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(54) IMPROVEMENTS TO MICROCONTAINERS FOR CLINICAL ASSAYS

(57) The improvements provide means for holding the stop body axially in its seat which are constituted by mechanical interference between the stop body and the seat region therein in the intermediate narrowed portion of the microcontainer and which extend to limited regions of the periphery of the stop body to leave gaps free for the passage, by centrifugation, of the sample from the mouth for entry into the microcontainer towards the cylindrical or tubular body carrying the reagent.

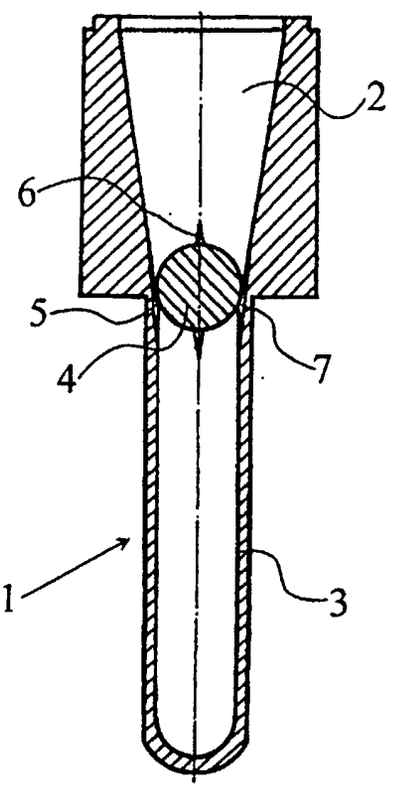

FIG. 1

EP 1 206 968 A1

Description

[0001] The present invention proposes improvements to microcontainers for clinical analyses, especially of blood groups, which bring substantial features of novelty and inventive activity to the function for which the microcontainers are intended.

[0002] In particular, the improvements to which the present invention relates are intended for microcontainers for clinical analyses which are provided with a lower body carrying a reagent, optionally with a gel incorporated for retention and filtration, and which are later to receive the sample to be analysed in the upper mouth of the container, which sample is to pass to the reagent contained in the lower body after suitable centrifugation. In a preferred version, the microcontainers form a unit in the form of a "plate" or "card" which facilitates the handling thereof.

[0003] Microcontainers for carrying out clinical analyses are already known on the market. Thus, for example, European patent 194 212 discloses microcontainers which are substantially cylindrical at their upper portion and which narrow at their lower portion after an intermediate conical region. In addition, European patent 305 337 discloses similar microcontainers which are provided with an optionally flattened side and which are fitted to a flat plate. All of the indicated microcontainers are open at their upper portion at the moment when they are used for their specific purpose, all of them being based on the fact that, in the case of blood analysis, the red blood corpuscles located on top of the mixture of particles or gel and absorbed in the agglutinating serum penetrate by centrifugation into the mentioned layer formed by the reagent and particles and, as they move down, they agglutinate if the reactive serum and the red blood corpuscles are of the same kind. When agglutination is complete, clots of a larger size are produced which cannot penetrate into the granular mass and, therefore, remain visible on top of the layer of granules or gel. When there is no reaction, the red blood corpuscles, which have not agglutinated, have a smaller size than the clots and pass through the layer of gel and particles to the bottom of the tube.

[0004] However, that type of known microcontainer can have some disadvantages owing to the lack of effective holding, with insecure location of the reagent in the cylindrical lower portion of the microcontainer, so that, when the cards of microcontainers of this type are put to practical use, there are often situations in which, owing to errors in handling, the falling of the card or the like, the reagent may be partially or completely expelled from the cylindrical body of the microcontainer, with the result that the latter is not in a suitable state for performing its function on receiving the sample to be analysed and may possibly produce incorrect results with the serious consequences which that might involve.

[0005] Another disadvantage of some of the currently known analysis microcontainers resides in the possibility that the introduction of the sample to be analysed might take place with excessive speed or with incorrect positioning of the pipette. That would not ensure a subsequent smooth and normal entry, by centrifugation, of the sample to be analysed, giving rise to mixtures at the wrong time, which may also produce incorrect readings.

[0006] It will be appreciated, therefore, that, in currently known microcontainers, it is possible to have incorrect analysis results which may have markedly serious consequences. In particular, in the case of blood analysis, an error in the results thereof may lead to fatal consequences for the patient, as shown by clinical experience in recent years.

