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(54) **METHOD AND DEVICE FOR THE ANALYSIS OF BODY FLUIDS**

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(57) **ABSTRACT**

The invention relates to a method and a device for analyzing body fluids (**21**). A picture recording device (**30**) is placed in a flare-free room (**16**) provided with a lighting equipment (**45**) and is connected to an electronic picture evaluating device. The picture recording device (**30**) is focused on a container (**20**) which is in an analysis position (**22**) and contains the body fluid (**21**) in order to take at least one picture of the body fluid (**21**). Said picture is analyzed by picture-evaluating software, whereby the quality and quantity of the body fluid (**21**) is detected.

Fig. 1

Fig. 2
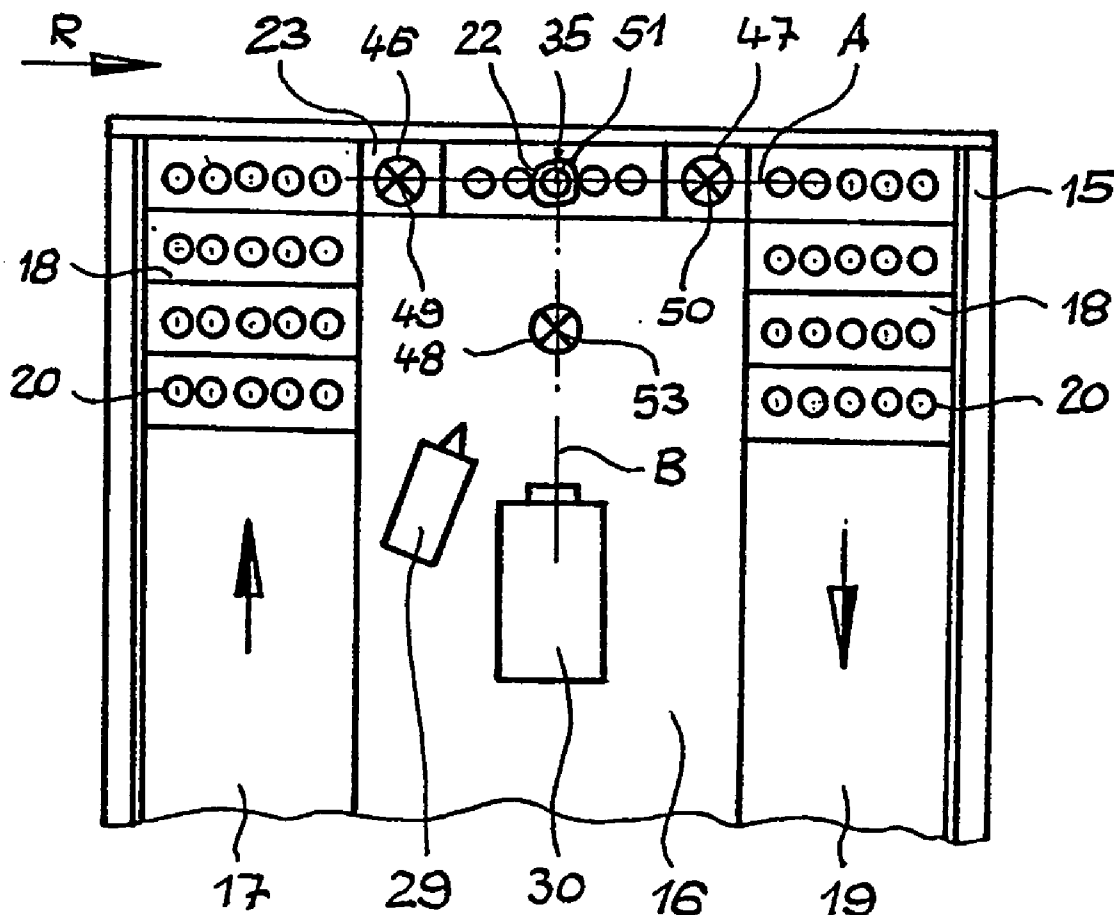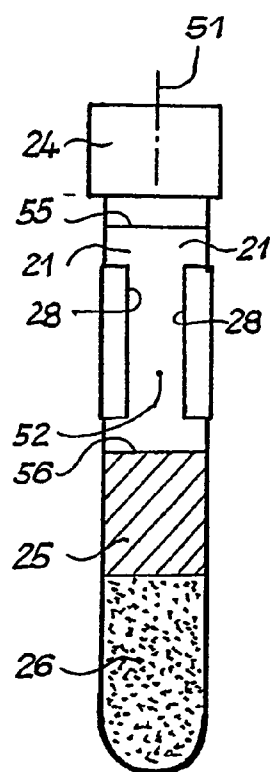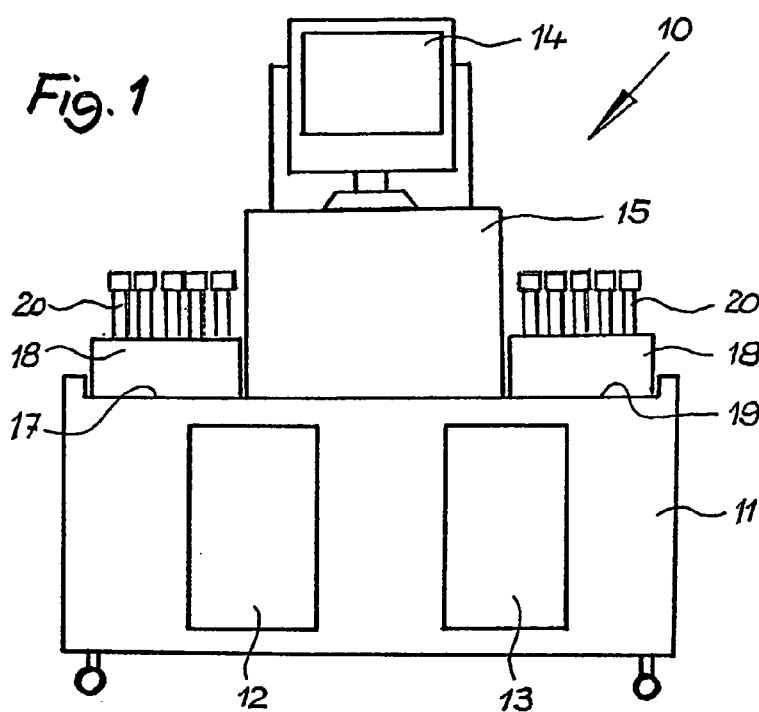
Fig. 7
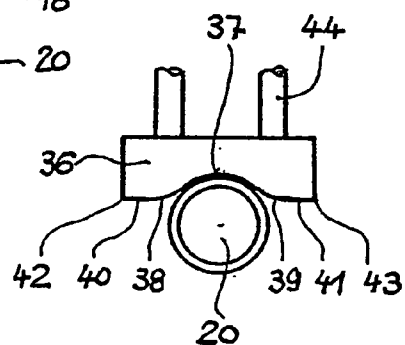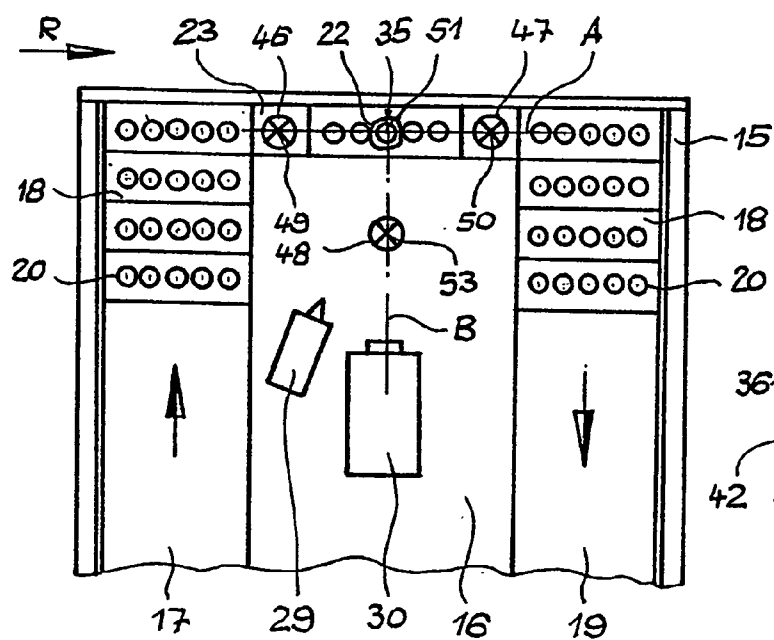
Fig. 8
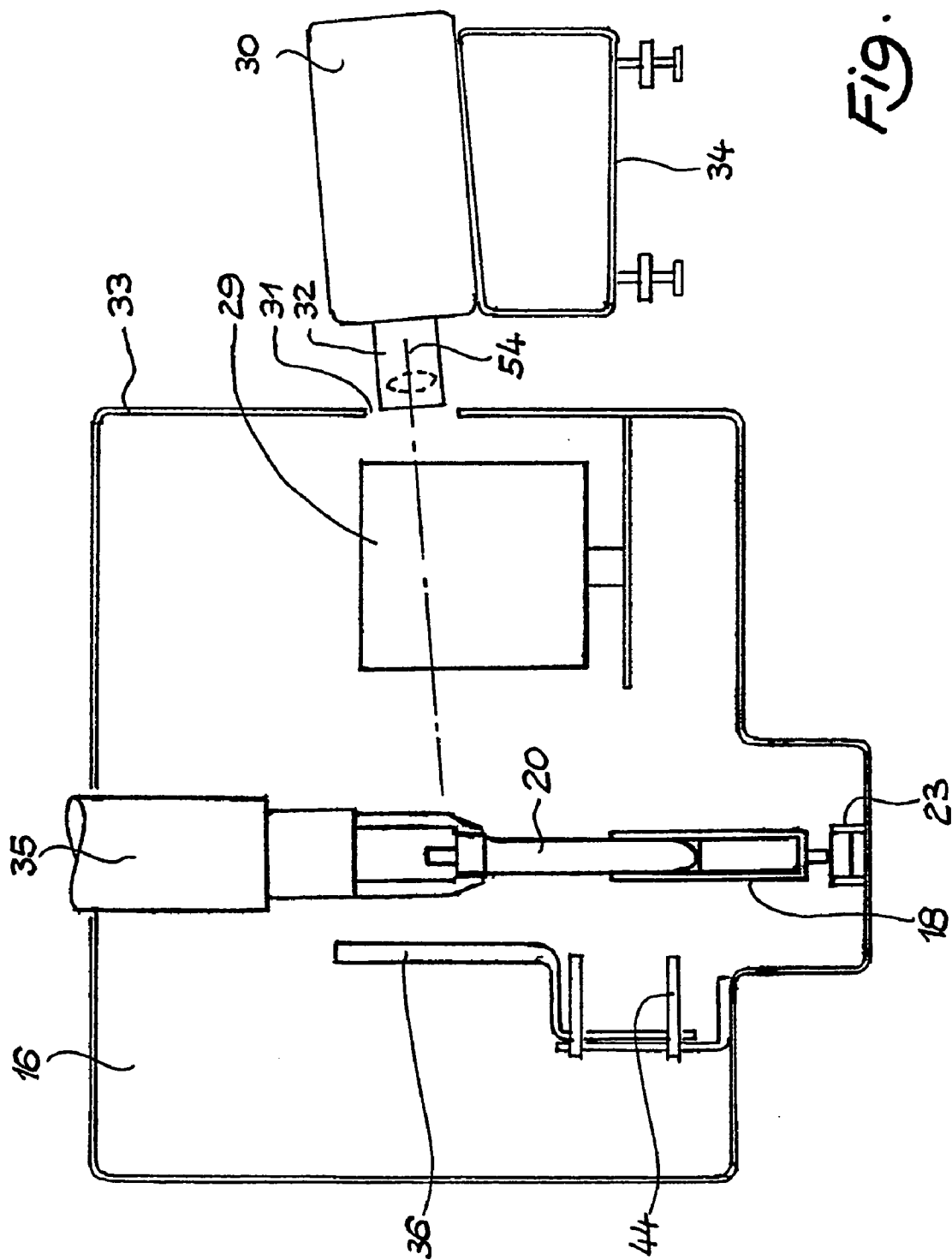
Fig. 3
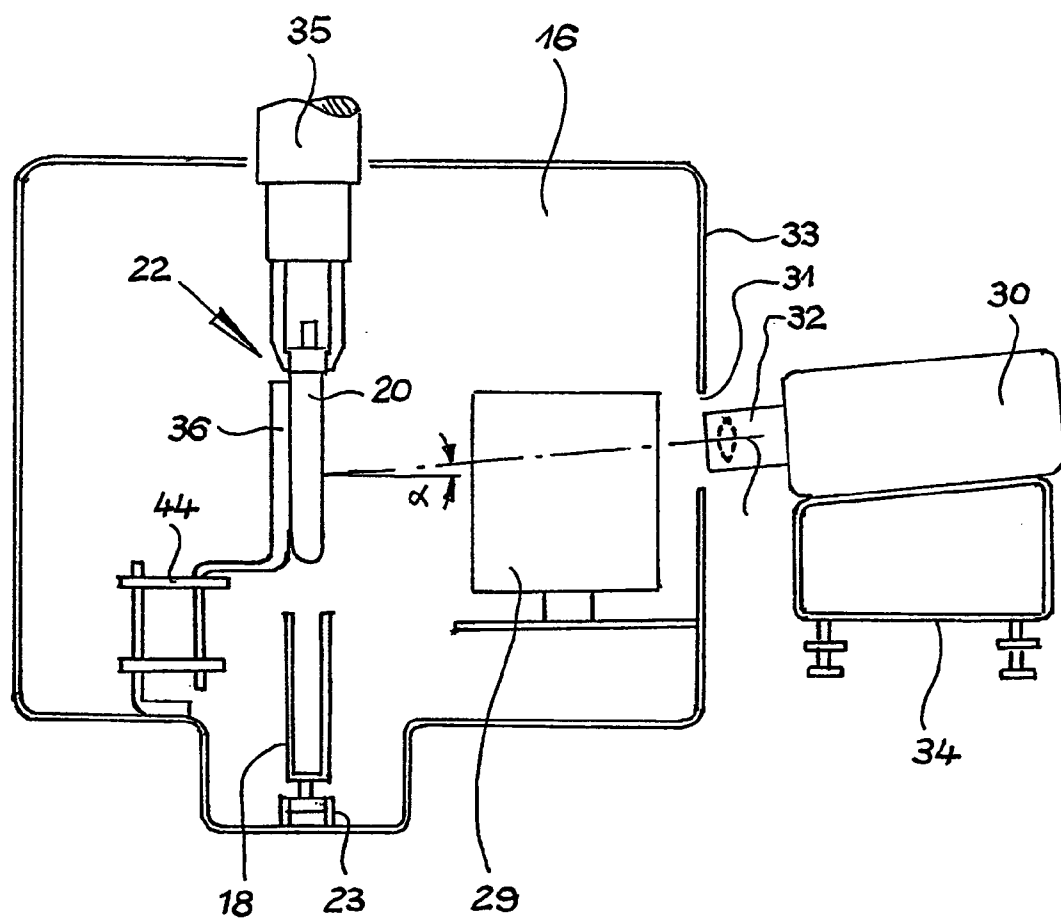
Fig. 4
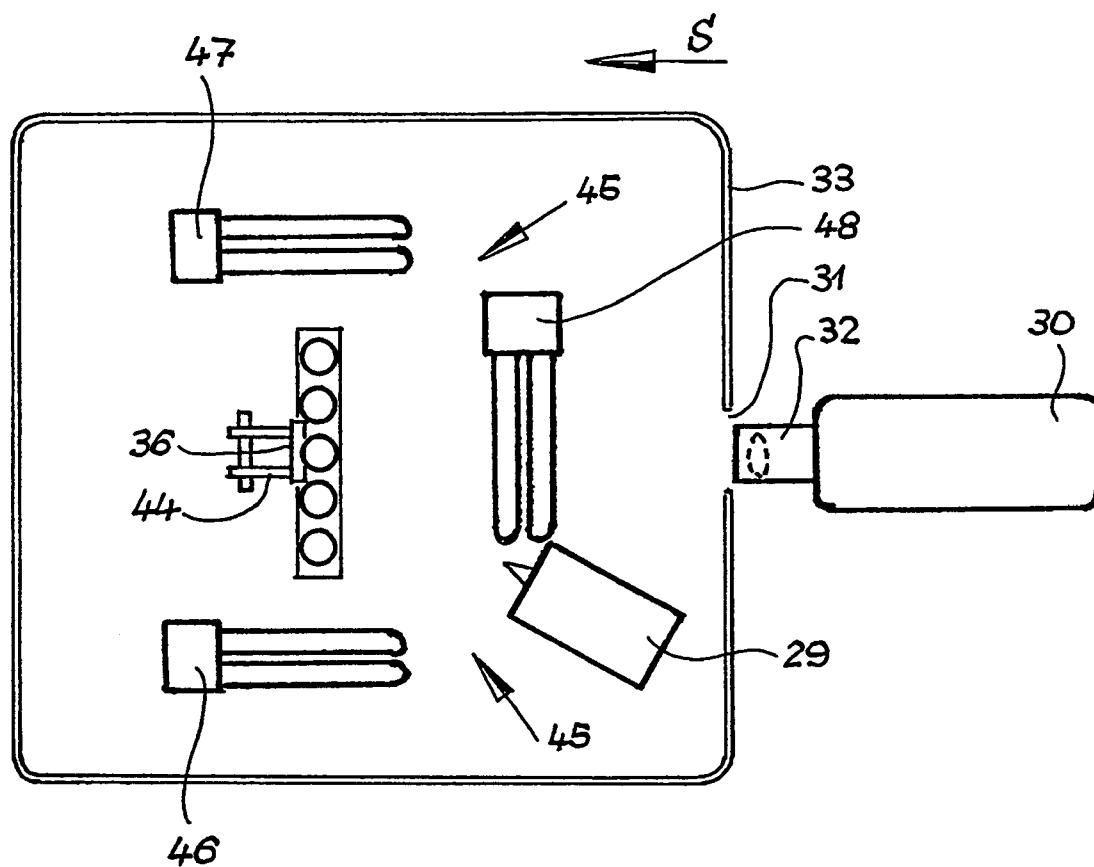
Fig. 5
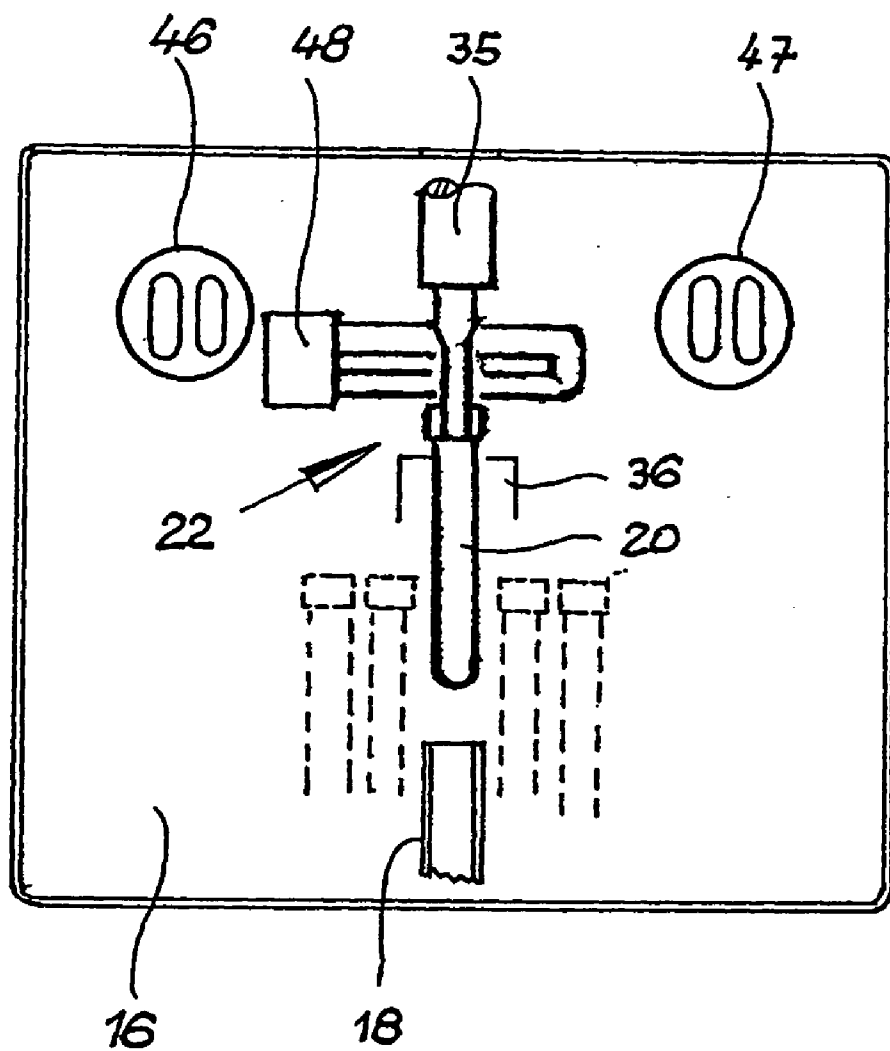
Fig. 6

