis) for each device was calculated by dividing the total plasma free hemoglobin in each sample by the total blood hemoglobin (ASTM F756-08). An independent, two-tailed t-test was used to compare the average hemolytic index of NovaCath with the control device. A baseline hemolytic index was determined from a sample of blood removed directly from the blood administration set, without flowing through an IV catheter system.

RESULTS
The average hemolytic index for NovaCath was not statistically different from the average hemolytic index of the control system (p=0.84), as illustrated in Figure 1. The percent hemolysis of the baseline blood sample indicates that neither IV catheter system induced hemolysis. All hemolytic indices measured in the current study were well below the minimum threshold of what ASTM defines as “slightly hemolytic” (2% hemolysis, represented by the dotted line in Figure 1).

CONCLUSION
The current study indicates that the unique design of the NovaCath Integrated IV Catheter System did not cause hemolysis of blood sampled through the device.

FIGURE 1. AVERAGE HEMOLYTIC INDEX

Average hemolytic index ± SD for NovaCath (n=5) and a control system (n=5) in a simulated blood sampling protocol. A baseline hemolytic index is also presented for a blood sample that did not pass through an IV catheter system. The ASTM minimum threshold for hemolysis is indicated by a dotted line.