[0007] In order to overcome the disadvantages indicated above, the present applicant in due time filed Spanish utility model application No. 9900372 which provided an element for controlled closure arranged between the upper portion of the microcontainer or receiving cavity and the lower portion thereof, so that the communication between the upper and lower portions necessarily had to take place by the action of centrifugation, given that the closure element interposed between the two chambers left free passages of reduced cross-section which were sufficient for passage by centrifugation but which prevented free passage from the upper chamber to the lower chamber of the microcontainer as occurred in practice. That invention already signified an important advance in that it provided for the arrangement of an intermediate stop body between the upper mouth of the microcontainer and the lower body containing the reagent, in order to prevent the sudden entry of the sample to be analysed into the portion of the body containing the reagent.

[0008] The present invention constitutes an improvement to Spanish Utility Model Application No. 9900372 of the current applicant, since studies and investigations carried out by the inventor showed that, although his invention, which consisted in providing a body for controlled closure between the upper mouth of the microcontainer and the lower body thereof, had clear positive effects, there was still a possibility that if, owing to incorrect handling by a non-expert operator, the pipette carrying the sample to be analysed is introduced with excessive force and/or to an excessive depth, that action could bring about the partial lifting of the intermediate closure body. That would permit the accidental passage of the pipette towards the lower portion of the microcontainer and therefore the reaction would not be seen, which could give rise to a totally incorrect reading which would be especially dangerous in the case of blood analysis.

[0009] Therefore, the object of the present invention is to provide microcontainers for clinical analyses which not only have sufficient features of protection against sudden entry or against incorrect positioning of the sample to be analysed but which also at the same time avoid any loss of efficiency in the intermediate stop body, preventing any release thereof.

[0010] In order to achieve its objects, the present invention proposes microcontainers for clinical analyses in which the intermediate body for controlled separation between the inlet mouth of the microcontainer and the lower body thereof, which contains the reagent, is held by means of a specific structure of the seat receiving the intermediate body, which structure, permitting the passage, by centrifugation, of the sample to be analysed from the introduction mouth, passing via the narrow gaps controlled by the intermediate body, towards the lower body containing the reagent, prevents the intermediate body from leaving its seat and thereby ensures the desired efficiency.

[0011] The intermediate body can be held in position preferably by arranging in the seat region longitudinal ribs which define support regions for the limiting body, preventing it from accidentally leaving its seat, and which simultaneously define gaps permitting the passage of the sample towards the lower body of the microcontainer in which the reagent is located.

[0012] To summarise, the present improvements are characterised by the provision of means for holding the stop body axially in its seat which are constituted by the mechanical interference between the stop body and the seat region therein in the intermediate narrowed portion of the microcontainer, and which extend to limited regions of the periphery of the stop body to leave gaps free for the passage, by centrifugation, of the sample from the mouth for entry into the microcontainer towards the body carrying the reagent. The interference can be achieved, for example, by forming housings in the front edges of longitudinal ribs arranged in the narrowed portion of the microcontainer, which housings have a shape matching the lateral surface of the stop body, permitting the introduction thereof owing to the resilience of the microcontainer and/or of the stop body, or also, according to another example, by forming a prismatic housing in the narrowed portion of the microcontainer, which housing is to receive, with interference, a spherical stop body or the like.

[0013] Some drawings representing a preferred embodiment of the present invention are added by way of non-limiting example for a better understanding thereof.

[0014] Figures 1 and 2 are longitudinal sections through a microcontainer which includes the present improvements, in accordance with mutually perpendicular planes.

[0015] Figure 3 is a plan view of the microcontainer.

[0016] Figures 4 and 5 are sections similar to Figures 1 and 2, respectively, through a variant of the present invention.

[0017] Figure 6 is a plan view of the microcontainer represented in Figures 4 and 5.