Fig. 9
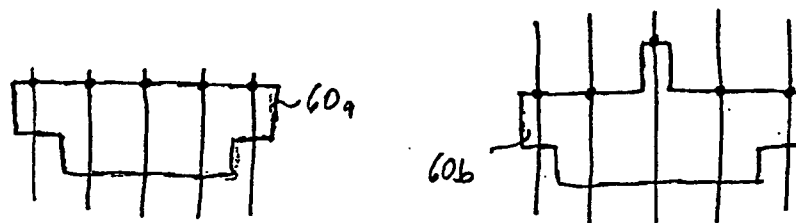
Fig. 10
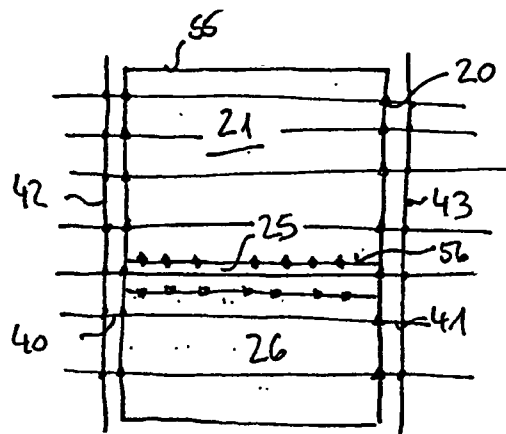
METHOD AND DEVICE FOR THE ANALYSIS OF BODY FLUIDS

