

Nov. 4, 1952

F. J. SCHILLING ET AL

2,616,796

APPARATUS FOR DETERMINING A COAGULATION FACTOR OF BLOOD SAMPLES

Filed Nov. 25, 1950

Fig. 1.

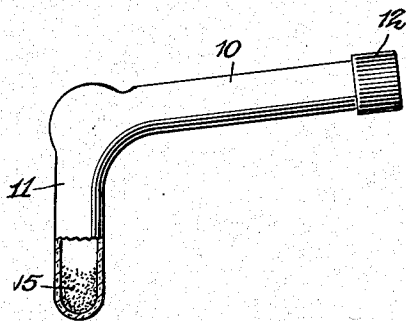


Fig. 2^a

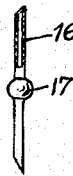


Fig. 3.

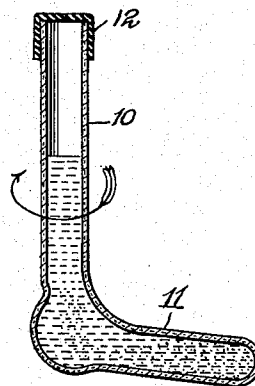
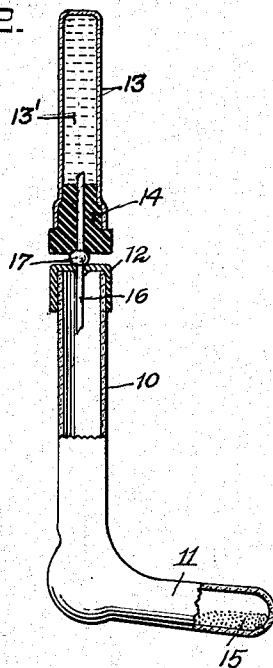


Fig. 2.



INVENTOR.
Fred J. Schilling
and Albert DeNatale
By
Munn, Liddy & Glacum
Attorneys

UNITED STATES PATENT OFFICE

2,616,796

APPARATUS FOR DETERMINING A COAGULATION FACTOR OF BLOOD SAMPLES

Fred J. Schilling, New York, and Albert De Natale,
Bayside, N. Y.

Application November 25, 1950, Serial No. 197,552

3 Claims. (Cl. 23-253)

1

This invention relates to a new and improved method and apparatus to permit the physician at the bedside of a patient to quickly and easily determine a coagulation factor of blood taken from the patient in cases where the patient may be suffering from blood clot conditions of one form or another.

In accordance to previous procedures with patients suffering from these conditions, the well known prothrombin test has been employed to determine a coagulation factor of the patient's blood of which samples have been extracted. The only difficulty with this test is that it generally is required that the samples thus obtained have to be processed in conformity with this well known test in a laboratory where there is the necessary equipment. This naturally has involved the expenditure of time, and in some cases this time factor has been exceedingly important where the condition of the patient called for a much more rapid determination than has hitherto been available.

The determination of this coagulation factor which relates to the nature of the blood of the patient, and the time it takes to coagulate, is a very important factor to determine prior to the administration to the patient of certain anti-coagulation drugs such as Dicumarol and/or Tromexan.

The main object of this invention is to provide a simple and efficient and rapid method and apparatus whereby the physician at the bedside of the patient may take samples of his blood and quickly and easily process the blood to determine the coagulation time factor there rapidly and easily.

A further object is to provide a simple device in the form of a tube, preferably L-shape, of glass or similar material which is closed at an open end with a hermetically sealed cover, such as rubber, which is penetrable and contains a predetermined quantity of coagulant such as stable thromboplastin in dry powdered form. This tube, with the powdered coagulant therein forms part of a kit which the physician may take with him to the bedside of the patient. To complete this kit, there is provided a small vial in which is disposed a quantity of diluent and the vial is sealed off by a penetrable rubber stopper. With this vial there is provided a special needle so constructed that it may penetrate the stopper only to a predetermined extent. This needle is hollow and open at both ends and, after it has been inserted into the vial, the vial and the needle are inverted and the other end of the needle inserted through the hermetic seal on the above mentioned tube so that a predetermined amount of diluent may be drawn into the tube by reason of the vacuum therein.

