(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
04 April 2019 (04.04.2019)

W 1P O | PCT

(10) International Publication Number
WO 2019/067848 Al

(51) International Patent Classification:
*BOIL 3/14* (2006.01) *G01N 33/50* (2006.01)

(21) International Application Number:
PCT/US20 18/053333

(22) International Filing Date:
28 September 2018 (28.09.2018)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/564,449 28 September 2017 (28.09.2017) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)* : AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)* : ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

**Published:**
— *with international search report (Art. 21(3))*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(54) Title: SINGLE UNIT ASSAY DEVICE, METHOD, AND ASSEMBLY

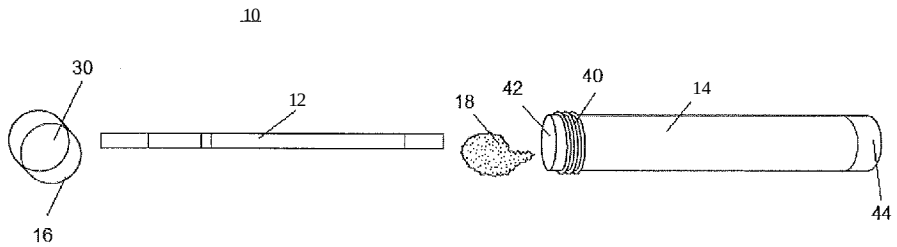


FIG 1

(57) Abstract: A single unit assay device, method, and assembly is shown and described. In one embodiment, a method for analyzing a sample for a presence of one or more analytes, residues, and the like includes comparing visual intensity of a detectable signal of a test area to a visual intensity of a control area. The result is an improved field test for efficient and effective qualitative analysis.

WO 2019/067848 A1

# SINGLE UNIT ASSAY DEVICE, METHOD, AND ASSEMBLY

## Reference to Prior Applications

This application claims the benefit of U.S. Provisional Application No. 62/564449, filed September 28, 2017, and is hereby incorporated by reference in its entirety.

## Field of the Technology

The present disclosure relates generally to the detection of an analyte or a residue, and more particularly to improved field test devices, methods, and assemblies.

## Background

Various types of testing apparatuses detect the presence of one or more analytes in a sample. Onsite testing tools may be preferable for certain tasks, such as detecting contaminants in food supplies at a farm and the like. However, conventional systems and methods limit onsite applicability. For instance, current screening applications fail to provide rapid analysis without additional equipment, expertise, and/or tedious preparation.

Therefore, Applicant desires systems and methods for detecting an analyte, or a residue, effectively and efficiently without the drawbacks presented by traditional systems and methods.

**Summary**

In accordance with the present disclosure, test strips and systems are provided for the analysis of a sample. This disclosure provides improved test strip and tube devices and methods that are convenient, efficient, and safe for the user, particularly when used to detect the presence or absence of an analyte in a sample free of additional equipment and/or expertise.

One embodiment of the present disclosure includes a method for analyzing a grain sample for a presence of one or more analytes including providing a sample tube having an extraction material and a test strip with a glass fiber membrane supporting a control area and a test area; removing the test strip from a releasable cap of the sample tube; adding a predetermined volume of the grain sample into the sample tube; adding a predetermined volume of water into the sample tube; solubilizing the extraction material, the grain sample, and the water to define a solution adapted to extract the analyte, when present; introducing the test strip into the solution; incubating the tube free of an incubator; and comparing intensity of a detectable signal of the test area to the control area, wherein a greater intensity of the detectable signal in the test area as compared to the control area indicates a negative result for a particular analyte and a greater intensity of the detectable signal in the control area compared to the test area indicates a positive result for the particular analyte.

In some examples, the method includes mixing the solution by manipulating the sample tube prior to introducing the test strip. The method may include mixing the solution including manipulating the sample tube free of a centrifuge. The method may include providing the extraction material includes providing an extraction material housed within the sample tube. The method may include providing a Fusion 5 membrane substrate adhered to a solid support on the test strip. The method may include a Fusion 5 membrane substrate that maintains adhesion to the test strip during operation.

In certain examples, the method may include adding a predetermined volume of the grain sample includes measuring a capful volume of a measuring removable cap. The method may include adding water includes measuring two capfuls volume of water. The

method may include adding water free of a pipette. The method may include comparing intensity of the detectable results directly on the test strip without equipment.

