Sept. 8, 1970 M. MASS 3,527,569

PROTHROMBIN TIMER

Filed Oct. 6, 1967 2 Sheets-Sheet 1

Fig. 1.

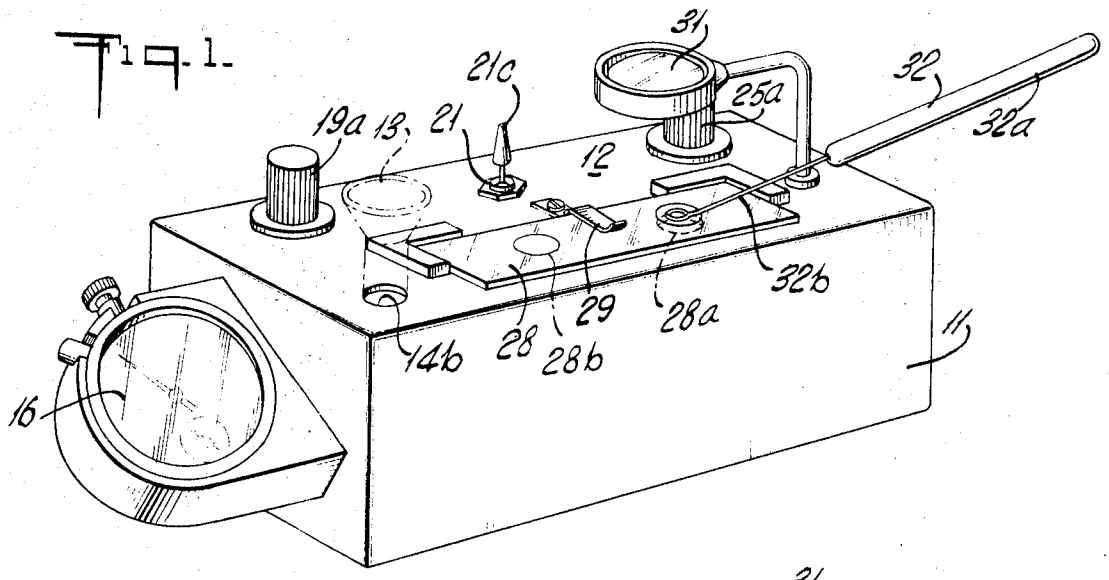
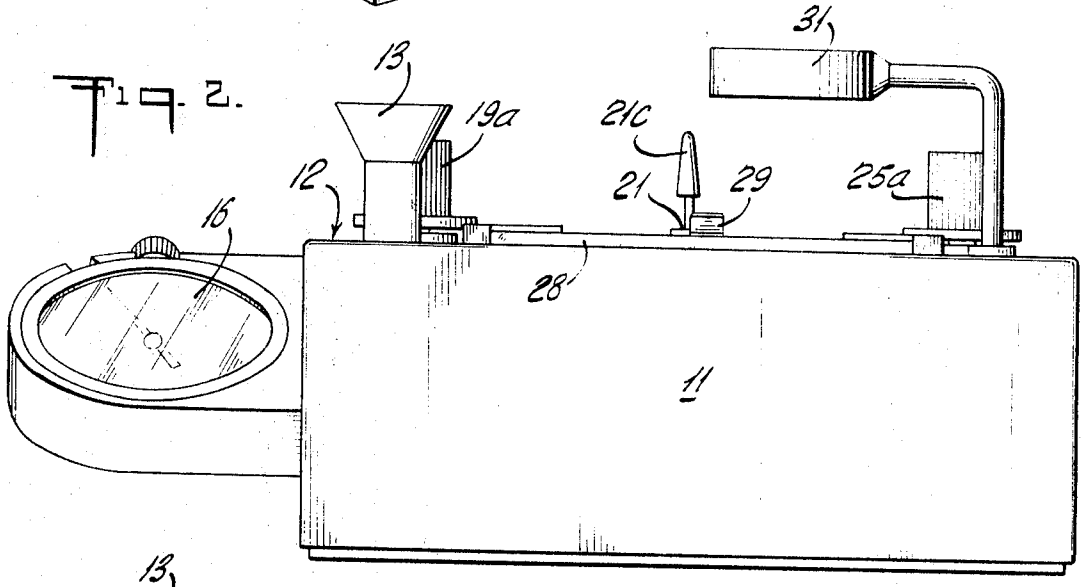


Fig. 2.



