Title: BLOOD CULTURE DEVICE

Abstract: A blood culture device (1, 28) and a method of collecting a culture sample from a living person to aid in the diagnosis of many systemic infections without the patient losing any appreciable amount of blood is provided. The device comprises a collection chamber (29), containing particulate blood culture substrate, which in use communicates with a variable volume chamber (3, 18) which is operated to introduce plural volumes of blood into the collection chamber consecutively. The blood culture device may be configured to operate as a modified syringe, or may be connected to a conventional syringe. The collection chamber may be provided as a single separate unit or as a collection chamber (8, 15), positioned as a central cylinder in a larger cylinder with an annular space surrounding the collection chamber forming a return chamber (10). Communication between different chambers may be by way of an operator controlled valve mechanism (11, 12, 21).

Figure 1

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BLOOD CULTURE DEVICE

FIELD OF THE INVENTION

This invention relates to a blood culture device and, more particularly, to a blood culture device that is suitable for use in culturing organisms carried by blood and that may be present in low concentrations. The device is particularly useful in relation to systemic infections that carry a high mortality, and especially systemic infections in relation to which the causative organism is difficult to isolate and identify in which instances empirical therapy may be applied.

An important example of such an infection is the heart disease infective endocarditis.

BACKGROUND TO THE INVENTION

Throughout the world infective endocarditis is a serious disease that poses both diagnostic and therapeutic challenges. One of the most significant challenges in the management of infective endocarditis is identifying the causative organism. Positive blood cultures are reportedly obtained in less than 50% of cases. It has also been recorded that patients treated for culture-negative endocarditis have a worse mortality than cases in which the causative organism has been identified.

A major contributing factor to the low positive yield of blood cultures in infective endocarditis is the pathophysiology of the condition which is characterized by the majority of the causative organisms being adherent to and sequestered within vegetations and circulating in low concentrations in the blood.

There is thus an apparent need for a blood culture device that can more
effectively collect organisms circulating in the blood of a patient for culture purposes.

**SUMMARY OF THE INVENTION**

In accordance with this invention there is provided a blood culture device comprising a collection chamber that is either in permanent communication with a variable volume chamber or has a communication inlet/outlet that has a coupling formation for attaching the collection chamber to a separate variable volume chamber such that, in use, plural volumes of blood can be introduced into, and discharged from, the collection chamber consecutively, wherein the collection chamber is adapted to contain a particulate blood culture substrate for the retention of organisms carried by blood drawn into the collection chamber and becoming mixed with the particulate blood culture substrate, and wherein the collection chamber communicates with a primary inlet/outlet that in use communicates with a cannula through which blood can be drawn in repeated cycles into the collection chamber from a patient in use and returned to the patient whilst the blood culture device retains the particulate blood culture substrate within the collection chamber, and wherein the blood culture device is configured to provide for the removal of the particulate blood culture substrate and associated retained blood from the collection chamber after contact thereof with plural volumes of blood.

A further feature of the invention provides for the variable volume chamber to be in the form of a manually operable syringe.

In a first variation of the invention the collection chamber is permanently associated with a variable volume chamber that is preferably in the form of a modified syringe and a return chamber is provided wherein the collection and return chambers communicate with the primary inlet/outlet that, in use, communicates with a cannula.
Further features of the first variation of the invention provide for the collection chamber to be positioned as a central cylinder within a larger cylinder wherein a generally annular space surrounding the collection chamber serves as the return chamber interposed between an inlet/outlet chamber on the one hand and the variable volume chamber on the other hand so that a single direction of movement of blood is provided through the collection chamber; for the cylindrical collection chamber to be concentric with the surrounding outer larger cylinder of the device; for communication between the different chambers to be by way of an operator controlled valve mechanism to selectively determine flow direction; for the operator controlled valve mechanism to cause apertures to be aligned so that when blood is drawn into the device it moves through the collection chamber and when blood is returned to a patient it moves through the return chamber; for the primary inlet/outlet to be detachable from the rest of the blood culture device; and for the device to contain saline solution optionally containing any required anticoagulant preparatory to the device being connected to a supply of blood in use.

Still further features of the first variation of the invention provide for the collection and return chambers to form part of a cartridge unit that is removably received within a cylindrical outer wall that receives the cartridge unit in one end region thereof and whereof the other end region forms a cylindrical variable volume chamber in which a manually operable plunger is movable; and for the outer wall to be circumferentially split to provide for the introduction and removal of a cartridge unit from the device.

In an alternative embodiment of the first variation of the invention the operator controlled valve mechanism may be replaced by suitable non-return valves.

