



Blood Sampling Hemolysis Study for the MaxPlus Positive Flow Connector

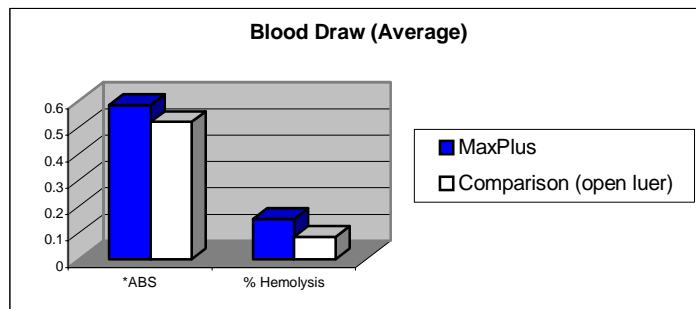
Apptec Laboratory Services of St. Paul, MN, an independent laboratory facility, performed an analysis of the rate of hemolysis after blood withdrawal through the MaxPlus Connector for Maximus Medical Products, Inc.

Objective: The purpose of this study was to determine if the MaxPlus Connector causes statistically significant hemolysis during blood withdrawal through the unit. To achieve this, the device was compared versus an open luer that represented the comparison control.

Method: One blood bag unit (500cc bag whole citrated human blood) was prepared per laboratory protocol. A 1ml sample was taken from the bag and used to determine the “critical volume” (volume of blood necessary to yield an absorbance range of 1.0 – 0.9). For the test samples, a MaxPlus was connected to a female/female luer adapter, which was then attached to the male luer of the Blood Administration set. A Vacutainer Direct Blood Draw device, containing a male luer adapter, was attached to the other end of the MaxPlus. A blood collection tube was inserted into the Vacutainer device and the collection tube was filled approximately 1/3 full. Nine (9) additional samples were taken for a total of ten (10) test samples. These samples were placed on ice until their absorbances could be read.

A Vacutainer Direct Blood Draw device with male luer adapter was then connected directly to the female/female adapter before being attached to the male luer of the Blood Administration set (without the MaxPlus test sample). Ten (10) samples were taken through this open end to serve as comparison samples. These samples were also placed on ice until their absorbances could be read.

Hemolysis Determination: One “critical volume” was added to 10ml of 0.9% saline and served as the negative control. Similarly, one “critical volume” of the initial blood sample taken from the bag was added to 10ml of sodium carbonate and served as the positive control. One “critical volume” of each test sample and comparison sample was added to 10ml of 0.9% saline. Each sample was mixed gently by inverting at least 10 times. Samples were then centrifuged at 500 x g for 5 minutes. The absorbance of the supernatant of each sample was read on a spectrophotometer. Readings were taken at 545 nm using a 0.9% saline blank. After reading the absorbance of each sample, the percent hemolysis was calculated for each.



* ABS is represented as 10^2

Test Results: As indicated in the graph, on average the MaxPlus performs nearly as well as the open luer control group at preventing hemolysis during blood draw. Statistical analysis of the comparison versus test group was performed using the student t-test and Mann-Whitney rank sum test. This was performed using Jandel Sigma Stat Version 2.0.

Conclusion: Evaluation of the data from the blood draw testing indicates all of the test samples and comparison samples had percent hemolysis results well below the NIH limit of <5.0% for medical devices. Therefore, use of the MaxPlus with a “vacutainer” device was not found to cause significant hemolysis during blood withdrawal.