

Blood Compatibility Studies for the CLC2000®

Introduction

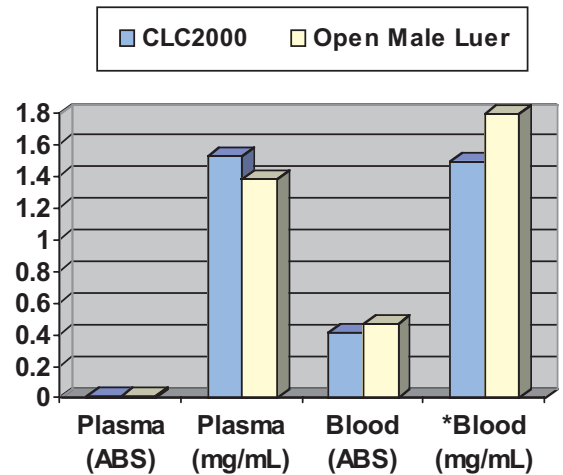
A new intravenous connecting device by ICU Medical is evaluated in this study to determine its performance when used with blood. Concerns in the medical marketplace are commonly directed toward the use of a product and whether it functions well with, or is compatible for use with applications involving either the aspiration or administration of blood. ICU Medical has designed the CLC2000 to be safe and effective for the use of blood. Three independent studies were done on the CLC2000 in order to determine its performance as compared to standard IV connectors.

ASTM Hemolysis Study

An independent study was conducted at NAMSA of Irvine, California to evaluate the rate of hemolysis occurring in the CLC2000. 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. Blood was then delivered through the transfusion set to obtain the control sample. The ABBOTT set was used as a 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:

Ten samples of the CLC2000 were attached to the ten blood delivery sets described in our model. The 500cc of blood was delivered through the connectors over a period of two hours and samples were taken for evaluation of percent hemolysis at 250cc and 475cc using the spectrophotometer. The adjacent graph shows how the CLC2000 compares to an open ended male luer in regards to the rate of hemolysis.



*Blood (mg/mL) is represented as 10².

Conclusion:

The CLC2000 performs significantly as well in preventing the incidence of hemolysis as using an open ended luer (no connector). Using t-Test P(T<=t) one tail with a P score of greater than 0.05 with a 95% confidence level, in all cases this study demonstrates that no significant hemolysis occurs with the use of the CLC2000.

Flow Rate Study

In a different independent study the flow rate characteristics of the CLC2000 with blood were measured under a clinical model at ICU Medical, Inc. San Clemente, California. The clinical model used a 500cc bag of whole citrated blood hung at 36" and 48" head heights. An ABBOTT blood transfusion set Catalog No. 9155-68 with standard luer lock fitting was used to deliver the blood. The blood was warmed to 98°F and the flow rate at both head heights was measured through the CLC2000. A 16 gauge needle was used as the control and a baseline flow rate measurement was taken. The results are illustrated in the following table.

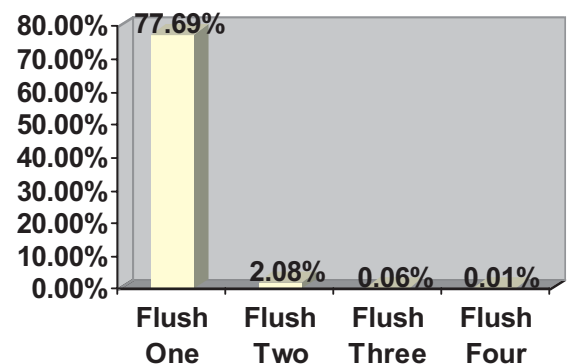
	CLC2000	16 Gauge Needle
36" Head Height	63.6mL/min	57mL/min
48" Head Height	80.1mL/min	72mL/min

Conclusion:

Results indicate that the CLC2000 has a greater flow rate of whole citrated blood at 36" and 48" head heights than that of a standard 16 gauge needle.

Flush Analysis

Immediately following the flow rate study the CLC2000 samples were used to conduct the flush analysis. In the flush analysis each of the 20 samples received four consecutive 5cc bolus injections of sterile 0.9% sodium chloride (normal saline). Each of the individual 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 first bolus flush used to clear the connector of blood contained about 78% hemoglobin in the wash. The adjacent chart shows the percent of residual hemoglobin after each of the four 5cc flushes.



Conclusion and Recommendations:

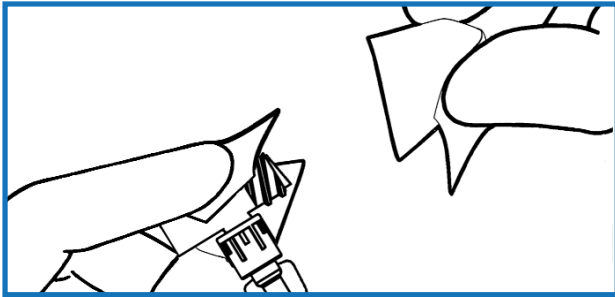
This study demonstrates that the CLC2000 can be effectively flushed to remove blood residue with the use of normal saline. It is recommended the CLC2000 be flushed after each use according to facility protocol.