In a second variation of the invention the collection chamber has a communication inlet/outlet that has a fitting for attachment of the collection
chamber to a separate variable volume chamber that may assume the form of a conventional manually operable syringe of a suitable capacity that may be ordinarily available in a medical facility.

In all instances in which the particulate blood culture substrate is to be discharged from the collection chamber (as opposed to it being retained in a removable cartridge), a separate outlet is provided that accommodates the size particle of the particulate blood culture substrate so that it can be discharged together with blood with which it is mixed. Other inlet/outlets may be appropriately dimensioned or have associated therewith retaining meshes or the like such that the passage of the particulate blood culture substrate from the collection chamber other than as may be required in order to discharge the particulate blood culture substrate after contact with plural volumes of blood is prevented.

The invention provides a method of collecting a culture sample from a living person wherein a blood culture device as defined above is connected to a supply of blood in a vein or artery of the person by way of a cannula and the variable volume chamber is operated to introduce plural volumes of blood into the collection chamber consecutively to mix with the particulate blood culture substrate, and thereafter the particulate blood culture substrate and any blood with which it is mixed may be cultured with a view to identifying any organisms retained by the blood culture substrate.

Further features of the method of the invention will be quite apparent to those of ordinary skill in the art.

It will be understood that use of a blood culture device as defined above enables multiple volumes of blood to be drawn into the collection chamber during a cycle of increasing the volume of the variable volume chamber. At least some of the blood will subsequently be returned to a patient's body by a cycle of decreasing the volume of the variable volume chamber. This
enables a particulate blood culture substrate contained in the collection chamber to be contacted with multiple volumes of blood without the patient losing any appreciable amount of blood and thereby enabling dilute organisms to be collected and identified.

The culture substrate is preferably contained in the device in a conformation promoting sequestration and adherence of the organisms. This is aimed at enhancing the ability to culture fastidious organisms and organisms present in blood at low concentration and is expected to aid in the diagnosis of many systemic infections.

In this specification the term particulate blood culture substrate is intended to mean any suitable substrate in a subdivided form in which individual particles may be suitably retained in the collection chamber during successive volumes of blood being drawn into the collection chamber and discharged from it. The size of the particles will depend to a large extent on the physical properties of the blood culture substrate and will typically be of the order of from less than 1 millimetre in diameter to about 5 mm in diameter with a preferred size being of the order of about 2.5 mm.

It is to be noted that the blood culture device provided by this invention may be designed as a simple to operate device as opposed to any complicated device that may be inappropriate in many instances as it may require more specialist operators.

In order that the invention may be more fully understood two different embodiments thereof will now be described with reference to the accompanying drawings.
BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:-

Figure 1 is a schematic diagram illustrating the basic principles of the blood culture device according to the invention with the blood culture device illustrated in longitudinal section;

Figure 2 is a somewhat larger schematic longitudinal section through an embodiment of the first variation of the blood culture device according to the invention;

Figure 3 is an isometric view showing the top part of the operator controlled valve mechanism;

Figure 4a shows the setting of the operator controlled valve mechanism where blood flows through the return chamber and out of the device;

Figure 4b shows the setting of the operator controlled valve mechanism where blood can be drawn into the device through the collection chamber;

Figure 5 is an exploded view of a cartridge that may form a part of the embodiment illustrated in Figure 2;

Figure 6 is an isometric view of the assembled cartridge;

Figure 7 is an exploded isometric view of the components that form the outer wall of the embodiment illustrated in Figure 2;

Figure 8 is an isometric view of the assembled components
illustrated in Figure 6 and Figure 7;

Figure 9 is a schematic diagram of an embodiment of the second variation of the blood culture device according to the invention, in use with a syringe;

Figure 10 is a schematic diagram of an embodiment of the second variation of the invention shown in Figure 9 illustrated in longitudinal section and with a modification as regards the position of the discharge outlet;

Figure 11 is a front view of the embodiment shown in Figure 10 and Figure 10 showing the primary inlet/outlet and discharge outlet of the device; and

Figure 12 is a longitudinal sectional view of the embodiment shown in Figure 11, taken along the line XII to XII.