[0018] As may be appreciated from the drawings, the present improvements are applicable to microcontainers having a mouth or upper body 1 and a lower body 2 that is to contain the reagent, the two being separated by a narrower region 3 in which is located an intermediate body 4 which acts as a stop to prevent the sample from entering at too high a speed or with an error in the positioning of the dispensing pipette or nozzle, possibly leading to direct mixing with the reagent of the container 2. The present improvements provide for means for holding the body 4 axially in its housing. This is achieved by various arrangements which use the natural resilience of the microcontainer and of the body 4 to permit the introduction of the stop body 4, normally a small sphere, into its service position, overcoming the slight interference with the microcontainer by the resilience of the material thereof, permitting the introduction of the ball. It is the resilience of the material, combined with the specific shape of the seat intended for the stop body 4, that prevents the stop body from leaving its seat. In the case represented in the mouth region 3, there are several longitudinal thin walls or ribs such as those shown with the numerals 5, 6, 7 and 8, which are variable in number and which are characterised in that their front edge can be straight or can have respective recesses 20 of a shape matching the stop body 4, that is to say, having a curved shape if the stop body is a spherical ball, as represented in the drawings.

[0019] In a variant of the present invention represented in Figures 4 to 6, the mouth 9 of the microcontainer has a narrowed portion 10 which may have a prismatic transverse shape, for example a square prismatic transverse shape with sides 11, 12, 13 and 14, and which is to receive the stop body, which is preferably in the form of a ball 15 which can be held under pressure inside the prismatic housing, the edges defining respective passages 16, 17, 18 and 19 for communication between the mouth of the upper portion and the lower body of the microcontainer.

[0020] The stop body can be held inside the prismatic housing by simple resilience, both of the stop body and of the container, or by producing regions of matching shape which are to receive the mentioned stop body when it has been introduced. As will be appreciated, this form of holding can also be applied to the structure represented in Figures 1 to 3.

Claims

1. Improvements to microcontainers for clinical analyses, of the type which comprise an upper mouth and a generally cylindrical lower container carrying the reagent, with an intermediate stop body which defines controlled gaps for the passage, by centrifugation, of the sample to be analysed towards the body carrying the reagent, **characterised by** the provision of means for holding the stop body axially in its seat which are constituted by mechanical interference between the stop body and the seat region therein in the intermediate narrowed portion of the microcontainer, and which extend to limited regions of the periphery of the stop body to leave gaps

free for the passage, by centrifugation, of the sample from the mouth for entry into the microcontainer towards the body carrying the reagent, preventing the accidental lifting of the intermediate stop body from its seat.

2. Improvements to microcontainers for clinical analyses according to claim 1, **characterised in that** the mechanical interference between the stop body and its seat in the microcontainer is achieved by forming housings in the front edges of longitudinal ribs arranged in the narrowed portion of the microcontainer, which housings have a shape matching the lateral surface of the stop body, permitting the introduction thereof owing to the resilience of the microcontainer and/or of the stop body.

3. Improvements to microcontainers for clinical analyses according to claim 2, **characterised in that** the thin longitudinal walls have curved housings in their front edges for receiving a stop body which is in the form of a ball.

4. Improvements to microcontainers for clinical analyses according to claim 1, **characterised by** the formation of a prismatic housing in the narrowed portion of the microcontainer, which housing is to receive, with interference, a spherical stop body or the like.