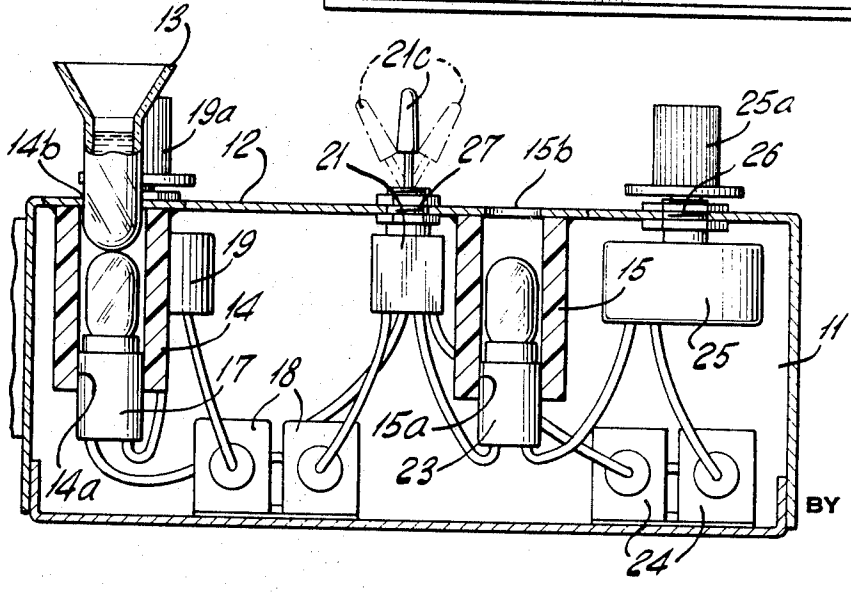


Fig. 4.

INVENTOR
MORRIS MASS

BY

Nolte & Nolte
ATTORNEYS

Sept. 8, 1970 M. MASS 3,527,569

PROTHROMBIN TIMER

Filed Oct. 6, 1967 2 Sheets-Sheet 2

Fig. 3.

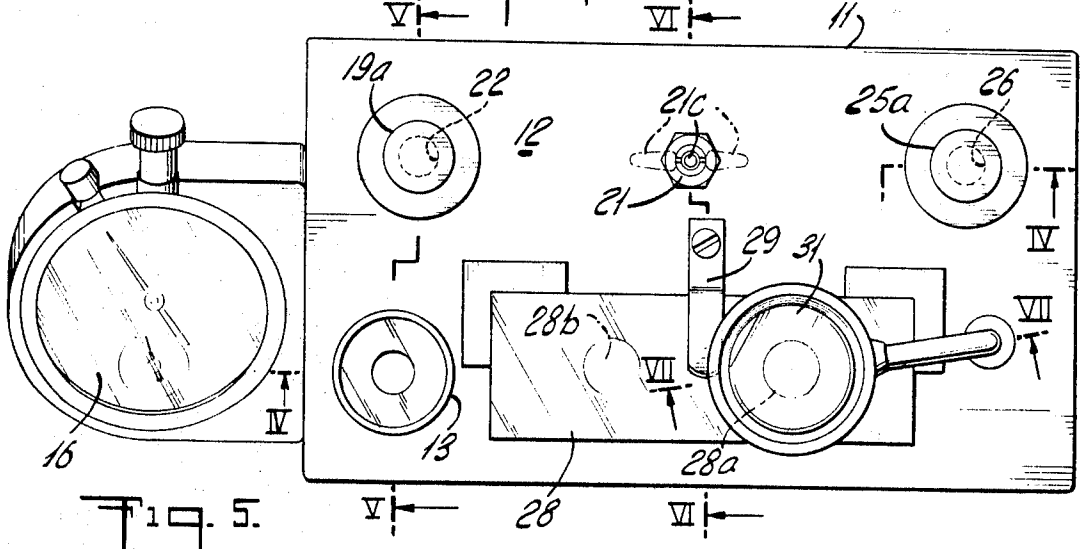


Fig. 5.