[0001] The invention relates to a method and an apparatus for analyzing body fluids.

[0002] Before body fluid, such as blood serum or blood plasma, is analyzed, centrifuged samples of body fluid are examined as to whether they are "good", that is to say suitable for analysis, or whether they are discolored or cloudy because of contaminants or specific clinical pictures. This is the case, for example, when so-called clots (conglomerations of solid components) are contained in the blood sample, or when the blood samples are hemolytic, lipemic or icteric. The detection is currently performed manually by visual inspection of the samples before the latter are further processed. This mode of procedure is time consuming and labor intensive and leads to errors in subsequent laboratory operation, and is attended by downtimes for analytic equipment and by time consuming reworking.

[0003] It is the object of the invention to provide a method and an apparatus for analyzing body fluids with the aid of which method and apparatus it is possible to determine reliably the quality of the body fluid to be analyzed and its quantity.

[0004] The solution consists in a method having the features of claim 1, and an apparatus having the features of claim. Thus, it is provided according to the invention that in order to determine the quality and the quantity of the body fluid by means of an image recording device, an image of the body fluid to be analyzed is recorded and evaluated by means of image processing software. A reliable, quick and automatic determination by machine of the quality and quantity of the body fluid to be analyzed is thereby possible. The method according to the invention permits a substantial automation and rationalization of the analysis of blood samples, and thus a substantial saving in time and cost.

[0005] Advantageous developments follow from the subclaims. For example, it is advantageous firstly to determine the type and size of the container automatically. It is possible for this purpose, for example, to use the image recording device to produce an image of the container, and to compare it with stored image files of known containers by means of evaluation software. If, as may well mostly be the case, the body fluid is located in a sample or analysis tube, it is possible to produce merely images of the caps of these tubes and compare them with stored image files of known tubes in order to determine tube type and tube size, for example the tube height.

[0006] One advantage of this determination consists in that the container can subsequently be brought into a position in which the image recording device can detect the body fluid located in this container as completely as possible, and produce a correspondingly complete image. Thus, the container is moved such that it is positioned as completely as possible in the image section defined by the optics of the image recording device. In the case of sample or analysis tubes, this movement is a lifting movement, as a rule, since such tubes differ from one another chiefly in their height. Depending on the tube type, they must therefore be lifted to a different extent so that the body fluid can be positioned in the image section of the image recording device. As a rule, this movement is performed by means of control software

that takes over the dimensions, stored in a file, of the identified tube type and thereby controls a handling apparatus for the container, for example a lifting rotary gripper.

[0007] Depending on the circumstances of the individual case, the container can also be moved automatically in different ways such that as complete an image as possible of the body fluid can be produced. This is the case, in particular, whenever the container has a cover, for example a label or an inscription that obstructs the view onto the body fluid. The container should then be moved such that the cover is located outside the image section defined by the optics of the image recording device. One possibility of implementing this consists, for example, in that in order to detect the cover the edges of the cover are detected by means of a scanner and the container is moved automatically by rotating the lifting rotary gripper such that the cover is situated on the side of the container averted from the image recording device.

[0008] The data determined by the scanner, preferably a bar code scanner, therefore trigger the movement of the container. As a rule, this is implemented by control software that records the data determined by the scanner and thereby controls a handling apparatus, for example a lifting rotary gripper.

[0009] Particularly whenever the cover is a label, for example having details of the sample and/or patient, it is advantageous after the rotation, just described, of the container to mask out the cover optically by masking out the entire corresponding region of the container. If the aim is to mask out a white label, it is particularly suitable for this purpose to use, for example, a white background surface that covers, for example, 15 to 50%, preferably 20 to 25% of the surface of the container.

[0010] Thus, the image recording device can be used to produce at least one image of the body fluid that is analyzed by means of image processing software. Depending on the requirement, one or more detail images are produced, that are combined by means of the image processing software to form an overall image. In order to raise the throughput for a large number of samples, it is advantageous when the image recording device (30) is used to produce simultaneously an image of the body fluid in a first container and an image of a subsequent second container for the purpose of determining the type and size of the second container. It is then simultaneously possible to evaluate the image of the body fluid and, at the same time, to identify the following container so that it can be aligned as quickly as possible into a position that permits as complete an image as possible of the body fluid to be recorded.

[0011] It is firstly preferable to produce a color image of the body fluid and of the container, since color value differences can be more accurately detected than brightness value differences of gray value images. Of course, it is also possible to produce a gray value image, or to convert the color image into a gray value image.

[0012] A preferred method for detecting the type and size of the container provides that a number of vertical lines are laid in the image of the container, the color values and/or brightness values of the pixels lying on these lines are detected, and changes in color value and/or brightness value are determined and compared with the data of known

containers. In this way, the type and size of the container can be determined when the data of all the known, or at least current containers are stored in a file within the image processing software. It is then possible to use the data determined for the container to control the handling apparatus by passing the data from the image processing software to the control software, which subsequently controls the handling apparatus such that the container is brought into an optimum position with regard to the image recording apparatus.

[0013] For the case where a part of a cover projects into the image section detected by the image processing apparatus (30), it is advantageous when one or more detail images are produced that are combined by means of the image processing software to form an overall image.

[0014] An advantageous development provides that for the purpose of evaluating the image of the body fluid, a number of perpendicular and/or horizontal lines are laid in the image of the body fluid, the color values and/or brightness values of the pixels lying on these lines are detected, changes in color value and/or brightness value are determined, and the background region and/or upper edge of the body fluid are determined. It is possible in this way to remove the background region from the image computationally, thus permitting savings in storage space and computer time.

[0015] In order to identify the separating means and/or the blood clot in a centrifuged sample of body liquid, it is possible, for example, to scan each pixel row of the image from bottom to top, and to detect the transition from dark color or brightness values to brighter color or brightness values and define it as the phase boundary between blood clot and separating means or separating means and serum. The image region determined for the blood clot or the separating means can once again be removed from the image computationally.

[0016] Another possibility for identifying blood serum and/or separating means and/or blood clot is the use of the so-called region-grow method. In this case, regions of pixels with similar color values are determined, and the resulting regions are defined as serum, separating means and/or blood clot. In this case, as well, the image regions that correspond to the separating means and the blood clot can be removed from the image computationally.

