

Blood Compatibility Studies for the CLAVE[®] Connector

Introduction

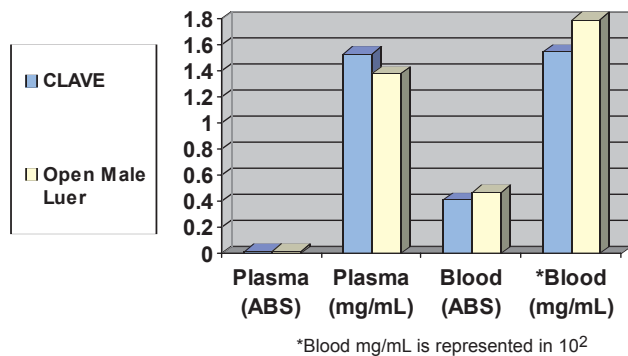
The CLAVE Connector manufactured by *ICU Medical, Inc.* is evaluated in this report for use with blood. Concerns in the clinical environment relate to the percent hemolysis caused by an IV Connector such as the CLAVE, and the ability to effectively flush the product with normal saline (0.9% Sodium Chloride). The following two independent studies describe the rate of hemolysis measured with ASTM standards and a Flush Analysis.

ASTM Hemolysis Study

An independent study was conducted at NAMSA of Irvine, California to evaluate the rate of hemolysis for the CLAVE Connector as compared to an open ended luer (no connector). Ten ABBOTT blood transfusion sets Catalog No. 9155-68 with standard male luer lock fittings were used to access 500cc bags of whole citrated blood. The blood transfusion set was hung at 72" head height to simulate clinical use. The ABBOTT set was used as the control to demonstrate the best case clinical scenario, where blood would be delivered through an open ended luer. All hemolysis readings were done with the use of a spectrophotometer and obtained according to ASTM standards of practice.

Procedure:

Blood was delivered through the transfusion set to obtain the control sample. Ten samples of the CLAVE were then attached to the ten blood delivery sets as described in our model. The 500cc of blood was delivered through the connectors over a period of two hours and samples were taken for hemolysis evaluation at 250cc and 475cc using the spectrophotometer. The following graph shows how the CLAVE Connector compares to an open ended male luer in regards to hemolysis.



Conclusion:

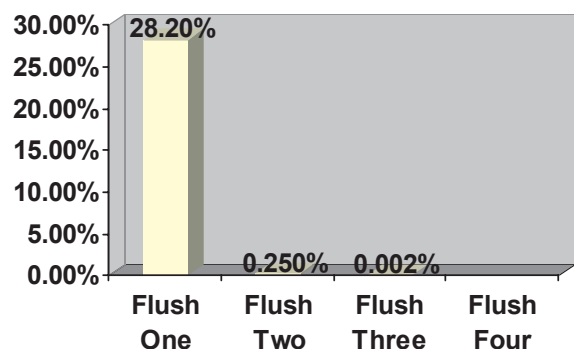
Using t-Test $P(T \leq t)$ one tail with a P score of greater than 0.05 with a 95% confidence level, this study shows that no significant hemolysis occurs with the use of the CLAVE Connector.

Flush Analysis

The CLAVE Connector has also been challenged for its ability to be effectively flushed with normal saline following the administration or aspiration of blood. Sterile normal saline (NS) was used in this study to demonstrate the worst case, or most benign flushing agent.

Procedure:

A 500cc bag of bovine blood was warmed to 98.6° F and a 2" extension set was attached. Ten samples of the CLAVE Connector were individually attached to the extension set distal to the blood bag and 5cc of blood was aspirated through the connector into a syringe and discarded. Each of the CLAVE Connector samples then received four consecutive 5cc bolus injections of NS. The bolus washes were collected in test tubes and sent to BioScreen Laboratories of Torrance California, an independent contract laboratory to measure the hemoglobin residual in mcg/DL. The following chart shows the percent of residual hemoglobin after each of the four 5cc flushes.



Conclusion:

The first bolus flush used to clear the connector of blood contained about 28% hemoglobin in the wash. The fourth flush contained less than <0.0001% hemoglobin. This study demonstrates that blood residue can effectively be flushed from the CLAVE Connector using normal saline.

Recommendation:

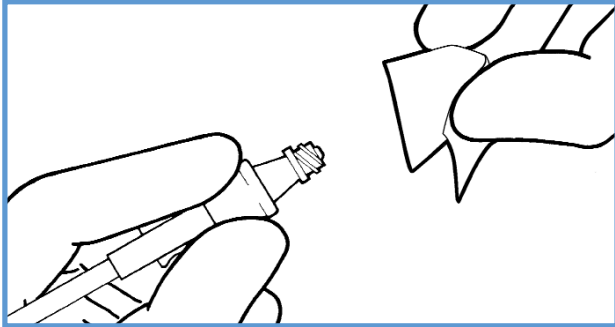
It is recommended the CLAVE Connector be flushed after each use in accordance with facility protocol.