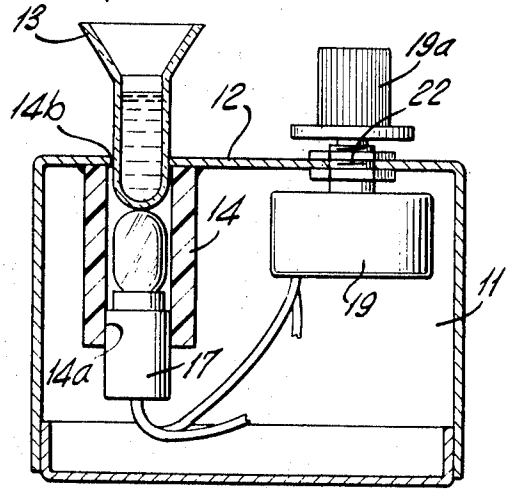


Fig. 6.

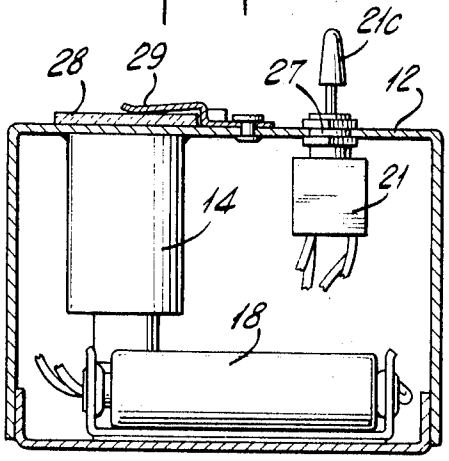


Fig. 8.

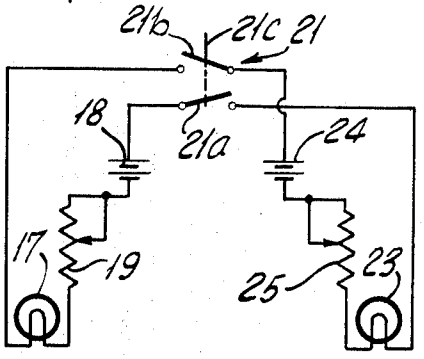
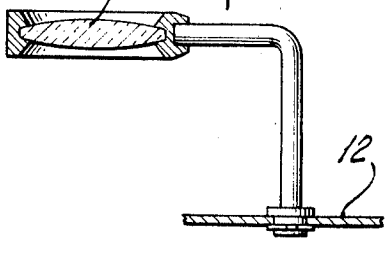


Fig. 7.



INVENTOR
MORRIS MASS

BY

Nolte & Nolte
ATTORNEYS

United States Patent Office 3,527,569 Patented Sept. 8, 1970

3,527,569

PROTHROMBIN TIMER

Morris Mass, Kew Gardens, N.Y., assignor to Haematronics, Inc., New Rochelle, N.Y., a corporation of New York

Filed Oct. 6, 1967, Ser. No. 673,511
Int. Cl. G01n 33/16, 11/00
U.S. Cl. 23—253 4 Claims

ABSTRACT OF THE DISCLOSURE

Includes first and second channels each having a first end opening in a housing and a second end opening in a principal surface of the housing. The second end opening of each of the first and second channels is adapted to accommodate a receptacle for blood and reagent. A timer is on the housing. A heater is in the housing at the first end of the first channel and a light is in the housing at the first end of the second channel. Low voltage batteries energize the heater and the light and a first variable resistor is connected in a first circuit portion in the housing with the heater and the batteries for varying the magnitude of electrical energy supplied to the heater and a second variable resistor is connected in a second circuit portion in the housing with the light and the batteries for varying the magnitude of electrical energy supplied to the light. A switch is connected in the first and second circuit portions and selectively energizes and deenergizes the heater and the light.