An ordinary pipette is then employed to draw a predetermined amount of blood from the patient and before the pipette is so employed it is

2

rinsed in any suitable manner by a sodium oxalate solution. When the blood sample is thus in the pipette the seal of the tube is taken off and the blood sample is blown into the tube to mix with the coagulant which is now in liquid form. From the moment the blood is introduced, the tube is grasped in the hand and spun back and forth to mix the elements therein and until the blood starts to coagulate. From the moment of blood introduction a stop watch is started so that the exact time it takes to coagulate the blood in this manner may be noted. This manipulation of the tube in the hand of the physician is performed at room temperature which is noted.

It will therefore be seen that we have provided a simple method which comprises the disposition in a hermetically sealed tube of a predetermined quantity of a coagulant in stable form, the introduction into the tube of a predetermined quantity of diluent by penetration of the seal, followed by the introduction of a definite quantity of blood sample after which the tube is rapidly spun in the hand at room temperature and under accurate notation of the time consumed from the introduction of the blood until it coagulates. This simple method may be employed at the bedside or in the doctor's office and does not require reference to a laboratory with the consequent loss of time in making the necessary determination, upon which depends the application of the proper anti-coagulation drug.

Merely for the purpose of illustration, a preferred form of the apparatus employed in practicing this invention is shown in the drawings, of which:

Fig. 1 is a side elevation of the hermetically sealed tube containing a powdered coagulant;

Fig. 2 is a general side view of the tube shown in Fig. 1 with portions broken away and showing associated therewith a diluent vial;

Fig. 2A is a detail showing a special needle used in connection with the diluent vial for the introduction of diluent into the tube; and,

Fig. 3 is a section showing the tube with the coagulant, the diluent, and the blood sample therein.

Referring now merely to the specific form of the apparatus shown in the drawings, which is employed to make effective this new method of determining coagulation time factors of blood, it will be seen that one element of the apparatus comprises a tube, preferably of glass, and of L-shape, having a vertical leg 10 open at its upper end, a connected lower horizontal leg 11, and a sealing cap 12, preferably of rubber, whereby the tube may be hermetically sealed and a predetermined vacuum established therein.

Another element of the apparatus is a glass vial 13 adapted to contain any suitable diluent 13' such as distilled water. The open end of this vial is closed, preferably by a rubber stopper 14.

Before the tube above mentioned is hermetically sealed off, a predetermined amount of coagulant 15 in dry powdered form is disposed therein. This coagulant is preferably thromboplastin, which in this form is stable, whereas in solution it is unstable.

Another element of the apparatus is a special needle shown in Fig. 2-A which is in the form of a hollow capillary tube 16 open at each end, and with the ends beveled to facilitate penetration. This needle, intermediate at length, is provided with an enlarged portion 17 or similar element to act as a stop or abutment as and for the purposes to be described. It is to be clearly understood that this enlargement may take other forms, but in the form shown it is an enlarged bead on the outside of the needle and does not obstruct the passage through the needle from one end to the other of any fluid. The only other element which is used in connection with this novel procedure is an ordinary pipette used for the purpose of drawing the predetermined amounts of blood into it from the patient for the purposes hereinafter set forth and not shown, since it is a well known device.