[0017] In order to detect solid particles in the serum, it is provided according to the invention that the region corresponding to the serum is compared with stored color values of reference samples and classified as "clear" or "not clear". This is advantageous, since it is possible to use for this purpose the stored color values that are obtained in the identification of the serum region. The method according to the invention also offers the advantage that the volume of the blood serum can be determined easily. For this purpose, the upper and lower limits of the serum region are determined automatically, and the volume is calculated automatically with the aid of the diameter of the container.

[0018] It is proposed for the actual color analysis of the serum to determine the color value for each pixel, compare it with stored color values of classified reference samples, and to classify it as "good" or "not good". It is advantageous to undertake the comparison in a color space, preferably in

a "CIE Lab" space. In order to avoid erroneous classification, the serum is preferably classified overall as "good" whenever the majority of the pixels are classified as "good" or is classified overall as "not good" when the majority of the pixels are classified as "not good".

[0019] The handling apparatus can be controlled, in turn, with the aid of the classification determined for the serum such that "good" and/or "clear" samples are passed for further analysis, and "not good" and/or "not clear" samples are rejected.

[0020] The proposed method requires reference samples for evaluating the images produced. It is proposed for this purpose to produce images of known samples, to classify them into classes, and to store them in data file/files. It is particularly advantageous to extract color features once for all the images of the individual classes.

[0021] Since this can be repeated as often as desired, it is possible in this way to supplement and update the classification, and to refine the individual methods of comparison.

[0022] The apparatus according to the invention for analyzing body fluids is distinguished in that an image recording device is provided and connected to an electronic image evaluation apparatus. This purpose is advantageously served by at least one computer that is programmed for carrying out the method according to the invention. This at least one computer is preferably integrated in the apparatus. It is particularly advantageous to provide two computers, the control software being installed on one computer, and the image processing software being installed on the other computer. This software can, of course, be stored on any desired readable storage medium with the aid of the corresponding electronically readable control signals that can cooperate with a programmed computer system such that the method according to the invention is executed. A dedicated storage medium can be provided for each item of software.

[0023] The further features and advantages are to be gathered from the description of an exemplary embodiment of the invention illustrated in the following drawings and from the further subclaims. In the drawings:

[0024] FIG. 1 shows the analysis device according to the invention in a front view, in a schematic illustration that is not true to scale;

[0025] FIG. 2 shows the arrangement according to the invention for analyzing body fluid, in a plan view in a schematic illustration that is not true to scale;

[0026] FIG. 3 shows the arrangement in accordance with FIG. 2 in the direction of view R with a container located in the transport position, in a schematic illustration that is not true to scale;

[0027] FIG. 4 shows the arrangement in accordance with FIG. 2 in the direction of view R with a container located in the analysis position, in a schematic illustration that is not true to scale;

[0028] FIG. 5 shows the arrangement in accordance with FIG. 2 with an illuminating device in a plan view, in a schematic illustration that is not true to scale;

[0029] FIG. 6 shows the arrangement in accordance with FIG. 5 in the direction of view S, in a schematic illustration that is not true to scale;

[0030] FIG. 7 shows a container used with the arrangement according to the invention;

[0031] FIG. 8 shows an illustration of a detail of a reflection plate in plan view, in a schematic illustration that is not true to scale;

[0032] FIG. 9 shows an exemplary illustration of the evaluation of the image of a cap of a sample tube; and

[0033] FIG. 10 shows an exemplary illustration of the evaluation of the image of a container.

[0034] FIG. 1 illustrates the whole of a device 10 for analyzing body fluid. In essence, the device 10 comprises a cabinet 11 for holding a control computer 12 operated by control software, and for holding an image processing computer 13 operated by image processing software. The data determined by the computers 12 and 13 are displayed on a computer display screen 14. Arranged on the cabinet 11 is a housing 15 that surrounds a chamber 16 with no optical reflections.

[0035] A transport track 17 for feeding into the housing 15 containers 20 containing body fluid 21 located in racks 18 is provided on one side of the housing 15. On the side of the housing 15 opposite the transport track 17, a transport track 19 is provided for carrying off containers 20 with analyzed body fluid 21. The body fluid 21 to be analyzed can be blood serum, blood plasma or the like.

[0036] FIG. 2 shows a plan view of the open housing 15. The transport tracks 17 and 19 are connected to one another by a transversely running transport track 23. The containers 20 located in the racks 18 are brought one after another into an analysis position 22 on the transport track 23.

[0037] The analysis position is fed containers 20 with centrifuged body fluid 21 such that, as illustrated in FIG. 7, the body fluid 21, for example blood serum, is located in the upper region of the container 20, a separating means 25 is located in the middle region, and a blood clot 26 is located in the lower region. The container 20 is sealed with a cap 24. Affixed in the region of the body fluid 21 is a label 27 whose mutually opposite end edges 28 have a mutual spacing of at least 6.5 millimeters that permits a window 52 for a free view of the body fluid 21.

[0038] The chamber 16 which has few optical reflections is equipped, for example, with inner walls having matt black surfaces. An image recording device 30 and a scanner 29 are accommodated in the chamber 16 which has no optical reflections, the image recording device 30 being aligned with and focused on the container 20 containing the body fluid 21, while the scanner 29 is aligned with and focused on the label 27.

[0039] The image recording device 30 can also be arranged outside the chamber 16, although then a lightproof opening 31 for the passage of the objective 32 of the image recording device 30 is formed in a wall 33 of the chamber 16 (as shown in FIGS. 3, 4 and 5). The image recording device 30 can be a still camera, a color image camera, a video camera, a spectral camera or the like. A color image camera, for example a 3-chip CCD video camera, is preferred. Depending on the geometry of the arrangement according to the invention, the settings of the color camera, such as focusing, white balance, diaphragm setting, filling-in, can be permanently preset. However, they can also be

readjusted with the aid of the image evaluation software when the data reported by the image evaluation software to the control software (see further below on this point) are of reduced quality with reference to the reference data stored in the computer 13.

[0040] The connection between the image recording device 30, for example such a 3-chip CCD video camera, and the image evaluation computer 13 necessitates a conversion of the color signal produced by the image recording device 30 in the form of an analog voltage signal into a digital that can be processed by the computer 13. This can be performed, for example, via a so-called framegrabber, known per se. These devices can also be integrated in the image recording device 30 such that the latter can be connected directly via a cable or a bus sysem (for example "firewire") to the computer 13.

[0041] The image recording device 30 is fastened on an adjustable frame 34, and it is inclined with its optical axis 54 in its vertical alignment by a variable acute angle α of preferably 5 degrees of angle with reference to the perpendicularly arranged container 20. The cylindrical container 20 and/or the body fluid 21 located therein can be recorded with comparatively few optical reflections with the aid of this measure. Here, the optical axis 54 of the image recording device 30 runs in a vertical plane that lies perpendicular to the line A, the line B lying in this vertical plane.

[0042] Arranged above and in the middle relative to the analysis position 22 is a lifting rotary gripper 35 whose drive is controlled by the control computer 12. The lifting rotary gripper 35 grips a container 20 located in the rack 18 and lifts it into the analysis position 22 and lowers it back into the rack 18 after recording by the image recording device 30.