BACKGROUND OF THE INVENTION

Field of the invention

The present invention relates to a prothrombin timer. More particularly, the invention relates to a method and apparatus for determining the prothrombin time of whole blood which may be obtained from a finger tip or an ear lobe.

Description of the prior art

Blood clotting is the formation of a semi-solid gel or clot from components of whole blood that come in contact with damaged tissues or with a surface that it wets. The process is important in closing broken blood vessels and in stopping loss of blood from small wounds. Clotting occurs in the blood of vertebrates and of some invertebrates, including anthropoids. In vertebrates and certain anthropoids, the critical phenomenon in blood clotting is the conversion of soluble protein, fibrinogen, to an insoluble fibrous form known as fibrin. This change is brought about by the enzyme thrombin. Thrombin is not normally present in blood plasma, but is formed during the initiation of clotting from prothrombin, a plasma constituent. Conversion of prothrombin to thrombin requires calcium ions, and clotting may be prevented by adding to the blood such substances as citrate or oxalate, which combine with calcium ions. Formation of thrombin also requires a substance known as thromboplastin, which is formed when blood platelets break down, as they do when in contact with wettable surfaces or damaged tissues, which damaged tissues may also liberate thromboplastin. Formation of thromboplastin may be prevented by the substance heparin, which is formed by the basophil granulocytes, or one type of white blood cell, and which probably has a normal role in preventing clotting of blood while in the vessels. The steps in the clotting of vertebrate blood are thus:

Platelets+tissue and plasma components→Thromboplastin

$$\text{Prothrombin} \xrightarrow[\text{Calcium}]{\text{Thromboplastin}} \text{Thrombin}$$

$$\text{Fibrinogen} \xrightarrow{\text{Thrombin}} \text{Fibrin}$$

The clotting of invertebrate blood may also involve two stages or may occur in one stage. White blood cells break down or injury or contact and liberate a thrombin-like substance. Invertebrate thrombins do not act on vertebrate fibrinogens, nor do vertebrate thrombins act on invertebrate fibrinogens.

The determination of prothrombin time of blood is most often a matter of life or death. A known method of determining prothrombin time involves hospitalizing the patient, obtaining a blood sample intravenously, removing the calcium from the blood, placing the blood in a centrifuge to obtain the plasma and adding a reagent to the plasma in a test tube to determine the prothrombin time. The test is time consuming and therefore tends to be inaccurate in result, as well as detrimental to the patient, since the test results must be reported very promptly and the test itself is completed in seconds.

In the known method, the substance simplastin or the substance thromboplastin is placed in a test tube and heated to a determined temperature such as, for example, 37° or 380° C. A determined amount of the patient's blood plasma is added to the test tube contents and a stop watch is started simultaneously with thhe addition of such blood plasma. The instant that the contents of the test tube clot, the stop watch is stopped and the elapsed time is recorded. The elapsed time is the prothrombin time and is normally from 11 to 14 seconds.

SUMMARY OF THE INVENTION

The principal object of the present invention is to provide a new and improved prothrombin timer. The present invention provides a new and improved method and apparatus for determining the prothrombin time of the whole blood. The prothrombin timer of the present invention avoids the disadvantages of the known methods and apparatus. The present invention utilizes blood from the fingertip or ear lobe of the patient and thereby avoids the necessity of a centrifuge, sterile syringes, sterile hypodermic needles or sterile test tubes which are required in known methods utilizing intravenously obtained blood. The prothrombin timer of the present invention is portable and lightweight and may thus be utilized as and where desired, providing test results immediately. The prothrombin timer of the present invention is accurate, efficient, effective and reliable in operation and is considerably less expensive than known prothrombin timers.