Another embodiment of the disclosure is a single unit assay for the analysis of a sample having a sample tube having a releasable cap; an extraction material housed within the sample tube; and a test strip removably housed within the sample tube and comprising: a solid backing support; and a glass fiber membrane adhered to the solid backing support and including at least one control zone and at least one test zone.

In some examples, the glass fiber membrane comprises a Fusion 5 membrane substrate. The Fusion 5 membrane may maintain adhesion about the solid backing support following a fluid submersion within the sample tube. The test strip may include two or more control zones and two or more test zones for multiple analytes. The test strip may comprise an aflatoxin test strip or the like.

In certain examples, the extraction material comprises at least one extraction material. The sample tube having a removable cap to deliver a predetermined volume of sample to the tube. For instance, the removable cap may deliver one capful, or the like, of a grain sample to the tube. Further, the sample tube having a removable cap may deliver a predetermined volume of solution to the tube. For instance, the removable cap may deliver two capfuls, or the like, of water, or any equivalent, to the tube.

The above summary was intended to summarize certain embodiments of the present disclosure. Embodiments will be set forth in more detail in the figures and description of embodiments below. It will be apparent, however, that the description of embodiments is not intended to limit the present inventions, the scope of which should be properly determined by the appended claims.

## Brief Description of the Drawings

Embodiments of the disclosure will be better understood by a reading of the Description of Embodiments along with a review of the drawings, in which:

Figure 1 is an exploded view of a single unit assay according to an embodiment of the disclosure;

Figure 2 is a side perspective view of one embodiment of an isolated test strip according to Figure 1;

Figure 3 is a top view of one embodiment of an isolated test strip according to Figure 1; and

Figure 4 is a front perspective view of one embodiment of completion of a test assembly according to Figure 1.

**Description of Embodiments**

In the following description, like reference characters designate like or corresponding parts throughout the several views. Also in the following description, it is to be understood that such terms as "forward," "rearward," "left," "right," "upwardly," "downwardly," and the like are words of convenience and are not to be construed as limiting terms.

Referring now to the drawings in general, it will be understood that the illustrations are for the purpose of describing embodiments of the disclosure and are not intended to limit the disclosure or any invention thereto. As best seen in Figure 1, one embodiment of a single unit assay 10 includes a test strip 12, sample tube 14, extraction material 18, and a removable cap 16 for qualitative analyte, reside, or the like screening. In certain embodiments, the qualitative screening includes visual interpretation of intensities on the test strip 12 after completion of an equipment-free testing procedure.

Those skilled in the art having the benefit of this disclosure will recognize a variety of self-contained unit configurations and applications. As shown in Figure 1, the sample tube 14 includes a closed distal portion 44 with an opposing open proximate portion 42 adapted to provide access, i.e. delivery of any of the elements shown and described herein, to the tube 14. The removable cap 16 may be removably secured about the tube 14 in a variety of configurations, including a threaded orientation 40 having an open mating end 30, as illustrated in Figure 1.

Similarly, those skilled in the art having the benefit of this disclosure will recognize a variety of test strip applications to match the detection of a particular analyte and/or residue. For instance, any of the elements and teachings of US Patents 5985675, 6319446, 6475805, 7097983, 7410808, 7785899, 7785899, 7897365, 8481334, 8481334, 8592171, 8592171, and 9057724 as well as US Application No. 14/372088 maybe useful for the inventions shown and described herein, and are therefore incorporated by reference where consistent and useful as understood by those skilled in the art. In addition, as shown in Figure 2, test strip 12 includes a solid support 20 with a membrane adhered to at least one side of the solid support 20. Test strip 12 may provide any

combination of test zones/areas/lines shown and described herein, and Figures 2 and 3 illustrate one example of control zone 24 and a test zone 26.

The strip can also be wholly or partially of a material to bind proteins, such as carrier proteins for example, an extraction material or the like. A variety of materials can be used in various portions of the strip including fiberglass or glass fiber filter 22, for example WHATMAN Fusion 5 membrane (Whatman is a registered trademark of Whatman paper Limited, Kent, England). Solid support 20 provides a structural foundation for test strip 12 wherein any of various strip components shown and described herein may be attached. Solid support 20 may be comprised of any combination of plastics, such as polystyrene. In particular examples, a cover layer is aligned along the upper portion of the nitrocellulose. The cover layer may protect the nitrocellulose from contamination. Further, the cover layer may provide a capillary barrier, for instance to push sample flow up the strip as shown and described herein, for instance when the test strip is free of a sponge. In particular examples, the cover layer is a nonporous, non-liquid permeable membrane. Further, the cover layer may include an adhesive, for instance a semi- or clear adhesive to allow visual interpretation of line/zone intensities through the layer(s).