DETAILED DESCRIPTION WITH REFERENCE TO THE DRAWINGS

In the schematic diagram of Figure 1, one embodiment of blood culture device (1) according to the invention is in the form of a cylindrical chamber having a manually operable plunger (2) associated therewith so as to define a variable volume chamber (3) in the form of an adapted syringe with the plunger being manually operable from one end of the cylindrical chamber. The opposite end of the cylindrical chamber communicates with an inlet/outlet chamber (4) comprising a primary inlet/outlet (4a) that in use communicates with a cannula (5) installed on an arm or other limb (6) of a patient by way of any necessary tube (7) and a secondary inlet/outlet (4b) communicating with a coaxial collection chamber (8). The various attachments can be made in any suitable way using appropriate fittings of any description such as those embodying a Luer taper.
The cylindrical collection chamber (8) extends over approximately one half of the length of the cylindrical chamber and is in the form of a concentric cylindrical chamber of smaller diameter in communication at one end with the inlet/outlet chamber by way of the secondary inlet/outlet and with the variable volume chamber at the other end.

The collection chamber is adapted to contain a blood culture substrate (9) in particulate form, preferably having a particle size of about 2.5 mm, for the retention of organisms carried by blood that it may contact in the collection chamber. The blood culture substrate will typically include a composition of agar that can be varied to suit any particular organisms being sought. The arrangement is selected to increase surface area and cause turbulence of flow through the collection chamber with a view to promoting the sequestration and adherence of organisms.

This arrangement of the collection chamber defines an annular return path (10) for blood that has passed through the collection chamber in a single direction.

Simply by way of indication, the variable volume chamber may have a maximum capacity of about 20 ml and the collection chamber may have a capacity of about 10 ml.

In this embodiment of the invention, communication between the inlet/outlet chamber and the collection chamber, and between the collection chamber and the variable volume chamber is by way of an operator controlled valve mechanism (11, 12) to ensure the selective flow of blood. Similarly, communication between the variable volume chamber and the return chamber, and between the return chamber and the inlet/outlet chamber is also by way of the operator controlled valve mechanism (11, 12). This enables the selective flow of blood in a single direction through the collection chamber to be achieved.
The primary inlet/outlet (4a) may be detachable from the rest of the device, conveniently by means of a spigot and socket arrangement indicated by numeral (13), for purposes of assembly and depositing of the content of the collection chamber into a culture bottle after completion of blood sampling.

Access to the interior may be facilitated by splitting the outer wall of the device at a position opposite the collection chamber, also conveniently by way of a spigot and socket joint that is indicated by numeral (14).

The device may contain saline solution containing any appropriate anticoagulant ensuring that blood does not clot in the device during operation.

The method of the invention is initiated by obtaining venous access by standard needle puncture using a standard syringe that may be used to remove air from the system. Once this is done the syringe is removed and the tubing connected to the blood culture device described above which functions as an adapted syringe.

The method for collecting a culture sample from a living person therefore involves the connection of a blood culture device as described above to a supply of blood in a vein or artery of the person by way of a cannula, and the variable volume chamber is operated to introduce plural volumes of blood into the collection chamber consecutively and to return blood to the patient after mixing with the particulate blood culture substrate. Blood will thus be drawn into the collection chamber when the variable volume chamber is expanded by withdrawing the plunger and will be returned to the patient by way of the return path when the variable volume chamber is contracted by depressing the plunger.

The blood culture device of the invention therefore, in effect, circulates blood through the external collection chamber before returning blood to the body of
the patient. This enables the blood culture substrate contained in the collection chamber to be in contact with multiple volumes of blood without the patient losing any appreciable amount of blood.

The number of volumes of blood introduced into the collection chamber can be varied widely, as will be quite apparent to those of ordinary skill in the art, and as will be dictated by the likely concentration of any organisms that are being sought. Typically it is expected that between 5 and 20 volumes should cover most possibilities but, of course, any number of volumes can be used.

At the end of a collection procedure, the entire contents of the collection chamber are transferred to a standard blood culture bottle and the blood culture substrate and any blood with which it is mixed is cultured in the usual way with a view to identifying any organisms retained by the blood culture substrate.

Turning now to the somewhat more sophisticated embodiment of the invention illustrated in Figures 2 to 8 of the drawings, the collection chamber (15) forms part of a cartridge unit (16) that is removably received within a cylindrical outer wall (17) that receives the cartridge unit in one end region thereof. The other end region forms a cylindrical variable volume chamber (18) in which a manually operable plunger (19) is movable. As described above, the outer wall is split to provide for the introduction and removal of a cartridge unit from the device and the split is conveniently in the form of a spigot and socket joint that is indicated by numeral (20).