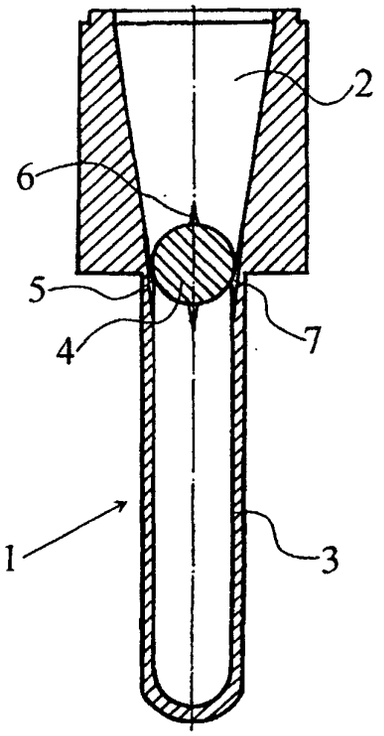

FIG. 1

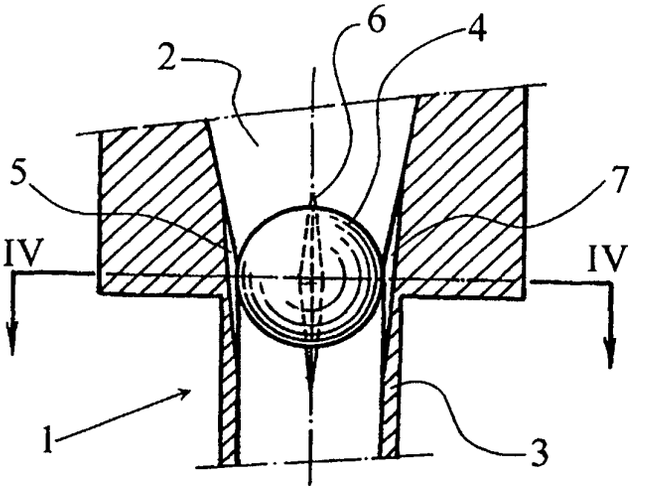

FIG. 2

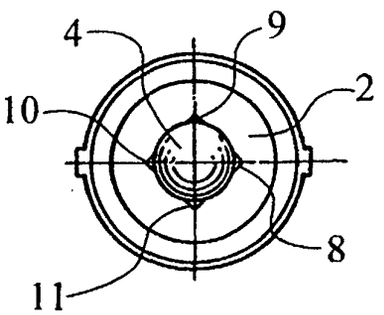

FIG. 3

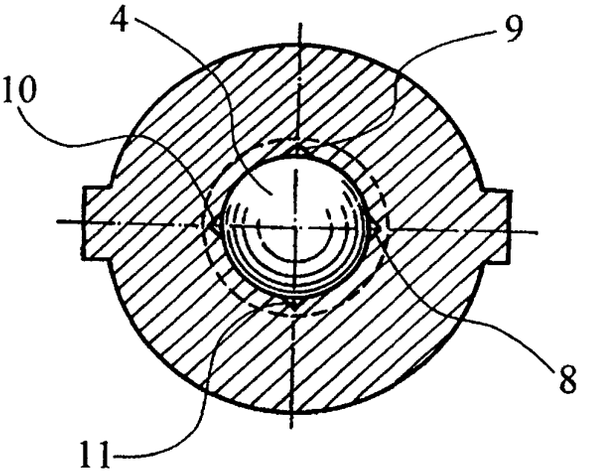

FIG. 4

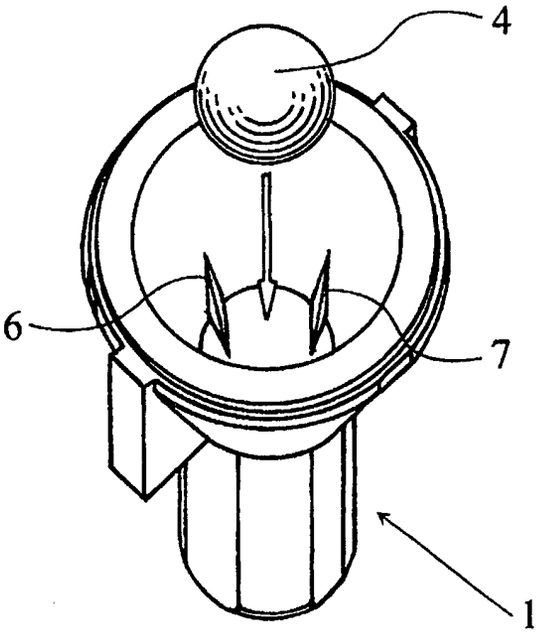

FIG. 5

INTERNATIONAL SEARCH REPORT

Inte[illegible]al Application No
PCT/ES 00/00339

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 B01L3/14

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)
IPC 7 B01L G01N A61B

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

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	ES 1 042 236 A (V GRIFOLS LUCAS) 16 August 1999 (1999-08-16) the whole document ---	1
A	EP 0 875 202 A (BECTON DICKINSON CO) 4 November 1998 (1998-11-04) column 4, line 2 - line 39; figures ---	1
A	US 4 417 981 A (NUGENT EDWARD L) 29 November 1983 (1983-11-29) column 4, line 42 -column 5, line 41 column 6, line 35 - line 47; figures 1-4 ---	1
A	US 3 935 113 A (AYRES WALDEMAR A) 27 January 1976 (1976-01-27) -----	

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☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
13 November 2000	29. 11. 00

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Inmaculada R. Asensio

Form PCT/ISA/210 (second sheet) (July 1992)

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PCT/ES 00/00339

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US 3935113 A	27-01-1976	NONE	

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