

# Blood Transfusion 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 of the MaxPlus Connector for Medegen MMS, Inc.

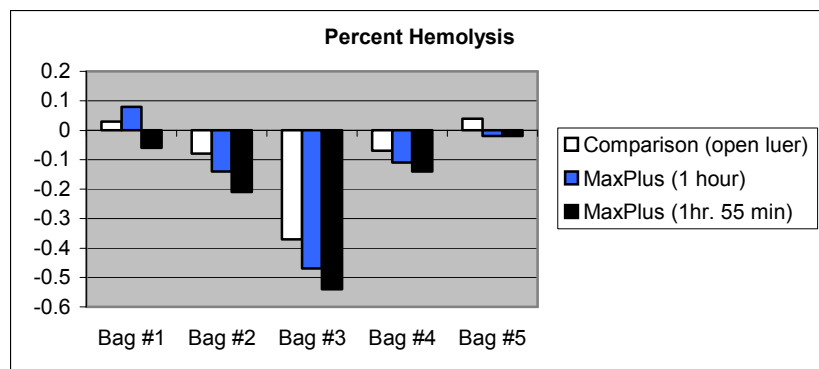
**OBJECTIVE:** The purpose of this study was to ascertain if the MaxPlus Connector causes statistically significant hemolysis during **mock BLOOD TRANSFUSION** when compared to an open (no connector) male luer.

**Method:** Five Amsino Blood Transfusion Sets, Catalog Number AS007, with standard male luer lock fittings, were used to access 500cc bags of whole citrated blood. The spiked blood bags were hung at 48 inches above head height to simulate clinical use. A test sample (female luer) was attached to the transfusion set of each blood bag. A mock transfusion was then delivered, at 10 drops per minute over a period of two hours, for each blood bag unit.

From a 1 ml sample from each bag, the “critical volume” was determined for each blood bag unit. This volume was determined by adding the appropriate amount of blood to 10ml of 0.1% sodium carbonate to result in an absorbance value between 1.0 and 0.9. The absorbance was read on a spectrophotometer (wavelength of 545 nm using a 0.9% saline blank). Blood from each bag was slowly delivered to a test tube to serve as the comparison control for each bag.

**Hemolysis Determination:** One “critical volume” (as determined for each individual blood bag unit) of the initial blood sample taken from each bag was added to 10ml of 0.9% saline and served as the negative control. Similarly, one “critical volume” on the initial blood sample taken from each 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. After reading the absorbance of each sample, the percent hemolysis was calculated for each and compared to control samples.

**Test Results:** As indicated in the graph, the MaxPlus performs statistically as well as an open luer at preventing hemolysis at periods of one hour and greater. Statistical analysis was performed using the student t-test and Mann-Whitney rank sum test. This was performed using Jandel Sigma Stat Version 2.0.



**Conclusion:** For the mock transfusion there is not a statistically significant difference between the percent hemolysis of the test samples at one hour and comparison samples, or between the test samples at 1 hour 55 minutes and comparison samples. When using the t-test to evaluate the data from the test samples and comparison samples, the results showed percent hemolysis well below the NIH limit of <5.0% for medical devices. Therefore, the MaxPlus, was not found to cause significant hemolysis during blood infusion.