

TO: File

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SUBJECT: Blood Separator and the Like

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ABSTRACT:

This presentation describes a simple disposable device that offers a 30 second serum or plasma extraction from whole blood. It is a filtration device to be used in lieu of centrifugation. The device delivers about ½ cc of serum from a 2cc BD Vacutainer™ collection tube.

The Blood Separator's attractive features are:

- Cost reduction, labor and supplies
- Plasma derivation without delay minimizes number of required tubes.
- Time saving
- Sample security, protection from contamination
- Protection of the operator (reduced biohazard exposure)
- Simplicity of operation
- Error reduction

BACKGROUND

As traditionally conducted, a set of adult blood tests necessitates collection of whole blood with 3 to 6 evacuated blood collection tubes (Vacutainer™, Becton Dickinson) each with 5 to 10 milliliter capacity. Each tube contains one of several chemicals intended to preserve the plasma from coagulation. Serum is obtained after blood has been kept for a period of time in a tube without an anticoagulant, allowing the formation of a fibrinogen clot.

If plasma is extracted prior to any appreciable blood exposure to air the number of different tubes may be reduced as the extract is shared with multiple tests.

The availability of sensitive biological assays makes it possible to run accurate tests employing much smaller sample volumes than traditionally used. For instance, multiple tests can be preformed employing less than 1/2 milliliter of plasma or serum (generally diluted 2 or 4 to 1 with buffer) using multiwell plates or microarray techniques. No simple and rapidly operable device is presently available for providing serum or plasma extraction at this volume.

The need for small volume blood collection itself has been recognized for blood tests as assay precision has improved and smaller volumes are processed faster. This has always been the case when working with infants and small animals. Evacuated collection tubes have long been available for obtaining a fraction of a milliliter or a few milliliters of blood. The 2 cc Vacutainer™ used here is a standard product.

Extremely small blood volumes are traditionally obtained by use of a simple skin puncture. The finger for instance, is pricked with a lancet and then squeezed until a fluid drop of, e.g., 5-20 microliters, is obtained.

In most cases blood samples used for assays are further processed. The sample may be mixed with a stabilizing agent or anti-coagulant, contained within the collection tube, to permit storage at room temperature or to prevent clotting prior to separation. Depending on the assay for which the sample is intended, it may also be necessary to add diluents and/or reagents to facilitate assay processing.

It is desirable to work efficiently with blood samples of the order of 1 or 2 milliliter. Most protein analyzers for instance necessitate 50 to 100 micro-liters of diluted serum or plasma per test and it is common to require 10 individual tests per sample. Multiplex biomarker cassettes, e.g. those employing micro arrays, typically run 8 to 12 assays simultaneously and call for 100 to 200 micro-liter of serum or plasma frequently diluted 1 to 1.

The device presented here meets these needs without requiring use of a centrifuge or other inconvenient separation techniques.

PRODUCT DESCRIPTION

Figure 1 shows the Blood Separator appropriate for a 2 cc Vacutainer™ (1/2 cc of plasma). Figure 2 shows sections and details of the construction of the device as well as its operating principle.

A choice of two Collection Capsules are offered: the closed capsule shown in Figure 2 and the septum tipped capsule of Figures 1 & 3.

The finger pump transfers the blood from the Vacutainer™ to the filtering chamber. When the lower end of the device is unsealed, the second push forces the blood through the filter mesh where cells are captured without clogging the filter. Then a second fine pore filter insures that no cells flow through and stops any debris from the first filter system from flowing into the serum.

The Collection Capsule can be a simple receptacle or septum fitted for pipette extraction of blood plasma or serum. The device permits all functions to be performed rapidly and with minimum danger of exposure of the operator or contamination of the sample while enabling standard evacuated collection tubes to be used.

USING THE BLOOD SEPARATOR

The separation process is quite simple and can be accomplished in less than 30 seconds. Figure 2 shows the separation process:

1. The process starts with a blood sample collection with a conventional evacuated collection tube, (Vacutainer™). When inverted with its access seal/septum end down, blood may reach level L, occupying approximately 70% of the collection tube.
2. (a) Holding the Blood Separator vertically, open end up, as shown in Figure 2A, the collection tube is introduced and pressed down gently into the main body. A first gentle stop is

sensed when the needle pierces the septum of the Vacutainer™ as shown on Figure 2B. The tube should be pushed down to the bottom stop to the position shown in Figure 2C and then released. The downward motion pressurizes both the collection tube and the Blood Separator.

(b) Some of the compressed air passes through hypodermic needle and into the Vacutainer™ and bubbles to the top of the collection tube pressurizing the air at the top. When released, the collection tube rises to close to the original position pushed up by the compressed air between the collection tube and the closed lower end of the main body of the Blood Separator, as exemplified in Figure 2D. Simultaneously the pressure within the collection tube is lowered, causing the air volume to expand, pushing out blood into the body of the Blood Separator.

