

DEVICE COMPRISING A LAYER OF ABSORBENT MATERIAL FOR COLLECTING SAMPLES FOR CLINICAL AND DIAGNOSTIC ANALYSES

Field of the invention

The present invention relates to a device comprising a layer of absorbent material for collecting biological samples for clinical and diagnostic analyses.

Background of the invention

In the field of clinical and diagnostic analyses, wads of absorbent material for collecting biological specimens of organic material are known, usually applied to a cylindrical rod around one end of which, known as the tip, a wad of fibre is wrapped such as rayon or a natural fibre such as cotton, with essentially hydrophilic properties to allow rapid absorption of the quantity of specimen to be collected and tested. Stable adherence of the fibre wrapped around the tip of the rod is generally achieved by gluing.

Usually, and especially if the specimen is to be examined by culturing the microorganisms gathered by collection, the wad of absorbent material is immersed in a test-tube containing culture medium immediately after collection, for appropriate conservation of the specimen during storage and/or transport thereof to the analytical laboratory.

The tip of the cylindrical rod, generally manufactured from essentially rigid material such as plastic, for example by extrusion, commonly presents a truncating cut which would make it difficult to insert the wad of absorbent material rod into the cavities (oral, nasal, ocular or rectal, urethra, vaginal etc.) of the patient from whom the specimen is taken, if the tip is not adequately protected. Therefore, the wad of hydrophilic fibre wrapped around said truncated end must not only contain sufficient material to allow absorption of the specimen in the desired quantity, in general 100 microlitres, but must also have a sufficiently thick and rounded shape to sheathe the edge of the truncated end so that it cannot cause damage or irritation to the patient during specimen collection. For this reason the fibre wad is wrapped around the tip of the rod in a rounded shape, typically developing into an ogive or similar shape so that it gradually becomes thicker towards the end of the rod, thus reaching maximum thickness and therefore maximum protective effect, precisely around the truncated end. A wad of such a shape, while protecting the

patient from any risk of contact with said truncated end of the rod, results in a number of drawbacks. The main one is that the thickness of the wad, because of the hydrophilic nature of the fibre, leads to penetration of collected specimen into the mass of said wad. As, for practical reasons, the sample is released from the wad of absorbent material at the moment of analysis by simply gripping the rod of the wad of absorbent material and delicately sliding its tip and hence the fibre impregnated with liquid, along for example a petri dish with culture medium, in practice by spreading the specimen onto this latter (swabbing), even if this operation is repeated and is careful, it does not enable the entire volume, e. g. 100 ml, of absorbed specimen to be released, because that part of it which has penetrated into the interior of the wad in the direction of its tip cannot be pressed out towards the surface and hence released from the wad of absorbent material during this operation

Due to this defect, on average only about 40% of the specimen collected can in practice be recovered for analysis. Such loss of specimen inevitably leads to a reduced sensitivity of the analysis and increased false negatives. In this respect, referring to the aforementioned average specimen loss after swabbing the wad of absorbent material, by testing only the 40 microlitres released by swabbing out of the 100 microlitres of specimen initially collected, it becomes difficult to establish whether a negative test effectively refers to the absence of the microorganism sought or rather to its non-or insufficient transfer from the wad of absorbent material to the test plate.

A further problem derived from the bulky fibre wad of absorbent material of the known art is particularly evident for example in the case of urethra or ocular use of said wad of absorbent material.

In these and other particular applications it would actually be even more desirable to be able to minimize the thickness of the wad of absorbent material and hence patient discomfort during collection.

As a solution to these problems, and also to achieve other advantages which will be apparent from the description, the present invention proposes a device comprising a wad of absorbent material for collecting samples for clinical and diagnostic analyses, of the type consisting of a rod terminating with a tip covered

with the said wad made from fibres to allow absorption of said samples, characterised in that said fibres cover said tip in the form of a brushlike layer having hydrophilic properties applied in an electrostatic field under which the fibres are deposited on the said tip in an oriented orderly arrangement normal to the surface of the rod and in a uniform thickness.

Said fibres deposited in an oriented orderly arrangement enhance a capillarity effect by which absorption of the sample, be it in liquid form or as cells, is improved.

The brush effect of the brushlike layer of fibres also provides an improved collection of a sample made of cells, which can be fully trapped among the oriented fibres, and finally an improved release of said cells from said device.

With the aim of better understanding the characteristics and advantages of the invention, a non-limiting example of a practical embodiment thereof is described hereinafter, with reference to the figures of the accompanying drawings. Said example refers to the case of a wad of absorbent material suitable for both the collection and storage of a biological specimen, such as of the type including a test-tube containing a culture medium suitable for the collected microorganisms into which the wad of absorbent material is to be immersed after collection.