In accordance with the present invention, apparatus for determining prothrombin time comprises a receptacle for a reagent. A housing has a principal surface. First and second channels each have a first end opening in the housing and a second end opening in the principal surface. The second end opening of the first channel is adapted to accommodate the receptacle. A timer is on the housing. A heater is in the housing at the first end of the first channel. A light is in the housing at the first end of the second channel. A source of electrical energy provides energy for the heater and the light. A first variable resistor is connected in a first circuit portion in the housing with the

heater and the source of electrical energy for varying the magnitude of electrical energy supplied to the heater. A second variable resistor is connected in a second circuit portion in the housing with the light and the source of electrical energy for varying the magnitude of electrical energy supplied to the light. A switch arrangement is connected in the first and second circuit portions for selectively energizing and deenergizing the heater and the light.

A pair of apertures are formed through the principal surface of the housing. Each of the first and second variable resistors comprises a resistance-varying knob and is positioned with its resistance-varying knob extending through a corresponding one of the apertures. The switch extends through another aperture formed through the principal surface of the housing. An optical magnifier is pivotally mounted adjacent the second end opening of the second channel on the principal surface of the housing. The source of electrical energy comprises low voltage batteries. A manual stirrer for stirring a mixture of blood and reagent comprises a glass rod having Nichrome wire affixed to and extending from one end thereof.

In accordance with the present invention, a method for determining prothrombin time comprises heating a reagent in a receptacle, placing a predetermined amount of fingertip blood in a cavity formed in a glass specimen slide, adding a predetermined amount of heated reagent to said blood, simultaneously instituting operation of a timer, stirring the mixture of blood and reagent, the intensity of illumination as desired, and stopping the operation of the timer upon clotting of the contents of the receptacle.

BRIEF DESCRIPTION OF THE DRAWINGS

In order that the present invention may be readily carried into effect, it will now be described with reference to the accompanying drawings, wherein:

FIG. 1 is a perspective view of an embodiment of the prothrombin timer of the present invention;

FIG. 2 is a side view of the embodiment of FIG. 1 without the stirrer;

FIG. 3 is a top view of the embodiment of FIG. 1 without the stirrer;

FIG. 4 is a side view taken along the lines IV—IV of FIG. 3;

FIG. 5 is a side view taken along the lines V—V of FIG. 3;

FIG. 6 is a view taken along the line VI—VI of FIG. 3;

FIG. 7 is a view taken along the lines VII—VII of FIG. 3; and

FIG. 8 is a circuit diagram of the embodiment of FIG. 1.

DESCRIPTION OF THE PREFERRED EMBODIMENT

In the figures a housing **11** has a principal surface **12**. A receptacle **13** is provided for blood and a reagent such as thromboplastin. As more clearly shown in FIG. 4, a first channel **14** has a first end opening **14***a* in the housing **11** and a second end opening **14***b* in the principal surface **12**. The second end opening **14***b* of the first channel **14** is adapted to accommodate receptacle **13**. A second channel **15** has a first end opening **15***a* in the housing **11** and a second end opening **15***b* in the principal surface **12**. The second end opening **15***b* of the second channel **15** is adapted to accommodate the receptacle **13**.

The first and second channels **14** and **15** may be of any suitable size, shape and material. A preferred size, shape and material for each of the first and second channels is an elongated, open-ended, cylindrical tube of Lucite, for example. Receptacle **13** comprises any suitable clear transparent material such as "Pyrex" or other suitable glass, for example. Receptacle **13** may have the general configuration of a small test tube with a wide-flanged mouth of relatively large diameter.

A timer or stop watch **16** may be affixed to or mounted on the housing **11** or mounted in said housing. A heater **17** is provided in housing **11** at first end **14***a* of first channel **14**. The heater **17** may comprise any suitable electrically energized device for producing heat in accordance with the magnitude of electrical energy supplied to it such as, for example, an incandescent lamp, as shown in FIGS. 4 and 5.