With these elements of the apparatus provided in a suitable kit or case, the physician has ready at hand simple means for an accurate, quick, and easy determination of the coagulation factor of the patient whether the patient is seated in his office, or the physician is at the bedside of the patient, and this determination can be effected without the necessity of referring to a laboratory, which involves loss of time and added expense. In employing the above apparatus, the physician first takes the needle shown in Fig. 2-A and thrusts one end of it through the stopper 14 on the vial 13. He then inverts the vial with the needle thus disposed and projects the other end of the needle 16 through the seal 12 on the tube containing the stable coagulant. The capillary structure of the needle 16 will prevent diluent from flowing out of the vial even when the vial is inverted until the needle has been projected through the seal 13, whereupon the influence of a vacuum in the tube will cause a definite amount of diluent to be drawn out of the vial into the tube to mix with the coagulant powder 15. It will be, of course, clear that the stop member or exterior enlargement 17 intermediate the length of the needle 17 will limit penetration of the needle into the stopper 14 and through the seal 12.

The next step taken by the physician is to prepare a desired surface of the skin of the patient in any well known manner prior to the extraction of a blood sample. He then takes the usual pipette with the flexible rubber tubing connected to one end to be placed in his mouth and then, as a preliminary step, sucks up into the pipette a small amount of sodium oxalate solution in order to thoroughly rinse the interior surface of the pipette. This is done to prevent the blood drawn into the pipette from starting to coagulate in the pipette. The rinsed pipette is then used in the regular manner and is, as usual, calibrated on its exterior surface so that a predetermined amount of blood may be drawn up into it.

Just prior to this step of taking the blood sample from the patient, the vial 13 and the seal 12 are removed from the tube containing the coagulant now in solution, and the blood sample is blown into the tube from the pipette. At this instant of time, the physician grasps

the upper end of the tube and starts to spin it back and forth in his hand, while at the same time starting a stop watch so that accurate measurement of the time it takes the blood in the tube to coagulate may be measured. All these steps are conducted at ordinary room temperature and permits this time factor to be quickly and easily determined, whereby based on the value of the time factor, the desired dose of anti-coagulation drug can then be selected. In many conditions and circumstances where time is of the essence, this accurate, rapid, and easy method, and the simple apparatus employed may well be of extreme importance.

While the invention has been described in detail and shown with respect to the accompanying drawings, it is not to be limited to such details, since many changes and modifications may be made in the invention without departing from the spirit and scope thereof. Hence, it is desired to cover any and all forms and modifications of the invention which may come within the language and scope of any one or more of the appended claims.

We claim:

1. A kit for determining the coagulation time factor of blood including, in combination, an L-shaped vial having an opening at the top thereof, a penetrable closure disposed over said opening, a second vial having an opening and a penetrable closure disposed thereover and being adapted to contain a liquid, and a needle having a capillary passage, said needle detachably connecting said vial by insertion through said penetrable closures so that the liquid may flow from the second vial to the L-shaped vial, said L-shaped vial being adapted for oscillatable rotation when detached from said needle.

2. A kit for determining the coagulation time factor of blood including, in combination, a vial having a body portion, an outwardly extending portion at the bottom of said body portion, and an opening at the top of said body portion, a penetrable closure disposed over said opening, a second vial having an opening and a penetrable closure disposed over said opening, and a capillary needle inserted through each closure so as to connect said vials, said first mentioned vial being detachable from said needle and adapted to receive a coagulating material, a diluent, and blood.

3. The combination with a vial having a penetrable closure and a capillary needle adapted for insertion through said closure, of an L-shaped vial having an opening at one end and a penetrable closure disposed over said opening, said L-shaped vial being detachably connected to said first mentioned vial by means of said needle and being designed for oscillatable rotation.

FRED J. SCHILLING.
ALBERT DE NATALE.

REFERENCES CITED

The following references are of record in the file of this patent:

Wintrobe, "Clinical Hematology," 2d ed., Lea and Febiger, Philadelphia, April 19, 1949, pages 207-208.

Souter and Kark, "Quicks Prothrombin Test Simplified by the Use of Stable Thromboplastin," Am. Jour. Med. Sci. 200, page 603 (1940).

"How to Make Standard Volumetric Solutions in a Few Minutes," E. H. Sargent & Co., Chicago, Ill. March 31, 1947, 4 pages.