A device to collect amniotic fluid, detect and absorb excessive amniotic fluid discharge in pregnant woman

Abstract Title: Panty liner for collecting amniotic fluid

A device for pregnant women comprising a panty liner 2 with grooves 3 directed towards a central aperture 5. A collection bag 20 is attached to the central aperture 5. The bag 20 may have a pinhole covered by a peelable strip, or a tube 21 covered by a flap to allow a sample of fluid to be removed for testing. The peelable strip may comprise a test strip to detect the presence of amniotic fluid. A cap may be provided to allow the bag 20 to be sealed for transportation to a lab for testing.
Drawings

Figure 1 – Isometric view showing undergarment and channelled panty liner of Embodiment 1

Figure 2 – Collection device with neck and peel-off strip of Embodiment 1
Figure 3 – View showing laboratory glass slide used under microscopes of Embodiment 1

Figure 4 – Top view of sample collection and fluid storage device of Embodiment 1
Figure 5 – Front view of the sample collection and fluid storage device of Embodiment 1

Figure 6 – Detail view of the sample collection and fluid storage device of Embodiment 1
Figure 7 – Layered view showing the various parts in linear exploded view of Embodiment 1
Figure 8 – View showing bag filled with amniotic fluid in Embodiment 2
Figure 9 – View showing the expanded bag and open tube in Embodiment 2
Figure 10 – View showing the flap on the tube opened to release the fluid in Embodiment 2
Description

Construction

Two embodiments are described in detail, with both embodiments fulfilling the functions of sample collection and excessive fluid storage. Embodiment 1 is aimed at pregnant women with low amniotic fluid index and embodiment 2 is aimed at pregnant women with medium to high amniotic fluid index.

Embodiment 1

Figure 1 shows the isometric view of product with the woman’s under garment /panty’s inner surface represented by balloon 1. The panty liner (balloon 2) is fastened to the panty through balloon 14 (shown in Figure 7). Panty liner (balloon 2) is made of non-absorbent material and has channels /guides (balloons 3 and 4) to direct the flow of liquid to the central region (balloon 5). Figure 2 is a view of the sample collection and storage container (balloon 7). The neck of sample container (balloon 6) and is fastened to the panty liner (at balloon 5). It is stressed that the container (balloon 7) is not constrained to be of a rigid material and can be a concertinaed plastic bag similar to the ones used in Blood Donation. A peelable strip (balloon 8) covers a small hole (balloon 10) shown in Figure 6. Fluid is channelled along the panty liner (balloon 2) into container (balloon 7) through neck (balloon 6) and the hole (balloon 11) as can be seen in Figure 6. The peelable strip can be made of indicator dyes that currently exist such as pH.

A test slide (balloon 9) shown in Figure 3 can be fastened to container (balloon 7) albeit not shown as fastened. The intent is for the user to unfasten the peel strip (balloon 8) and pour a few drops to fall on the test slide (balloon 9) for testing under a microscope. Alternatively, the peel strip (balloon 8) can be left sealed and hole (balloon 11) covered using a cap (balloon 6). This allows the container to be transported as a sterile specimen to the laboratory for testing.

Figure 4 shows the top view of the container unit while Figure 5 shows the front view.

Embodiment 2

Figure 8 shows an expanded bag (balloon 20) which is filled up with amniotic fluid. The bag is initially concertinaed (not shown) and is fastened to the panty liner at the neck (balloon 5). Expandable bag (balloon 20) has a tube (balloon 21) as shown in Figure 9.

Figure 10 shows the tube end (balloon 21) with a central hole (balloon 22) covered with a flap (balloon 23). When the flap (balloon 22) is opened, the excessive fluid is released outside, which can either be a toilet bowl (if the volume of fluid is such that it is evident that it is amniotic fluid) or into a sample container (balloon 24) when the fluid is only a few drops and is uncertain if amniotic fluid or urine.
Working

Embodiment 1

This embodiment is intended to be used by pregnant women whose amniotic fluid index is low.