3. Partially unscrew the serum/plasma Collection Chamber 1/2 or 1 turn. The coarse threads will permit air to escape through the filter blocking any liquid.

4. Repeat step 2(a). With no opposing air pressure, the Vacutainer™ and puppet act as a piston forcing blood through the filter, and the filtrate (plasma or serum) enters the Collection Chamber. This is shown in Figure 2E.

5. Fully unscrew the cover of the Collection Chamber and pipette a desired volume of filtrate through an exposed septum as shown in Figure 3

6. Close the separation device with the supplied cover and discard or archive the unit.

It may be desirable to repeat steps 2(a) and 2(b) in order to maximize the blood volume to be expelled from the Vacutainer™.

CONCLUSION

The Blood Separator permits the nurse or the phlebotomist who draws the blood to extract the plasma without delay, minimizing opportunities of mislabeling or spoilage as well as reducing the total number of necessary tubes.

A device sharing the filtration cartridge and concept is also available. It is shaped as a conventional 5 cc syringes.

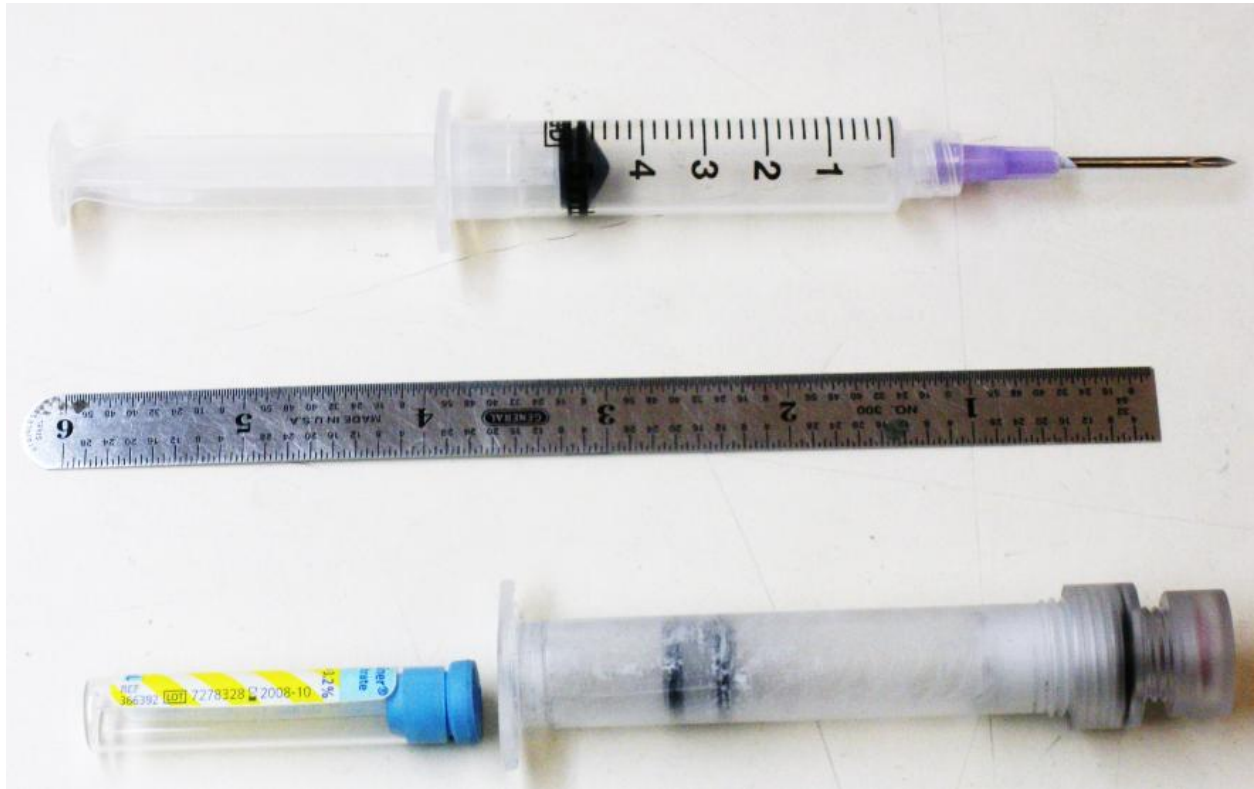


Figure 1- Blood Separator appropriate for a 2 cc Vacutainer™ (1/2 cc of plasma)