[0043] During a recording by the image recording device, a reflection plate 36 that can be moved to and fro horizontally in the exemplary embodiment (it can also be moved vertically) lies on the side averted from said device, in order during recording to mask out the characters, such as a bar code, for example, printed on the label. From a lowering of an analyzed container 20 by the lifting rotary gripper 35, the reflection plate 36 is moved away on guide bolts 44 from the container 20 in order to make room for the lifting rotary gripper 35.

[0044] A plan view of the reflection plate 36 is illustrated in FIG. 8. It is provided with a white, preferably dirt-repellant surface that is turned toward the container 20 and in which there is recessed a concave depression 37 adapted to the outer shape of the container 20.

[0045] This depression 37 merges into flat surfaces 40 and 41 on both sides via rounded-off portions 38 and 39. The flat surfaces end in vertically arranged sharp edges 42 and 43 that serve as measuring edges. 15 to 50%, preferably 20 to 25% of the surface of the container 20 are covered by the reflection plate 36, such that labels of different size can be masked out reliably.

[0046] Finally, provided in the chamber 16 which has no optical reflections, is an illuminating device 45 that, during the process of analyzing a container 20 filled with body fluid, illuminates with as few reflections as possible said container, and the body fluid 21 contained therein.

[0047] An extensive empirical determination has shown that the arrangement of lamps described below results in an illumination that has comparatively few reflections.

[0048] The illuminating device 45 is arranged above a container 20 located in the analysis position 22, and comprises three lamps 46, 47 and 48. In this case, arranged in each case on both sides of the container 20 located in the analysis position 22 is a lateral lamp 46 and 47, the arrangement being such that the mid points 49 and 50 of the two lamps 46 and 47 and the mid point 51 of the container 20 lie on a straight line A, and that a further, middle lamp 48 is provided in such a way that the mid points 53 and 51 of this middle lamp 48 and of the container 20 likewise lie on a straight line B, which runs perpendicular to the line A.

[0049] In addition, the three lamps 46, 47 and 48 have the same horizontal spacing from the container 22 located in the analysis position, which is sixty millimeters in the exemplary embodiment, for example. Furthermore, the vertical height of the lateral lamps 46 and 47 arranged on both sides of the container 20 located in the analysis position 22 is of greater dimension than the vertical height of the middle lamp 48. This difference is sixteen millimeters in the exemplary embodiment.

[0050] The mode of operation of the arrangement according to the invention is as follows:

[0051] Once a rack 18 filled with containers 20 has reached the analysis position with its first container 20, the image recording device 30 is used to determine the shape of the cap 24 sealing the container 20, and thus to determine the manufacturer, the type and the geometry of the container 20.

[0052] Then the lifting rotary gripper 35 lifts the container 20 on the basis of the dimensions determined into the suitable analysis position 22, rotates the container on the basis of the end edges 28 of the label 27 determined by the scanner 29 into a position ready for recording in which the window 52 is turned toward the image recording device 30. At the same time as the image recording device 30 is making one or more recordings of the body fluid 21, the shape of the cap 24 of the subsequent container is detected. The container 20 with the analyzed body fluid 21 is lowered again into the rack 18, the rack 18 is conveyed up to the subsequent container 20, and the latter is then gripped by the lifting rotary gripper 35 at the cap 24, moved into the analysis position 22 and aligned ready for recording.

[0053] The actual image evaluation is performed as follows:

[0054] The method according to the invention can be carried out with the aid of control software and image processing software. The two software packages are installed on different computers (12, 13) in the exemplary embodiment. The control software has the purpose of bringing the container 20 into a position that is favorable in relation to the image recording device, that is to say in concrete terms for the purpose of controlling the movement of the handling apparatus. In the exemplary embodiment, the image processing software is hierarchically subordinated to the control software (so-called "slave").

[0055] In order to identify the container 20, the image processing software firstly receives from the control software the command to record an image of the container or of the cap of the tube, to evaluate it and to report the resulting data back to the control software. The image recording device 30, a color image camera in the exemplary embodi-

ment, produces an image of the cap. This color image can be processed further directly, or be converted into a gray value image.

[0056] In order to process the image further, the color value (in the case of a color image) or the brightness value (in the case of a gray value image) of pixels situated vertically under one another are evaluated. This is illustrated schematically in FIG. 9 by depicting two current cap types 60a and 60b. Laid in each cap 60a, 60b in the exemplary embodiment are five vertical lines along which the color or brightness values of the pixels lying on them are determined. The change in color value or brightness value at the upper edge of the caps is also determined in this case at the transition from the background image to the upper cap edge. The corresponding pixels are emphasized in FIG. 9 by being thickened. In this way, a contour of the upper cap edge is determined that is characteristic for different manufacturers. The color value or brightness value data determined are compared with data of known caps that are stored in a file in the computer. If the image processing software determines a correspondence, the image processing software then takes over the stored data of the tube belonging to the identified cap, and sends these data to the control software. The latter uses the data in order to control the handling apparatus and to bring the tube into a position that is suitable for its dimensions and is prescribed in the computer, in order to detect the image.

[0057] The next step consists in rotating the container 20 in order to rotate any possibly present labels or other covers on the container 20 from the image section defined by the image detecting device. Provided for this purpose in the exemplary embodiment is a scanner, preferably a bar code scanner, that is capable of detecting a bar code on labels. When the scanner beam migrates over the container 20 and can detect a bar code that is present, it sends an appropriate signal ("good read") to the control software that controls the handling apparatus. The container is then rotated until the scanner no longer detects a bar code and once again sends an appropriate signal ("no good read") to the control software. The container is then further rotated until the label that has been exactly located by the bar code scanner is no longer located in the region of the optics of the image recording device.

[0058] After the image recording device, in the exemplary embodiment a color image camera, has produced a color image of the body fluid in the relevant container, and stored it as a data record, the actual analysis of the body fluid is performed as illustrated schematically in FIG. 10.

[0059] FIG. 10 shows, in an enlarged schematic illustration, a part of the reflection plate 36, specifically the surfaces 40, 41 and the sharp edges 42, 43, as well as the container 20 with the centrifuged body fluid, which is separated into serum or plasma 21, separating means 25 and blood clot 26. The color image is either processed further directly, or converted into a gray value image. The image processing software then lays in the image a number, 7 in the exemplary embodiment, of horizontal lines along which, in the case of a color image color values and, in the case of a gray value image, brightness values are determined for the pixels lying on the lines. A transition from black to white that corresponds to the course of the edges 42, 43 of the reflection plate 36 is firstly determined from outside inward. The outer

image edges are thus determined, and the actual pixel is fixed. This prevents the image background from being analyzed as well, which would cause a defective evaluation and, in addition, demand computer time and storage space. The corresponding pixels are marked by circles.

[0060] In a second step, the color or brightness values of the pixels on the lines are further evaluated from outside inward until it is possible to determine a transition from white to non-white. The edge of the container 20 is therefore defined such that the white background originating from the reflection plate 36 can likewise be removed by calculation. The image section actually to be evaluated is thereby defined. The corresponding pixels are marked by triangles.

[0061] The blood serum or plasma 21 actually to be evaluated must then be identified and be separated, computationally from the separating means 25 and the blood clot 26. The separating line 55 between the serum 21 and the background is firstly determined for this purpose. This is performed either as described via the analysis of pixels along horizontal or vertical lines, as was described above for the identification of the tube cap. Alternatively, the upper edge 21' of the serum 21 can also be determined by means of the threshold value method known per se.