Blood Aspiration Using the CLAVE Connector

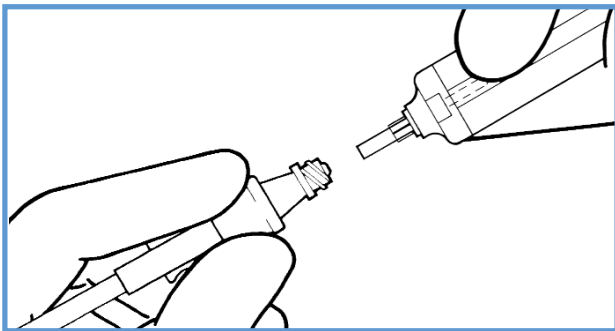
Vacutainer or Double Connector for blood tube access.

DIRECTIONS FOR USE

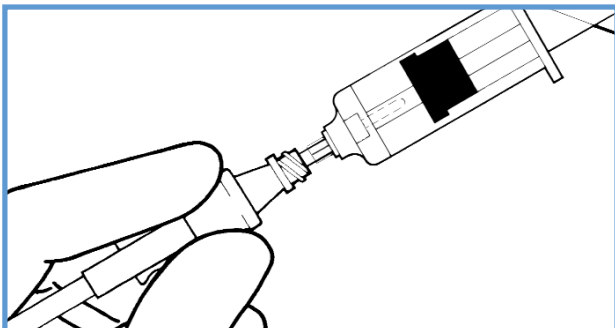
Using direct blood tube holder access.



1. Swab CLAVE Connector in accordance with facility protocol.



2. Using tube holder with luer slip adapter, attach holder to CLAVE. Push together and twist a quarter turn until tight.

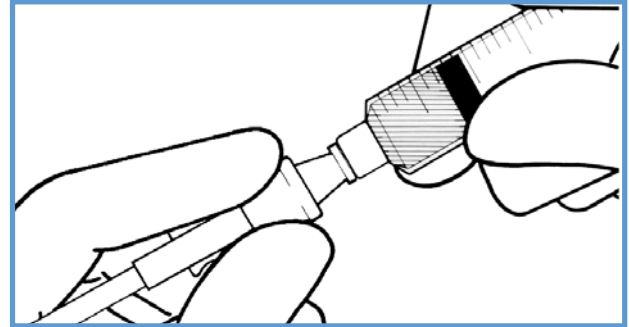


3. Insert blood tube into holder assembly and aspirate into blood tube. Remove blood tube for sample.
4. Remove tube holder from CLAVE by twisting away from CLAVE until loose. Take care not to unscrew luer slip adapter from tube holder.
5. Flush CLAVE Connector in accordance with facility protocol following blood aspiration.

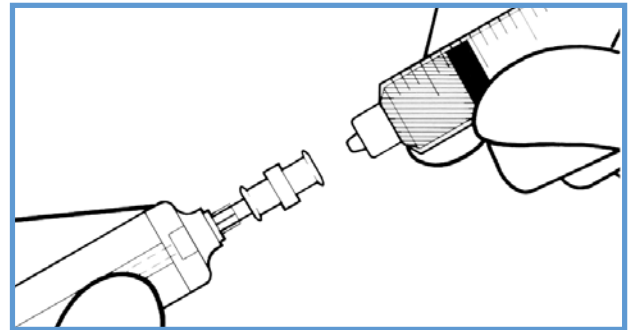
NOTE: Do not change CLAVE Connector after use with blood. Change CLAVE in accordance with facility protocol.

DIRECTIONS FOR USE

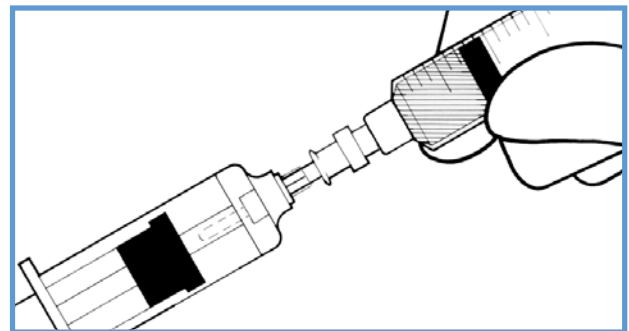
Using DC blood transfer assembly.



1. Swab CLAVE Connector in accordance with facility protocol.
2. Attach syringe to CLAVE. Push together and twist until tight. Aspirate blood in accordance with facility protocol.



3. Attach double connector to blood tube holder assembly by pushing luer slip into DC and twisting until tight.
4. Attach syringe with the blood sample to the needless blood transfer assembly.



5. Insert blood tube into holder. Blood will transfer from the syringe into the blood tube. When transfer is complete, remove blood tube from assembly.
6. Dispose of needless blood transfer assembly as one unit in accordance with facility protocol. Do not disassemble.