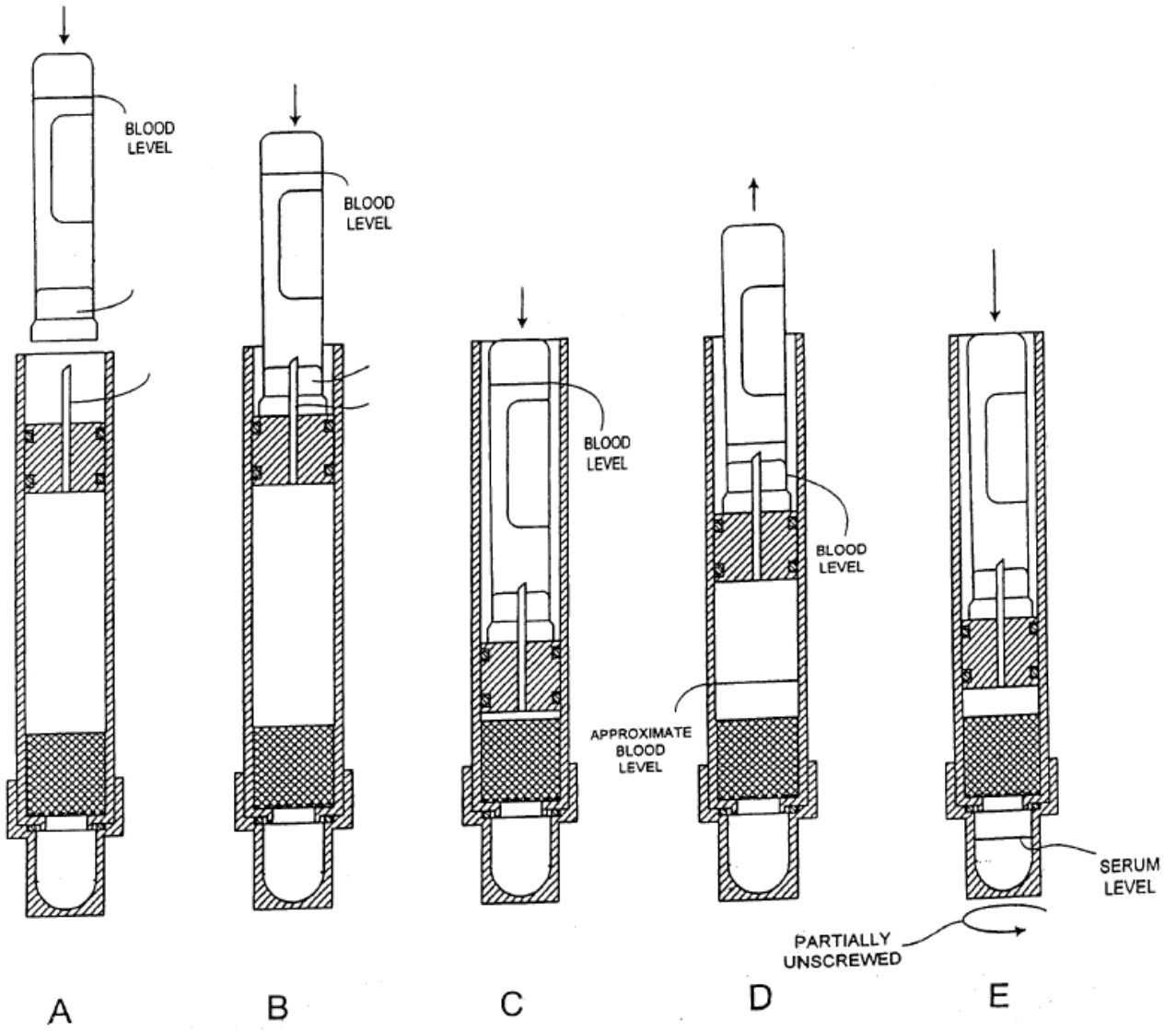


FIGURE 2 - Blood Separator in process

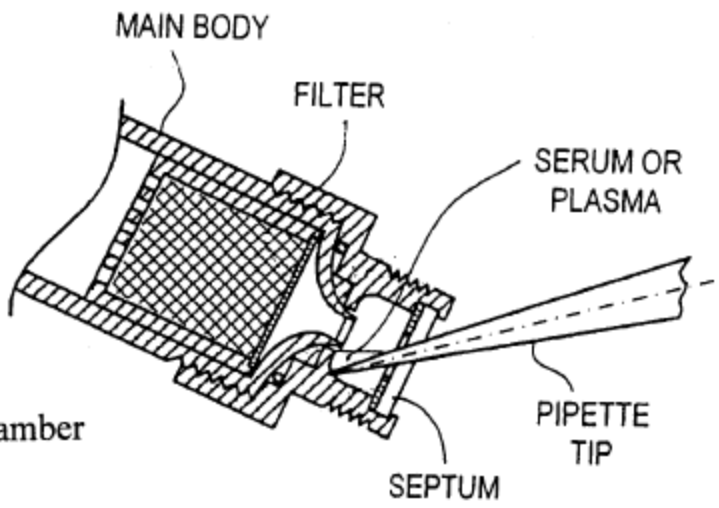


FIGURE 3
Septum tipped Collection Chamber