Embodiments of the extraction material include a variety of formulations and compositions for screening of a particular analyte, reside, and the like and/or at an associated concentration level. The Applicant has unexpectantly discovered the extraction material in this qualitative visual test procedure may provide both a blocking agent, for instance for the nitrocellulose, while assisting to block binding sites to improve flow. For instance, the blocking agent may flow ahead of bead flow and block the nitrocellulose ahead of the beads at the test zone(s) and control zone(s). Example of the extraction material includes a variety of proteins usefully employed alone or in combination, including, but not limited to, bovine collagen, ovalbumin, keyhole limpet hemocyanin, and thyroglobulin, albumin, e.g., fish serum albumin, bovine serum albumin, and the like, gelatin peptone, soy peptone, soy/casein Primatone, and Primatone RL. In one example, an afiatoxin screening detection extraction material includes about

sixty to about ninety-five percent serum albumin, about two to about twenty percent buffer material, and about one to about fifteen percent anionic detergent. Still a further aflatoxin screening detection extraction material includes about seventy to about ninety percent serum albumin, about three to about ten percent buffer material, and about two to about ten percent anionic detergent. While alternative embodiments include additional combinations thereof for establishing the improvements shown and described herein.

After completion of the testing procedure, a higher intensity at a test zone read visually, i.e. without a reader or the like equipment, generally indicates a negative result (i.e., absence of analyte) whereas a higher intensity at a control zone indicates a positive result (i.e., presence of analyte). In some examples, a false negative result may be caused by low sensitivity or low concentration of analyte. Similarly, a false positive result may be caused by oversensitive or unspecific binding to substances within the sample. Test sensitivity may be further adjusted to address environmental conditions, i.e. temperature, humidity, and the like, sample flow conditions, and by adding a mixture of additional receptors to the test strip.

Figure 4 illustrates one embodiment of differing test result intensities at completion of a testing operation shown and described herein. The five sample assemblies indicate visual findings, for instance field testing, of differing concentrations at the respective test zones 26 free of an incubator, reader machinery, and the like. As illustrated, the test strips 12 visually, i.e. without a reader or the like equipment, have a higher intensity at a test zones 26 to indicate a negative result (i.e., absence of analyte at a predetermined concentration). Whereas the test strips 12', 12", 12"' visually, i.e. without a reader or the like equipment, present a lower intensity at test zones 26', 26', and 26"' to indicate a positive result (i.e., presence of analyte at a predetermined concentration). In this particular example, the predetermined screening level was twenty parts-per-billion, wherein test strips 12 visually indicate higher intensity at a test zones 26 than the screening level to indicate a negative result. Whereas the test strips 12',12", 12"' visually indicate lower intensity at a test zones 26', 26', and 26"' than the screening level to indicate a positive result. For example, the test zone 26' of test strip

12' visually indicates a test result of a twenty parts-per-billion concentration. The test zone 26" of test strip 12" visually indicates a test result of a thirty parts-per-billion concentration, i.e. less intensity at the test zone 26' than the negative result intensity of test zone 26. Further, the zone 26"' of test strip 12"' visually indicates a test result of a one hundred parts-per-billion concentration, i.e. clearly visually indicates less intensity at the test zone 26' than the negative result intensity of test zone 26. Those having the benefit of this disclosure will recognize a variety of visual indicator orientations and arrangements for screening differing analyte/residue concentrations as supported herein.

Numerous characteristics and advantages have been set forth in the foregoing description, together with details of structure and function. Many of the novel features are pointed out in the appended claims. The disclosure, however, is illustrative only, and changes may be made in detail, especially in matters of shape, size, and arrangement of parts, within the principle of the disclosure, to the full extent indicated by the broad general meaning of the terms in which the general claims are expressed. It is further noted that, as used in this application, the singular forms "a," "an," and "the" include plural referents unless expressly and unequivocally limited to one referent.