The heater **17** is energized by any suitable source of electrical energy such as, for example, a low voltage battery **18** connected in circuit with said heater, as shown in FIG. 8. As shown in FIG. 8, the heater **17**, the battery **18**, a first variable resistor **19** and a first switch arm **21***a* of a switch **21** are connected in series circuit arrangement in a first circuit portion. The first variable resistor **19** varies the magnitude of electrical energy supplied to the heater **17** by varying the electrical resistance of the first circuit portion.

The first variable resistor **19** has a resistance-varying knob or dial **19***a*. The first variable resistor **19** is positioned with its resistance-varying knob **19***a* extending through an aperture **22** formed through the principal surface **12** of the housing **11**. The first variable resistor **19** is thus readily and facilely adjustable manually.

A light or source of illumination **23** is provided in the housing **11** at the first end **15***a* of the second channel **15**. The light **23** may comprise any suitable electrically energized device for producing light in accordance with the magnitude of electrical energy supplied to it such as, for example, an incandescent lamp, as shown in FIG. 4.

The light or lamp **23** is energized by a suitable source of electrical energy such as, for example, a low voltage battery **24** connected in circuit with said lamp, as shown in FIG. 8. As shown in FIG. 8, the lamp **23**, the battery **24**, a second variable resistor **25** and a second switch arm **21***b* of the switch **21** are connected in series circuit arrangement in a second circuit portion. The second variable resistor **25** varies the magnitude of electrical energy supplied to the lamp **23** by varying the electrical resistance of the second circuit portion.

The second variable resistor **25** has a resistance-varying knob or dial **25***a*. The second variable resistor **25** is positioned with its resistance-varying knob **25***a* extending through an aperture **26** formed through the principal surface **12** of the housing **1**. The second variable resistor in thus readily and facilely adjustable manually.

The circuit of FIG. 8 may comprise independent first and second circuit portions closed by the first switch arm **21***a* to close a closed loop of the first circuit portion components and closed by the second switch arm **21***b* to close a closed loop of the second circuit portion components. The circuit of FIG. 8 may also be modified, as desired, to provide a single common source of electrical energy for both the first and second circuit portions.

The switch **21** is connected in the first and second circuit portions for selectively energizing and deenergizing the heater **17** and the light source **23**, as shown in FIG. 8. The switch **21** has a manually operated switching member **21***c* which in its central or neutral position, as shown in FIGS. 1, 2, 3, 4 and 6, deenergizes both the heater **17** and the light source **23** by opening both the first and second circuit portions (FIG. 8). The switching member **21***c* extends through an aperture **27** formed through the principal surface **12** of the housing **11**. The switch **21** is thus operated manually with facility.

The switch **21** may be so designed that, when the switching member **21***c* of the switch **21** is in either of its side positions, shown by broken lines in FIGS. 3 and 4, both the heater **17** and the light source **23** are energized by the first and second switch arms **21***a* and **21***b* (FIG. 8) which close both the first and second circuit portions. If the first and second circuit portions are electrically independent loops, as shown in FIG. 8, and each switch arm **21***a* and **21***b* independently opens or closes the corresponding one of the first and second circuit portion loops, the switch member **21***c* in its left side position closes only the first circuit portion loop, leaving the sec-

ond circuit portion loop open, and in its right side position closes only the second circuit portion loop, leaving the first circuit portion loop open.

A specimen slide of any suitable transparent material such as, for example, glass or plastic, is provided with concavities for receiving predetermined amounts of blood and reagent, the mixture being simultaneously stirred and viewed.

Specimen slide **28** is shown in its operable position in FIGS. 1 and 6 and, in a preferred embodiment of the present invention, has formed in the upper surface thereof two concavities in spaced relation. In FIG. 1 concavity **28***a* is located directly over and is concentric with second end opening **15***b*. The distance between the concavities is such that reversal of the specimen slide **28** will result in concavity **28** occupying the position of concavity **28***a* as shown in FIG. 1.

The specimen slide **28** is removably affixed to the principal surface **12** of the housing **11** over the second end opening **15***b* by any suitable device such as, for example, a resilient arm or flat spring **2** which is affixed at one end to said principal surface.