[0062] In order to identify the blood clot, which is of a dark red color, as a rule, the image section to be evaluated, which has been identified with the aid of the method steps just described, is systematically searched through from bottom to top, each pixel row being scanned from bottom to top. This can be performed on color image or—preferably—on the gray value image. The transition from the dark blood clot 26 to the lighter separating means 25 is determined by means of the threshold value method known per se. The corresponding pixel row is indicated by rectangles. The image section that includes the blood clot 26 is removed computationally thereupon.

[0063] Finally, the separating layer 25, if present, must be identified and separated computationally from the serum or plasma 21. It is preferred to use the color image for this purpose, since the serum 21 and separating layer 25 are known from experience to have similar brightness values. The so-called region-growing method is used for this purpose. Here, each pixel is analyzed individually, and regions of pixels with similar color values are determined. In this case, "similar" means a maximum color value difference prescribed by the software which may exhibit two pixels in order still to belong to the same region. In detail, the color value that defines an image region is determined for a first pixel. When a neighboring pixel has a similar color value, that is to say when the color value difference does not exceed a prescribed maximum value, it is added to the same region as the first pixel. When, by contrast, a neighboring pixel has another color value, that is to say the color value difference exceeds the prescribed maximum value, this neighboring pixel defines a new region of pixels with similar color values.

[0064] Two regions are finally determined in this way, specifically a region that corresponds to the serum 21, and a region that corresponds to the separating means 25. The phase boundary between both regions is calculated by the image processing software. Empirical values are programmed for this purpose, for example that the serum region lies above the region of the separating means, and that the

serum region occupies a larger area than the region of the separating means. The image processing software therefore computationally determines the separating line 56 between the serum 21 and separating means 25. This calculated line is marked by lozenges.

[0065] The actual evaluation of the image of the serum 21 can then begin after all the other constituents of the image produced by the image recording device 30 have been identified and removed computationally. The volume of the serum 21 is firstly determined. The spacing between the separating line 55 and the separating line 56 is determined for this purpose by means of the image processing software. Subsequently, the image processing software calculates the quantity of the body fluid located in the container 20 on the basis of the data obtained, taking account of the diameter of container 20.

[0066] The diameter of the container 20 is known and stored in a file in the image processing computer 13 since, as described above, the type of tube has already been identified and the dimensions of the various types of tubes are stored in the image processing computer. Of course, the quantity of serum 21 can also be calculated with the aid of the measured widths of the container 20, although there is then the risk of regions of covers that project into the image simulating a lesser width and thus falsifying the result.

[0067] Finally, the actual color analysis further belongs to the evaluation of the serum image. The color analysis is used to check whether the serum 21 is "good" or "bad", that is to say whether the sample is passed to a further medical analysis of the serum, or rejected as incapable of medical analysis. The serum 21 is useful when it is clear, bright and, if appropriate, green is color. The serum 21 with other colorings or cloudiness is rejected as useless.

[0068] This color analysis is carried out by establishing the color value for each pixel of the image section representing the serum 21, and compared with stored color values. This comparison takes place in at least one so-called "color space". In the exemplary embodiment, this is the so-called "CIE Lab" space. This color space is spherical. Color differences inside the color sphere are measured in order to compare the color values. Reference data for typical serum samples are distributed in the interior of the sphere ("see also under "teach-in" further below for this purpose). The measured color value is compared with the reference values. What is required here is to determine the reference value closest to which the measured value lies, or the reference value from which the measured value has the smallest color difference. This evaluation is denoted as the "smallest difference classifier" or as the "nearest neighbor classifier". The more reference values that are present, the more reliable is the result of the evaluation.

[0069] In the exemplary embodiment, each pixel of the image section that represents the serum 21 is detected; which amounts to approximately 10,000 to 30,000 pixels. In this case, it is entirely possible for different pixels to be evaluated in various classes, for example as "good" or "not good". The final classification is performed in the exemplary embodiment by a "majority vote", that is to say when the majority of the images are evaluated as "good", the serum 21 is evaluated overall as useful, and when the majority of the pixels are evaluated as "not good" the serum 21 is evaluated overall as useless. This type of overall evaluation reduces the risk of erroneous evaluations and misjudgments.

[0070] Once the color evaluation just described has been completed, the acknowledgement of the result as "sample useful" or "sample useless" to the control software is made. In the case of the acknowledgement of "sample useless", the control software determines that the examination of this sample is concluded; the sample is rejected.

[0071] Given the acknowledgement of "sample useful", a further evaluation step follows in the exemplary embodiment, specifically the examination for solid particles, so-called clots, in the serum 21. These are solid blood constituents such as, for example, fibrinogen that have not been centrifuged out in the blood clots 26. These clots would block injection needles, for example, in the further processing of the sample, and therefore render the analysis equipment dysfunctional. Moreover, they can falsify the result of the medical analysis. Examinations for clots is performed with the aid of a color classifier that functions in a way similar to the abovedescribed color classifier, but which operates with separately produced reference data. Only the regions in the serum 21 that are actually clots are used to set this classifier. It is also possible to mark specific critical regions as "not clot" in order to improve the selectivity of the method; these are inscriptions on the sample tube 20, for example. It is possible, furthermore, to distinguish between "red clots" and "white clots". The results are reported, in turn, to the control software by the image processing software.

[0072] The sample is further processed if the result of the comparison is that the serum image corresponds to a "good" reference image without "clots". However, the control software terminates the examination of the relevant sample, and rejects it, if the result of the comparison is that the serum image corresponds to a "not good" reference image with "clots".

[0073] The evaluation just described is carried through completely once if the image section of the container 20 facing the image recording device is free from covers. Subsequently, the control commands of the control software are used with the aid of the handling apparatus either to place the container 20 onto a transport device for further processing, or onto a transport device for rejection of the sample.

[0074] However, when the image section is, for example, partially blocked by a particularly large cover, for example a particularly large label, the sample is aligned such that only an edge of the cover projects into the image section. This takes place because the data transmitted by the image processing software to the control software serve to control the handling apparatus appropriately. After the evaluation described above, the container 20 is rotated by the handling apparatus, under the control of the control software with the aid of the data transmitted by the image processing software, such that another region of the container 20, one not covered by the cover, passes into the region covered by the image recording device 30. A further evaluation is then undertaken as described above. This process is preferably repeated at most 5 to 6 times.

[0075] The image processing software requires reference data stored in the computer 13 in order to evaluate the image produced by the image recording device. These reference data can be produced, for example, by means of a so-called "teach in". In this case, known samples, no longer required,

that are preferably at most 10 days old are recorded, and the data are stored in the form of whole images. Each image is given a classification, for example "good", "hemolytic", "lipemic" or "icteric". The color quality of each probe is stored with the aid of this classification. The totality of this data is denoted as "classified learning sample". It is thereby possible, in particular, for the classification of "hemolytic", that is to say relatively strong red coloration through red blood pigment, to be adapted to the evaluation practice of individual laboratories, since such a red coloration can also be based on a procedural error during the withdrawal of blood.

[0076] In this case, the sample can be used for medical analysis despite the red coloration. In order to avoid unnecessarily high wastage, the tolerance threshold for the assessment of "useless" can be lowered to the customer's desire.

[0077] The classifier can be trained after the images have been assigned to the individual classes. For this purpose, it extracts other color features for all the images of the individual classes. This can be repeated as often as desired, that is to say the classifier can be updated at any time.