**We Claim:**

What is claimed is:

1. A single unit assay for the analysis of a sample, said single unit assay comprising:
    a. a sample tube having a releasable cap;
    b. an extraction material housed within said sample tube; and
    c. a test strip removably housed within said sample tube and comprising:
        i. a solid backing support, and
        ii. a glass fiber membrane adhered to said solid backing support and including at least one control zone and at least one test zone.

2. The single unit assay of Claim 1, wherein said glass fiber membrane comprises a Fusion 5 membrane substrate.

3. The single unit assay of Claim 2, wherein said Fusion 5 membrane adapted to maintain adhesion about said solid backing support following a fluid submersion within said sample tube.

4. The single unit assay of Claim 1, wherein said test strip includes two or more control zones and two or more test zones for multiple analytes.

5. The single unit assay of Claim 1, wherein a greater visual intensity of said detectable signal in said test area at test completion as compared to a visual intensity control area at test completion indicates a negative result for a particular analyte.

6. The single unit assay of Claim 1, wherein a greater visual intensity of said detectable signal in said control area at test completion compared to a visual intensity of said test area at test completion indicates a positive result for said particular analyte.

7. The single unit assay of Claim 1, wherein said sample tube having a removable cap adapted to deliver a predetermined volume of sample to said tube.

8. The single unit assay of Claim 7, wherein said removable cap adapted to deliver one capful of a grain sample to said tube.

9. The single unit assay of Claim 1, wherein said sample tube having a removable cap adapted to deliver a predetermined volume of solution to said tube.

10. The single unit assay of Claim 1, wherein said single unit assay screening for aflatoxin.

11. A method for analyzing a grain sample for a presence of one or more analytes, said method comprising:

a. providing a sample tube having an extraction material and a test strip with a glass fiber membrane supporting a control area and a test area;
b. removing said test strip from a releasable cap of said sample tube;
c. adding a predetermined volume of said grain sample into said sample tube;
d. adding a predetermined volume of water into said sample tube;
e. solubilizing said extraction material, said grain sample, and said water to define a solution adapted to extract said analyte, when present;
f. introducing said test strip into said solution;
g. incubating said tube free of an incubator; and
h. comparing visual intensity of a detectable signal of said test area to a visual intensity of said control area, wherein a greater intensity of said detectable signal in said test area as compared to said control area indicates a negative result for a particular analyte and a greater intensity of

said detectable signal in said control area compared to said test area indicates a positive result for said particular analyte.

12. The method of Claim 11, including mixing said solution by manipulating said sample tube prior to introducing said test strip.

13. The method of Claim 12, wherein mixing said solution including manipulating said sample tube free of a centrifuge.

14. The method of Claim 11, wherein providing said extraction material includes providing an extraction material housed within said sample tube.

15. The method of Claim 11, further including providing a Fusion 5 membrane substrate adhered to a solid support on said test strip.

16. The method of Claim 15, wherein said Fusion 5 membrane substrate maintaining adhesion to said test strip during operation.

17. The method of Claim 11, wherein adding a predetermined volume of said grain sample includes measuring a capful volume of a measuring removable cap.

18. The method of Claim 11, wherein adding water includes measuring two capfuls volume of water.

19. The method of Claim 18, wherein adding water includes adding water free of a pipette.

20. The method of Claim 11, wherein comparing intensity of said detectable signals includes visually observing said test strip without equipment.