The operator controlled valve mechanism (21) functions as follows:

At each end of the cartridge unit is a fixed disc that is rotatable (together with the cartridge unit) relative to the cylindrical outer wall of the device, in this instance by an angle of about 45°, between two terminal angular positions. In the first terminal angular position (illustrated in Figure 3 and Figure 4a), a
set of radially outer apertures (22) through the disc is aligned with a corresponding set of apertures in the transverse walls of the cylindrical outer wall at each end of the cartridge so that flow through the return chamber and out of the device is possible. In this first terminal position the set of radially inner apertures (23) in the cartridge discs are out of alignment with corresponding apertures through the transverse wall to disable flow in any direction through the collection chamber.

In the second terminal angular position (illustrated in Figure 4b) the set of radially outer apertures is out of alignment to disable flow through the return chamber and the set of radially inner apertures in the discs are in alignment with the corresponding transverse wall apertures to permit flow into the collection chamber.

In order to effect rotation of the cartridge (and therefore the discs) between the two terminal positions, the cartridge has an operating mechanism comprising two extensions (24, 25) that extend through slots (26, 27) in the outer wall so as to be operable by a thumb or finger of a hand holding the device.

The operator controlled valve mechanism and plunger may be operated repeatedly by moving the valve mechanism between its first and second terminal angular positions and moving the plunger appropriately so that plural volumes of blood may be drawn unidirectionally through the collection chamber and expelled through the return chamber. Flow of blood through the collection chamber is, in this variation of the invention, unidirectional through the collection chamber.

Referring now to Figures 9 to 12 of the drawings, an embodiment of the second variation of the invention is described in which a simplified blood culture device according to the invention is employed. In this embodiment of the invention the blood culture device (28) is in the form of a single collection
chamber (29) that serves as both the collection and return chambers of the blood culture device (28).

The variable volume chamber is, in this variation of the invention, in the form of a separate syringe (30) releasably attached to the collection chamber (29). The syringe may be of substantially conventional design and may be an item that is already available in a medical facility in which the blood culture device is to be used.

The collection chamber (29) has a primary inlet/outlet (31) that in use communicates with a cannula (32) and a secondary inlet/outlet (33) through which a blood culture substrate can be discharged at the end of a collection procedure and fresh blood culture substrate introduced prior to use.

Figure 9 illustrates an arrangement in which the primary inlet/outlet (31) is coaxial with the syringe (30) with the secondary inlet/outlet (33) extending out of the side of the collection chamber.

Figures 10 to 12 illustrate a slightly different physical arrangement in which the primary inlet/outlet (31) and secondary inlet/outlet (33) have their axes parallel to each other and offset from a central axis of the collection chamber.

Fittings on this embodiment of blood culture device (28) are designed to interface with standard syringes, medical tubing and butterfly needles. The chamber (29) may thus be screwed on to a syringe (30), which will drive the flow of the blood into and out of the collection chamber (29). The primary and secondary inlet/outlets (31, 33) are connected to standard butterfly tubes, known in the art, and, as may be required, may have a flow restricting clamp (34) and, in the instance of the primary inlet/outlet, the cannula (32) on the free end of the relevant tube.

In the instance of the arrangement illustrated in Figure 9 of the drawings, the
particulate blood collection substrate may be confined to the interior of the collection chamber during the introduction and return of multiple volumes of blood by operating the syringe by a single mesh (35) installed across the entire diameter of the collection chamber towards each end thereof so that the particles of blood collection substrate are retained within the volume between the meshes. The secondary inlet/outlet (33) on the other hand communicates with the space between the meshes so that the particles can be discharged together with blood with which it is mixed at the end of a collection procedure.

In the instance of the variation illustrated in Figures 10 and 12 of the drawings, a wire mesh (36) is provided over the primary inlet/outlet (31) and a wire mesh (37) over a communication inlet/outlet (38) that is connectable to a syringe (30) so as to retain particulate blood collection substrate within the collection chamber.

In operation, blood may be induced to flow into the collection chamber (29) through the primary inlet/outlet (31) during a collection procedure during which the syringe is operated to draw blood from a patient into the collection chamber so that it becomes mixed with the particulate blood collection substrate. Blood may then be returned to the patient by appropriate operation of the syringe. Once the required number of volumes of blood have been drawn into the collection chamber and returned to the patient, the residual blood together with the blood collection substrate that is mixed with it may be discharged through the secondary inlet/outlet (33).

It will be appreciated that the second variation of the invention enables an extremely simple and therefore cost effective blood culture device to be produced that can be combined with a standard syringe to act as the variable volume chamber.