Brief description of the drawing

Figure 1 shows a longitudinal section of the tip of a rod in a device comprising a wad of absorbent material according to the invention where the said brushlike layer of fibres is schematically illustrated.

Fig. 2 shows an enlarged detail of Fig. 1 in the case where the device is used to collect a liquid sample.

Fig. 3 shows an enlarged detail of Fig. 1 in the case where the device is used to collect a sample made of cells.

Detailed description of the invention

With reference to said figures, a device of the invention in accordance with the illustrated example comprises a wad of absorbent material 20 applied to a tip 16 of a rod 14 in the form of a brushlike layer applied in an electrostatic field under which the fibres are deposited on the said tip in an oriented orderly arrangement.

Therefore the rod 14 terminates with a tip 16 carrying as a wad of absorbent material 20, a layer of fibre as described above for collecting the specimen to be analysed. In the illustrated example, said tip 16 of the rod is shaped in a rounded geometry, similar to an ogive, and said fibre being disposed as a layer of uniform thickness.

In the detail of Fig. 2, it is schematically shown how said fibres 20 deposited in an oriented orderly arrangement, substantially normal to the surface of the rod, carry out an improved capillarity effect by which the absorption of a sample 10 in liquid form is fully achieved.

In the detail of Fig. 3, it is schematically shown how said brushlike layer of fibres 20 deposited in an oriented orderly arrangement, substantially normal to the surface of the rod, also provides an improved collection of a sample 11 made of cells, which can be fully trapped among the oriented fibres, and afterwards an improved release of said cells from said device. In general terms, in accordance with the fundamental characteristic of the invention, said wad with hydrophilic properties is applied in an electrostatic field under which the fibres are deposited in a uniform thickness and in an oriented orderly arrangement, normal (perpendicular) to the surface of the tip of the rod, which has been previously coated with adhesive for example by immersion or spraying.

The fibres are anchored to the surface of the tip, being retained by the adhesive thereon.

The adhesive is preferably water-based: after drying, it enables the fibre to be anchored in a stable manner and to resist abrasion.

The layer of absorbent material is then dried by exposing it to a source of heat or radio-frequency.

In a device of the invention, the tip of the rod is covered with a layer of fibre of uniform thickness in the range from 0.5 to 3 mm.

The amount of fibres to be deposited for forming the fibre layer in accordance with the invention is determined on the basis of the type of fibre and the selected layer characteristics of thickness and fineness, in such a manner as to enable 100 microlitres of specimen to be absorbed.

The number of fibres preferably vary between 2000 and 100.000 units depending on the intended use of the device.

The fibre count, or weight, is preferably between 1.0 and 22.0 Dtex (decitex), a measure of weight for fibre/yarn such that 1 Dtex equals 1 gram per 10.000 meters. In particular, a fibre of 0.5 mm length and 1.0 Dtex can be applied to obtain a fine nap, and a fibre up to 3 mm in length and 22.0 Dtex can be applied to obtain a long nap, thus providing corresponding intermediate characteristics of thickness and fineness of the layer for values inside the range defined above. Inside such ranges, thickness can increase whereas fineness decreases, and vice versa.

In a preferred embodiment, in said layer said fibres have a weight in a range between 1.7 and 3.3 Dtex.

Within the wide choice of such values, the expedient to be respected according to the objects of the invention is to maintain an orderly arrangement of the fibres, substantially normal to the surface of the rod, avoiding overlapping of fibres which can occur if the nap is too long. Indeed, in this manner the capillary represented by each fibre, by virtue of which it can carry out its task of absorbing and releasing essentially the same quantity of specimen, remains unimpaired and functional.

In accordance with the objects of the invention, the fibre is chosen from a wide range of materials provided they are hydrophilic by capillarity, such as for example, synthetic or artificial materials, e.g. rayon, polyester, polyamide, carbon fibre or alginate, natural materials e. g. cotton and silk, or mixtures thereof.

Examples

Some preparative examples are now given of a device comprising a wad of absorbent material according to the invention.

Such examples are not intended in any way to limit the scope of the invention.

EXAMPLE 1

A wad of absorbent material is prepared using a plastic rod, suitable for human clinical collection, of diameter 2.5 mm which decreases to 1 mm over a length of about 6 cm.

The tip of the part with the smallest diameter is dipped in, or sprayed with, an adhesive, then the rod is placed vertically in a apparatus under electrostatic field to deposit a polyamide fibre.

5 The polyamide flock of 0.7 mm length and 1.7 Dtex allows 0.5 μ l per 2 mm to be absorbed, therefore by covering the 10 mm long tip of said rod, the absorbing capacity obtained being 40 pi.

EXAMPLE 2

By proceeding as per example 1, a rod with a spatulate end is used, suited for example to collect organic specimens from the oral cavity of a patient.