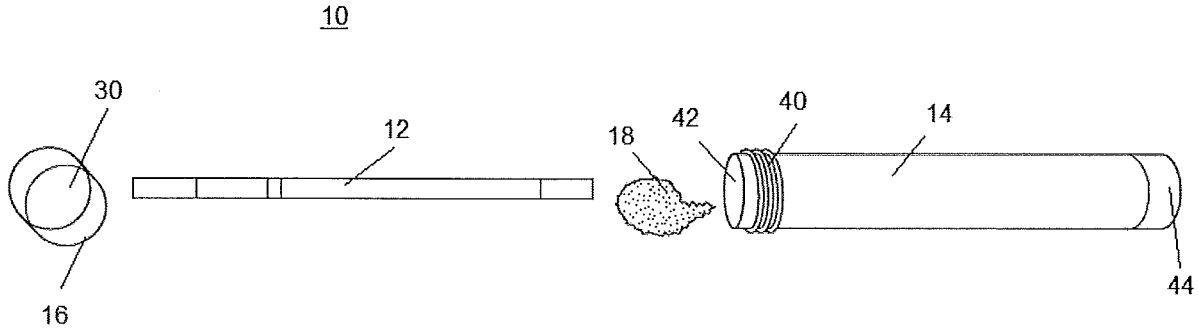


FIG 1

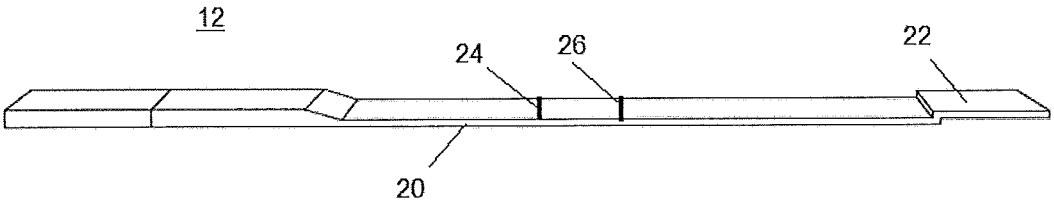


FIG 2

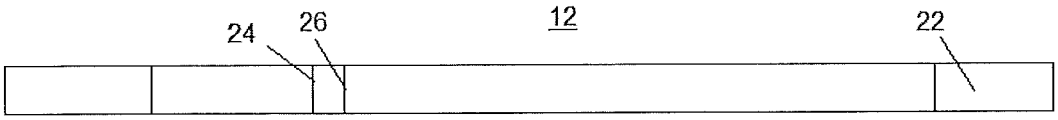


FIG 3

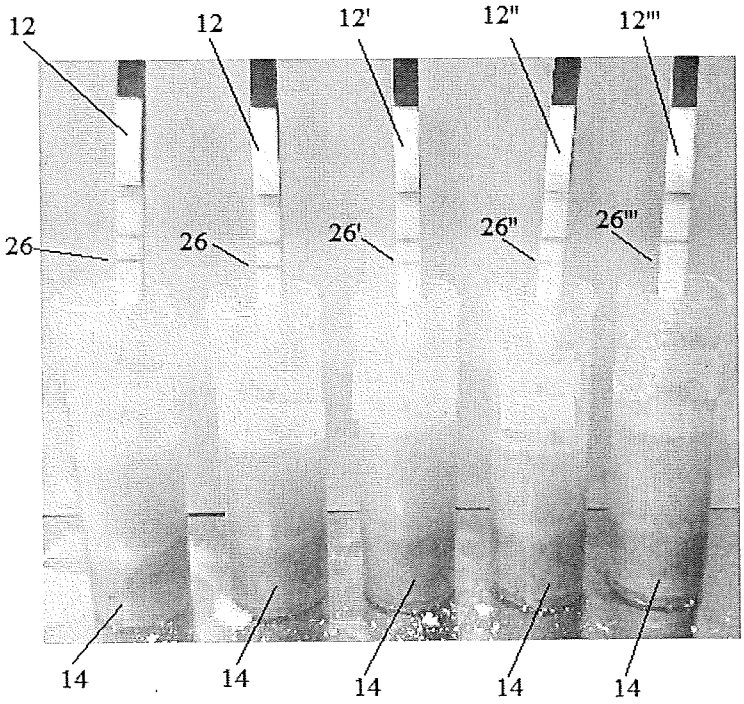


FIG. 4

**INTERNATIONAL SEARCH REPORT**

International application No.
PCT/US 18/53333

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. Ill Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this. international application, as follows:
—See Supplemental Sheet—

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Claims 1-10

**Remark on Protest**

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 18/53333

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - B01L 3/14; G01N 33/50 (2018.01)
CPC - B01L 3/50; B01L 3/14; G01N 33/50; Y10S 435/97

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)