When the fluid droplets are released (which can often be confused with urine), they are channelled into the central hole by the guides and non absorbent layer. The drops then get collected in the sample container which can be unscrewed from the panty liner and taken to the laboratory as a sterile specimen.

If the user wishes to self-test, then the peel off strip can be opened. If the strip is made of a pH strip or indicator dyes, it provides the first test result. This however is not always accurate. However the woman may want to self-test further. In that case, she opens the peelable strip and a few drops can be placed onto the glass test slide, which can be slid under a basic microscope. If the image of a FERN is detected, then the user can be assured to a high level of accuracy that the droplets were amniotic fluid and not urine.

Embodiment 2

This embodiment is intended to be used by pregnant women whose amniotic fluid index is medium to high.

The basic setup is similar to Embodiment 1 with the exception that instead of a container, a plastic bag is concertinaed and fastened to the panty liner. Depending on the volume of fluid leaked, the bag collects excessive fluid which can then be thrown away, saving the public embarrassment caused to the woman if the amniotic sac broke in public. No testing is required as it is obvious that membrane rupture has occurred.

If the amniotic fluid is not a gush, and is instead a few drops. Then the bag does not open as much, but the tube can be used to collect the drops onto a sample container, with further possibilities for laboratory or self test.
Need for invention

There are three major purposes for this invention application:

a) Detect leakage of amniotic fluid

A pregnant woman’s body consists of two membranes inside which the baby grows until the woman’s body begins to contract and push the baby along the birth canal. The membranes protect the baby from infection and if its rupture is not detected, can expose the child to infection. In some women, the rupture of membrane (followed with leaking of the amniotic fluid which protects the baby) can be just a trickle because of reduced gap when the baby’s head is ‘engaged’. This trickle is often confused with urine (due to the baby exerting pressure on the urinary bladder). If the contractions do not begin within a small window after leakage of amniotic fluid, the baby is exposed to bacterial infection (estimated as high as 1 in 100).

Some inventions have attempted to solve this problem and are identified in the Prior Art.

b) Store a sample which can be used for laboratory testing

Some women may suspect amniotic fluid leakage and call their Medical Practioners, but almost never have a specimen or sample with them. This causes stress and uncertainty for the women and often requires surgical intervention from Medical staff. This can be more pronounced when the woman has been tested positive for Group B streptococcus (GBS). In other cases, fluid can be stained with ‘meconium’ (often brown in colour) or in cases of Terminal meconium, the amniotic fluid remains clear, but individual clumps of meconium are in the fluid. Without samples, none of these can be stored and taken for testing.

No prior art has been detected for this need.

c) Absorbing of excessive fluid (which can be upto 800 ml)

Amniotic fluid can be as much as 800 ml in volume and sometimes can ‘gush through’ in a single membrane rupture. In other cases, it can be a stream of low flow trickle. Women have until now relied on usage of sanitary pads or tampons, but this cannot absorb higher flow rates. Such breaking of membrane is termed as SRM (Spontaneous Rupture of Membranes). Women are often worried that their ‘waters may break’ in public spaces and this causes further stress especially when considering that they cannot bend often. Some women use towels while others use plastic sheets in car seats and beds.

No prior art has been detected to absorb high flow amniotic fluid. This invention aims to address all the above needs.
Prior Art

Two patents have been identified from a search on Espacenet that the inventor considers are related to some aspects of the claimed invention. These are listed below along with a brief description of how the inventor considers the claimed invention to be different.


This patent describes an absorbent pad with pH indicator which helps women to self-detect expelled amniotic fluid. This invention is intrusive and poses a possibility of indicator chemical (nitrazine) potentially exposing the birth canal to a foreign object. This invention does not offer facility to store a sample or offers protection against high flow gushing of amniotic fluid.