It will be understood that numerous variations may be made to the
embodiments of the invention described above without departing from the scope hereof.
CLAIMS:

1. A blood culture device comprising a collection chamber that is either in permanent communication with a variable volume chamber or has a communication inlet/outlet that has a coupling formation for attaching the collection chamber to a separate variable volume chamber such that, in use, plural volumes of blood can be introduced into, and discharged from, the collection chamber consecutively, wherein the collection chamber is adapted to contain a particulate blood culture substrate for the retention of organisms carried by blood drawn into the collection chamber and becoming mixed with the particulate blood culture substrate, and wherein the collection chamber communicates with a primary inlet/outlet that in use communicates with a cannula through which blood can be drawn in repeated cycles into the collection chamber from a patient in use and returned to the patient whilst the blood culture device retains the particulate blood culture substrate within the collection chamber, and wherein the blood culture device is configured to provide for the removal of the particulate blood culture substrate and associated retained blood from the collection chamber after contact thereof with plural volumes of blood.

2. A blood culture device as claimed in claim 1 in which the variable volume chamber is in the form of a syringe.

3. A blood culture device as claimed in either one of claims 1 or 2 in which the collection chamber is permanently associated with a variable volume chamber that is in the form of a modified syringe and a return chamber is provided wherein the collection and return chambers communicate with the primary inlet/outlet that, in use, communicates with a cannula.

4. A blood culture device as claimed in claim 3 in which the collection
chamber is in the form of a central cylinder within a larger cylinder wherein a generally annular space surrounding the collection chamber serves as a return chamber interposed between an inlet/outlet chamber on the one hand and the variable volume chamber on the other hand so that a single direction of movement of blood may be provided through the collection chamber.

5. A blood culture device as claimed in either one of claims 3 or 4 in which communication between the different chambers is by way of an operator controlled valve mechanism to selectively determine flow direction.

6. A blood culture device as claimed in claim 5 in which the inlet and outlet of the collection chamber and return chamber are by way of the operator controlled valve mechanism where apertures in the valve and a transverse wall can be aligned or non-aligned to determine flow direction.

7. A blood culture device as claimed in any one of claims 3 to 6 in which the primary inlet/outlet is detachable from the rest of the blood culture device.

8. A blood culture device as claimed in any one of claims 3 to 7 in which the collection and return chambers form part of a cartridge unit that is removably received within a cylindrical outer wall that receives the cartridge unit in one end region thereof and whereof the other end region forms the cylindrical variable volume chamber in which a manually operable plunger is movable.

9. A blood culture device as claimed in claim 8 in which the outer wall is circumferentially split to provide for the introduction and removal of a cartridge unit from the device.
10. A blood culture device as claimed in either one of claims 1 or 2 in which the collection chamber has a communication inlet/outlet that has a fitting for attachment of the collection chamber to a separate variable volume chamber.

11. A blood culture device as claimed in claim 10 in which the variable volume chamber assumes the form of a conventional manually operable syringe.

12. A blood culture device as claimed in any one of claims 1 or 2 in which a secondary inlet/outlet is provided for the removal of particulate blood culture substrate from the collection chamber after contact thereof with plural volumes of blood.

13. A blood culture device as claimed in any one of the preceding claims in which a mesh is employed to retain particulate blood culture substrate within the collection chamber.

14. A method of collecting a culture sample from a living person wherein a blood culture device as claimed in any one of claims 1 to 13 is connected to a supply of blood in a vein or artery of the person by way of a cannula and the variable volume chamber is operated to introduce plural volumes of blood into the collection chamber consecutively to mix with the particulate blood culture substrate, and thereafter the particulate blood culture substrate and any blood with which it is mixed may be cultured with a view to identifying any organisms retained by the blood culture substrate.
Figure 1
### INTERNATIONAL SEARCH REPORT

**PCT/IB2013/059133**

#### A. CLASSIFICATION OF SUBJECT MATTER

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According to International Patent Classification (IPC) or to both national classification and IPC.

#### B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols): A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched.

Electronic database consulted during the international search (name of database and, where practicable, search terms used):

- EPO-Internal, WPI Data

#### C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>wo 2012/094671 A2 (SOMERSET GROUP ENTPR INC [US]; GREENBERG DAVID G [US]; PURITZ SCOTT [U]) 12 July 2012 (2012-07-12) abstract paragraph [0149]; figure 13</td>
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Futher documents are listed in the continuation of Box C. See patent family annex.

- "A" document defining the general state of the art which is not considered to be of particular relevance.
- "E" earlier application or patent but published on or after the international filing date.
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- "A" document member of the same patent family.

**Date of the actual completion of the international search:**

13 March 2014

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**Name and mailing address of the ISA:**

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**Authorized officer:**

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