10 Polyester fibre of 1 mm length and 1.7 Dtex count are used as a fibre.

EXAMPLE 3

By proceeding as per examples 1 and 2, polyester fibre of 2 mm length and 2.5 Dtex count is used.

15 Again in general terms, it is calculated that a wad of absorbent material of the invention is capable of releasing about 90% of the absorbed specimen by swabbing, in this manner considerably increasing the sensitivity of the analysis compared with a wad of absorbent materials of the prior art, in particular by almost completely eliminating the risk of false negatives resulting from the incomplete release of the collected specimen from the wad of absorbent material to the test
20 plate.

In addition, the fact of being able to form, according to the invention, a fibre layer of any thickness, even very small, around the tip of the rod rather than a mass to cover it as in the prior art, means that the required rounded shape of the wad of absorbent material, i. e. free of edges, no longer has to depend on the mass of
25 fibre itself but on the tip of the rod, which can therefore be preferably shaped into a round form, as indeed occurs in the afore described example and shown in the accompanying drawing.

Particularly in specific cases where a wad of absorbent material of the greatest possible thinness is required, for example urethral or ocular, this represents a
30 further definite advantage over known wads of absorbent material. Indeed a wad of absorbent material can be provided with a rounded tip by virtue of its shaping, around which a thin layer of fibre is deposited according to the present invention to

allow on the one hand a collection of a sufficient quantity of specimen for analysis, and on the other to minimize the total bulk of the part of the wad of absorbent material which is to penetrate the urethra, so reducing a discomfort for the patient undergoing the collection procedure.

- 5 The shape given to the tip of the wad of absorbent material nevertheless varies greatly according to the type of collection it is intended for, and can even be truncated or have edges when the type of collection (for example oral) allows it. According to the invention, the type of adhesive, type of fibre and fibre characteristics, such as length and count, are in any case chosen from a wide
10 range of options in order to obtain an ideal specific marker for identifying the microbiological specimen, whether by a direct diagnostic technique, by immuno-test, or by molecular biology techniques such as PCR, or with other known culturing, enrichment or selection techniques.

The specimen to be collected with a wad of absorbent material of the invention
15 generally consists of bacteria or viruses or DNA or RNA or a mixture thereof.

The present invention also covers any kit for collecting and transporting biological specimens characterised by comprising a test-tube, such as containing a culture medium, and a device comprising a wad as described above, and a method for preparing a wad as described above, characterised by comprising the steps of
20 applying an adhesive to the tip of said rod to be covered by the fibre layer, and subjecting said fibres to an electrostatic field to form thereon a brushlike layer where the fibres are deposited on the said tip in an oriented orderly arrangement normal to the surface of the rod and in a uniform thickness.

CLAIMS

1. Device comprising a wad of absorbent material for collecting samples for clinical and diagnostic analyses, of the type consisting of a rod terminating with a tip covered with the said wad made from fibres to allow absorption of said samples, wherein said fibres cover said tip in the form of a brushlike layer having hydrophilic properties applied in an electrostatic field under which the fibres are deposited on the said tip in an oriented orderly arrangement normal to the surface of the rod and in a uniform thickness, and wherein in said layer said fibres have a weight in a range between 1.0 and 22.0 Dtex.
2. Device as claimed in claim 1 characterised in that said tip is shaped with a rounded geometry, such as an ogive.
3. Device as claimed in claim 1, characterised in that said layer of said fibres has a thickness in a range between 0.5 and 3 mm.
4. Device as claimed in claim 1, characterised in that in said layer said fibres have a weight in a range between 1.7 and 3.3 Dtex.
5. Device as claimed in claim 1, characterised in that in said layer said fibres have a length and count varying from respectively 0.5 mm and 1.0 Dtex to provide a fine nap, to a length of 3 mm and a count of 22.0 Dtex to provide a long nap.
6. Device as claimed in claim 1, characterised in that said fibre is chosen from rayon, polyester, polyamide, carbon fibre, alginate; natural fibres such as cotton and silk; or their mixtures.
7. Kit for collecting and transporting biological specimens characterised by comprising a test-tube containing a culture medium and a device as claimed in one or more of the preceding claims, the device comprising a wad.
8. Method for preparing a device as claimed in one or more of claims 1 to 6, the device comprising a wad, characterised by comprising the steps of applying

an adhesive to the tip of said rod to be covered by the fibre layer, and
subjecting said fibres to an electrostatic field to form thereon a brushlike layer
where the fibres are deposited on the said tip in an oriented orderly
arrangement normal to the surface of the rod and in a uniform thickness.

- 5 9. Use of a device as claimed in claim 1 for an improved collection of a
liquid sample or a sample made of cells.