An optical magnifier **31**, shown in FIGS. 1, 2, 3 and 7, is pivotally mounted adjacent the second end opening **15***b* of the second channel **15** on the principal surface **12** of the housing **11**. The optical magnifier or magnifying glass **31** may be moved into position over the second end opening **15***b* of the second channel **15** to facilitate visual observation of the contents of the receptacle **13** when said receptacle is in said second channel.

A stirrer **32** is provided, as shown FIG. 1, for stirring the contents of the receptacle **13**.The stirrer **32** comprises a glass rod **32***a* and a length of Nichrome wire **32***b* affixed to and extending from one end of said glass rod.

In the method of the present invention for determining prothrombin time, utilizing the apparatus of the present invention, a reagent such as for example, thromboplastin, is heated in the receptacle **13** by placing the reagent in said receptacle and then placing said receptacle in the first channel **14** and energizing the heater **17** by moving the switch member **21***c* of the switch **21** to its closed circuit position. The intensity or degree of heating is adjusted by manipulation of the knob **19***a* of the first variable resistor **19**.

Blood is removed from an extremity such as a fingertip or an ear lobe of the patient and is placed in concavity **28***a* (FIG. 1) and, by turning knob **25***a*, light source **23** provides a selected amount of heat to the blood in concavity **28***a* such that the blood will be maintained at a selected temperature until use. Magnifying glass **31** may be pivoted over concavity **28***a* to obesrve the blood sampling. An amount of heated reagent equal in volume to that of the blood specimen is added to the blood specimen by means of receptacle **13**. The moment the reagent and blood are mixed together, timer **16** is started, such as by a foot switch or other suitable means. The mixture of blood and reagent is manually stirred with stirrer **32** such that portions of Nichrome wire **32***b* engage the mixture. The mixture that is being stirred is observed and, upon the formation of clots, the timer **16** is stopped. The time recorded by timer **16** is the prothrombin time. The temperature of the mixture of blood and reagent may be

adjusted by means of light source **23** which is electrically wired to enable varying the intensity of its illuminating properties. The intensity of illumination is controlled by manipulation of the knob **25***a* of the second variable resistor **25**. The observation of the mixture is facilitated by observing the mixture through magnifying glass **31**.

While the invention has been described by means of a specific example and in a specific embodiment, I do not wish to be limited thereto, for obvious modifications will occur to those skilled in the art without departing from the spirit and scope of the invention.

What I claim is:

1. Apparatus for determining prothrombin time, comprising

a receptacle for a reagent;

a housing having a principal surface;

first and second channels each having a first end opening within said housing and a second end opening in said principal surface, the second end opening of said first channel being adapted to accommodate said receptacle;

low voltage heating means in said housing associated with the first end of said first channel and adapted to heat said receptacle;

lighting means in said housing associated with said second channel and adapted to illuminate an object at the second end opening of said second channel;

electrical energizing means for providing electrical energy for both a first circuit containing said heating means and a second circuit containing said lighting means; and

switch means connected in said first and second circuits for energizing and deenergizing said heating means and said lighting means.

2. Apparatus as claimed in claim **1**, further comprising optical magnifying means mounted adjacent the second end opening of said second channel in a position to facilitate observation of an object at said second end opening of said second channel.

3. Apparatus as claimed in claim **1**, wherein said electrical energizing means comprises low voltage batteries.

4. Apparatus as claimed in claim **1**, further comprising a specimen slide for receiving predetermined amounts of blood and reagent, and adapted for placement at said second end opening of said second channel.

References Cited

UNITED STATES PATENTS

2,417,802	3/1947	Longstreet.	
2,878,715	3/1959	Rhees	23—253 XR
3,158,445	11/1964	Huff	23—253
3,267,364	8/1966	Page et al.	23—253 XR
3,271,112	9/1966	Williams et al.	23—253
3,450,501	6/1969	Oberhardt	23—253

MORRIS O. WOLK, Primary Examiner

B. S. RICHMAN, Assistant Examiner

U.S. Cl. X.R.

23—230; 73—64.1; 128—2; 424—2