[0078] The detection of the clots can likewise be controlled by means of reference data that are produced in a "teach in". The image section detected by an expert as clots and marked are stored for this purpose in the computer 13 and used as reference data. The classifier for the clots can use these reference data to become trained in detection by extraction of the color features. This classifier can also be updated at any time.

[0079] The software required for the evaluation described is produced in the exemplary embodiment as Microsoft C++ in ANSI C. The software uses API functions of Windows-NT 4.0 with service pack 6.0. Neither the Microsoft Foundation Classes (MFC) nor C++-specific elements are used. The command library WiT 7.11 of Logical Vision is used for image processing. This also includes the special C data structure that is explained in the handbooks on WiT. Libraries from WiT 7.11 are also used for controlling the framegrabber. These libraries use backups of two other software packages, "Sapera 3.10 Runtime Basic and Processing" and the Viper-RGB driver, Version 3.10, in order to control the frame driver.

[0080] Annex 1 offers an overview of the data and directory structure of the software according to the invention.

1. A method for analyzing body fluids, characterized in that an image recording device is used to produce at least one image of the body fluid located in a container that is analyzed by means of image processing software.

2. The method as claimed in claim 1, characterized in that firstly the type and size of the container are determined automatically.

3. The method as claimed in claim 1 or 2, characterized in that an image of the container is produced with the aid of the image recording device, and is compared with the aid of evaluation software with stored image files and/or dimensions of known containers.

4. The method as claimed in claim 3, characterized in that the caps of the tubes holding the body fluid are compared, and the type of tube and height of tube are determined thereby.

5. The method as claimed in claim 2, characterized in that after determination of the type and size of the container the latter is moved automatically in such a way that as complete an image as possible of the body fluid can be produced by means of the image recording device.

6. The method as claimed in claim 1, characterized in that the container is moved automatically such that as complete an image as possible of the body fluid can be produced.

7. The method as claimed in claim 6, characterized in that a scanner and/or image evaluation software are provided for detecting an inscription placed on the container, a label and/or a cover, and in that the scanner detects the bar code and the image evaluation software detects the edges of the cover, and the container is moved automatically such that the cover is situated on the side of the container averted from the image recording device.

8. The method as claimed in claim 7, characterized in that following the optical blanking out of a cover the container is covered on the side averted from the image recording device.

9. The method as claimed in claim 8, characterized in that 15 to 50%, preferably 20 to 25%, of the outer surface of the container is covered.

10. The method as claimed in claim 1, characterized in that the image recording device is used to produce simultaneously an image of the body fluid in a first container and an image of a subsequent second container for the purpose of determining the type and size of the second container.

11. The method as claimed in claim 1, characterized in that a color image of the body fluid and of the container is produced.

12. The method as claimed in claim 11, characterized in that the color image of the body fluid and/or of the container are/is converted automatically into a gray value image.

13. The method as claimed in one of claims 11 or 12, characterized in that for the purpose of detecting the type and size of the container, a number of vertical lines are laid in the image of the container, the color values and/or brightness values of the pixels lying on these lines are detected, and changes in color value and/or brightness value are determined and compared with the data of known containers.

14. The method as claimed in claim 13, characterized in that the handling apparatus is controlled with the aid of the data determined for the container.

15. The method as claimed in claim 1, characterized in that one or more detail images are produced that are combined by means of the image processing software to form an overall image.

16. The method as claimed in claim 1, characterized in that for the purpose of evaluating the image of the body fluid, a number of perpendicular and/or horizontal lines are laid in the image of the body fluid, the color values and/or brightness values of the pixels lying on these lines are detected, changes in color value and/or brightness value are determined, and the background region and/or upper edge of the body fluid are determined.

17. The method as claimed in claim 16, characterized in that the background region is removed from the image computationally.

18. The method as claimed in claim 1, characterized in that in order to identify the separating means and/or the blood clot in a centrifuged sample of body fluid, each pixel row of the image is scanned from bottom to top, and the transition from dark color or brightness values to brighter color or brightness values is detected and defined as phase boundary between blood clot and a separating means or between the separating means and serum.

19. The method as claimed in claim 18, characterized in that the image region determined for the separating means and/or the blood clot is removed from the image computationally.

20. The method as claimed in claim 1, characterized in that in order to identify blood serum/plasma and/or separating means and/or blood clot by means of the region-grow method, regions of pixels with similar color values are determined, and the resulting regions are defined as serum, separating means and/or blood clot.

21. The method as claimed in claim 20, characterized in that in order to detect solid particles in the serum and/or plasma, the region corresponding to the serum is compared with stored color values of reference samples and classified as "clear" or "not clear".

22. The method as claimed in claim 21, characterized in that in order to identify solid particles in the serum and/or plasma, the region corresponding to the serum is compared with stored color values of defined solid particles in reference samples, and classified in terms of shapes or colors, for example "red clots" and "white clots".

23. The method as claimed in claim 20, characterized in that the blood clot and/or the separating means are/is removed from the image computationally.

24. The method as claimed in claim 20 or 21, characterized in that in order to determine the volume of the blood serum, upper and lower limits of the serum region are determined automatically, and the volume is calculated automatically with the aid of the diameter of the container.

25. The method as claimed in claim 1, characterized in that the color value is determined for each pixel for the purpose of color analysis of the serum, is compared with stored color values of classified reference samples, and is classified as "good" or "not good".

26. The method as claimed in claim 24, characterized in that the comparison is undertaken in a color space, preferably in a "CIE Lab" space.

27. The method as claimed in claim 24, characterized in that the serum is classified overall as "good" when the majority of the pixels are classified as "good", and in that the serum is classified overall as "not good" when the majority of the pixels are classified as "not good".

28. The method as claimed in one of claims 21 to 23 or 25 to 27, characterized in that the handling apparatus is controlled with the aid of the classification determined for the serum such that "good" and/or "clear" samples are passed for further analysis, and "not good" and/or "not clear" samples are rejected.

29. The method as claimed in claim 1, characterized in that images of known samples are produced, classified into classes and stored in data file/files in order to produce reference data.

30. The method as claimed in claim 29, characterized in that color features are extracted at least once for all the images of the individual classes.

31. An apparatus for analyzing body fluids, characterized in that an image recording device is provided and is connected to an electronic image evaluation apparatus.

32. A computer programmed for carrying out the method as claimed in claim 1.

33. An apparatus for analyzing body fluids, characterized in that an image recording device is provided and is connected to an electronic image evaluation apparatus, said apparatus including at least one computer as claimed in claim 32.

34. A digital storage medium having electronically readable control signals that can cooperate with a programmed computer system such that a method as claimed in claim 1 is executed.

35. The storage medium as claimed in claim 33 that has control software for controlling an apparatus for analyzing body fluids, said apparatus being characterized in that an image recording device is provided and is connected to an electronic image evaluation apparatus.

36. The storage medium as claimed in claim 35 that has image processing software for analyzing images.

37. A computer program product for carrying out the method as claimed in claim 1.

38. The computer program product as claimed in claim 37, specifically control software for controlling an apparatus for analyzing body fluids, said apparatus being characterized in that an image recording device is provided and is connected to an electronic image evaluation apparatus.

39. The computer program product as claimed in claim 37, specifically image processing software for analyzing images.

40. The computer program product as claimed in one of claims 37 to 39 that is stored on a data carrier, in particular a hard disk, a floppy disk, a CD ROM or a storage tape.

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