Blood Aspiration Using the CLC2000®

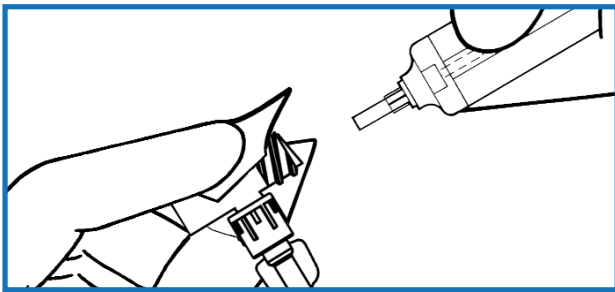
Tube Holder or Double Connector for blood tube access.

DIRECTIONS FOR USE

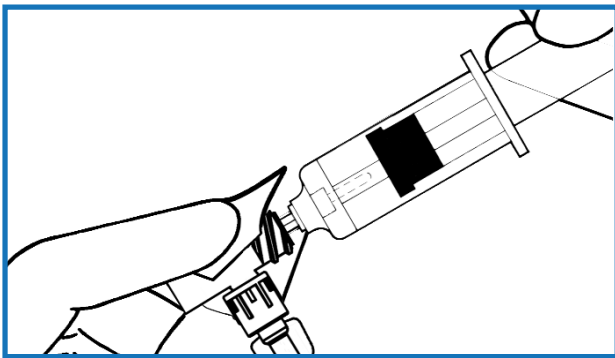
Using direct blood tube holder access.



1. Grasp CLC2000 using 2x2 swab. Disinfect female luer in accordance with facility protocol.



2. Using tube holder with luer slip adapter, attach barrel to CLC2000. Push together and twist a quarter turn until tight.

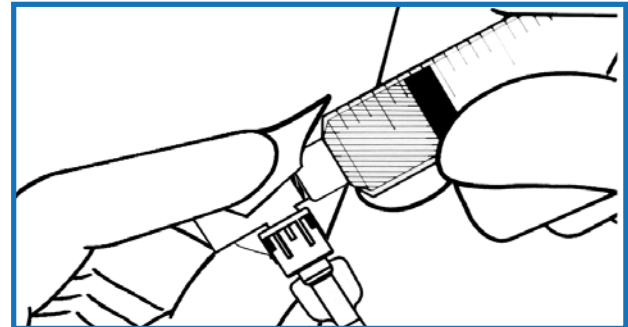


3. Insert blood tube into holder assembly and aspirate into blood tube. Remove blood tube for sample.
4. Remove tube holder from CLC2000 by twisting away from CLC2000 until loose. Take care not to unscrew luer slip adapter from tube holder. 2x2 swab may be used to remove any blood residue.
5. Flush CLC2000 in accordance with facility protocol following blood aspiration.

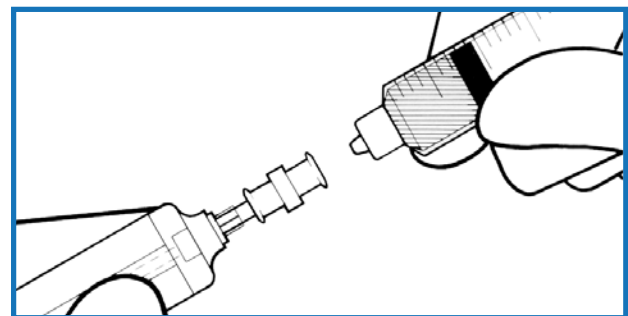
NOTE: Do not change CLC2000 after use with blood. Change CLC2000 in accordance with facility protocol.

DIRECTIONS FOR USE

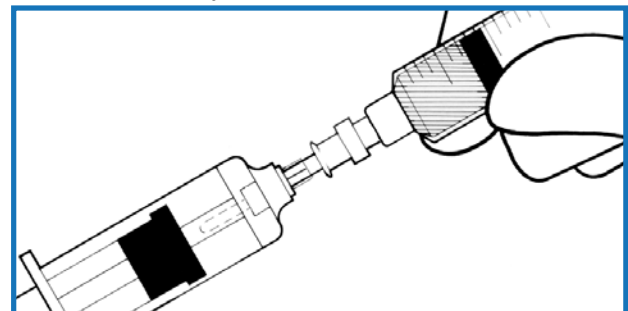
Using DC blood transfer assembly.



1. Grasp CLC2000 using 2x2 swab. Disinfect female luer in accordance with facility protocol.
2. Attach syringe to CLC2000. 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 needleless 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 needleless blood transfer assembly as one unit in accordance with facility protocol. Do not disassemble.