This patent describes a non-intrusive product similar to a sanitary pad with pH indicator and substrates which helps women to self-detect expelled amniotic fluid. This invention however does not help to absorb high volumes or allow samples to be taken.
Claims

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A device that enables pregnant women to collect a fluid sample for amniotic fluid detection tests whilst simultaneously offering the facility to store the amniotic fluid flow that often results from membrane rupture in pregnant women, comprising of:
   - a panty liner with groves to direct fluid discharged from woman’s genitals into a central hole in the panty liner,
   - a storage unit whose neck fastens onto the central hole in the panty liner, featuring one or more tiny holes to allow user self diagnostics,
   - atleast one peelable sticker covering the hole essentially allowing some or all of the collected fluid to be transferred onto a laboratory sample collection device or self-tested under a microscope or disposed off,
   - atleast one strip to cover the hole to act as a peelable sticker, which may further be coated with an indicator,
   - a cap to cover the storage unit to act as a sample collection unit allowing for easy transportation to the laboratory,
   - provision of a tube on the storage unit to release fluid from the storage device,
   - any other parts and features illustrated in the embodiments and as required to perform the functions described,
2. The panty liner and other components described in claim 1 may be built or incorporated onto the undergarment for ease of use and assembly,
3. Either the panty liner or its grooves as described in claim 1 may be made of non-absorbent material and of a suitable colour to allow visual detection of meconium or other discharges,
4. The storage unit described in claim 1 is not constrained to be a rigid material and instead can be a plastic bag in depressed form until the fluid volume expands it to the desired extent,
5. The storage unit described in claim 4 can internally comprise of one or more compartments to allow one sub compartment to be used for self-testing whilst the other sub compartment remains sterile for laboratory testing,
6. The peelable sticker or strip described in claim 1 can be coated with a pH or nitrazine or other publicly disclosed dyes to offer a second level of amniotic fluid detection and increase the accuracy of detection,
7. The tube described in claim 1 to be fastened to the storage unit and to comprise of a peelable sticker to allow fluid from storage unit to be disposed off or facilitate transfer into a laboratory specimen collection unit.
Amendments to the claims have been filed as follows.

**Claims**

1. A device that enables pregnant women to collect a fluid sample for amniotic fluid detection tests whilst simultaneously offering the facility to store the amniotic fluid flow that often results from membrane rupture in pregnant women, comprising:

   a panty liner with groves leading to a central aperture to direct fluid discharged from a woman’s genitals; and

   a bag suitable for collecting a small volume of fluid connected to the central aperture, wherein the bag has at least one tiny hole covered by a strip in the form of a peelable sticker, and may be closed with a cap for sterile transport.

2. The device of claim 1, wherein the at least one strip to cover the hole by means of a peelable sticker, is further coated with an indicator.

3. The device of claim 1, wherein the panty liner, bag, peelable stick, and cap are built or incorporated onto the undergarment.

4. The device of claim 1, wherein the panty liner or its groves are made of nonabsorbent material and of a suitable colour to allow visual detection of meconium or other discharges.

5. The device of claim 1, wherein the bag is constructed form a plastic bag in depressed form until the fluid volume expands it to a desired extent.

6. The device of claim 5, wherein the bag is further comprise of one or more internal compartments to allow one sub compartment to be used for self-testing whilst the other sub compartment remains sterile for laboratory testing.

7. The device of claim 2, wherein the peelable sticker or strip is coated with a pH or nitrazine or other dye to offer a second level of amniotic fluid detection.
**Application No:** GB1109221.0  
**Examiner:** Dr Joanna Manning  
**Claims searched:** 1-7  
**Date of search:** 29 September 2011

### Patents Act 1977: Search Report under Section 17

#### Documents considered to be relevant:

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| A        | -                  | US 2006/069359 A1  
(DIPALMA) Whole document relevant |
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(PROCER & GAMBLE) Whole document relevant |
| A        | -                  | GB 1573029 A  
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### Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC:

- Worldwide search of patent documents classified in the following areas of the IPC
- A61B: A61F
- The following online and other databases have been used in the preparation of this search report
- EPODOC, WPI

### International Classification:

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