See Search History Document

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

See Search History Document

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

See Search History Document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| Y | US 7,785,899 B2 (Saul et al.) 31 August 2010 (31.08.2010); entire document, but especially: col 1 lines 12-14, col 1 lines 30-31, col 4 lines 34-43, col 4 lines 55-59, col 5 lines 31-33, col 8 lines 47-55, col 8 lines 65-67, col 9 lines 1-7, col 9 lines 40-42, col 9 lines 47-49 | 1-10 |
| Y | US 7,097,983 B2 (Markovsky et al.) 29 August 2006 (29.08.2006); entire document, but especially: col 1 lines 64-67, col 2 lines 26-32, col 4 lines 6-9, col 7 lines 64-67, col 8 lines 1-6, col 8 lines 11-13, col 8 lines 26-29, col 8 lines 47-52, col 24 lines 29-35, table 4 | 1-10 |
| A | "Whatman FUSION 5" Whatman Inc. (March 2004); pages 1-2; page 1 features and benefits | 2-3 |
| A | US 2011/0136258 A1 (Sambursky et al.) 09 June 2011 (09.06.2011); entire document, but especially: para [0096]- para [0097], para [0100], para [0130], para [0133] | 1-10 |
| A | US 5,356,782 A (Moorman et al.) 18 October 1994 (18.10.1994); entire document, but especially: col 7 lines 59-68 to col 8 lines 1-8, col 13 lines 50-52, example 7 | 1-10 |
| A | US 2014/0065647 A1 (Mamenta) 06 March 2014 (06.03.2014); entire document | 1-10 |

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 29 November 2018 | 08 FEB 2019 |

| Name and mailing address of the ISA/US | Authorized officer: |
|---|---|
| Mail Stop PCT, Attn: ISA/US, Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-8300 | Lee W. Young<br>PCT Helpdesk: 571-272-4300<br>PCT OSP: 571-272-7774 |

INTERNATIONAL SEARCH REPORT

International application No.
TCT/U3 18/03333

Lack of Unity Invention

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1 . In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I: Claims 1-10 directed to a single unit assay for the analysis of a sample.

Group II: Claims 11-20 directed to a method for analyzing a grain sample for a presence of one or more analytes.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of a test strip comprising a solid backing support and a glass fiber membrane adhered to the solid backing support, not required by the claims of Group II.

The invention of Group II includes the special technical feature of a method for analyzing a grain sample for a presence of one or more analytes, comprising: adding a predetermined volume of said grain sample into said sample tube, adding a predetermined volume of water into said sample tube, solubilizing said extraction material, said grain sample, and said water to define a solution adapted to extract said analyte, when present, introducing said test strip into said solution, incubating said tube free of an incubator and comparing visual intensity of a detectable signal of said test area to a visual intensity of said control area, wherein a greater intensity of said detectable signal in said test area as compared to said control area indicates a negative result for a particular analyte and a greater intensity of said detectable signal in said control area compared to said test area indicates a positive result for said particular analyte, not required by the claims of Group I.

COMMON TECHNICAL FEATURES

Groups I-II share the common technical feature of a sample tube having a releasable cap, an extraction material and a test strip within the sample tube, the test strip comprising a glass fiber membrane supporting a control area and a test area. However, this shared technical feature does not represent a contribution over prior art as being obvious over US 7,785,899 B2 to Saul et al. (hereinafter Saul) in view of US 7,097,983 B2 to Markovsky et al. (hereinafter Markovsky). Saul discloses of sample housing comprising a test strip (col 9 lines 40-42: "The materials were arranged as shown FIG. 1... [t]he strip assembly was encased within a plastic housing..."), and an extraction material (col 8 lines 47-49: "Many sample matrices... require an extraction of analyte into a liquid matrix before application"; col 8 lines 65-67 to col 9 line 1: "...the sample extract, can be mixed with a dilution buffer that allows a mobile phase to flow uniformly over the test strip..."; i.e. the sample containing the extract is on the test strip in the sample housing), wherein the test strip comprises a glass fiber membrane (col 4 lines 34-43: "A lateral flow strip... [a] variety of materials can be used... glass fiber filter, for example WHATMAN Fusion 5 membrane...") supporting a control area and a test area (col 5 lines 31-33: "Locations on the test strip where receptors can be captured include a test zone and control zone"; col 1 lines 30-31 : "FIG. 1 is a side view of an embodiment having two test areas 9,4 and a control area/zone 5"; see fig. 1). However, Saul does not disclose that the sample housing is a tube having a releasable cap. In a similar invention, Markovsky discloses of a sample tube having a releasable cap (col 7 lines 64-67 to col 8 lines 1-6: "In the drawings, FIGS. 1?6 show analyte test device 10 which includes elongated, molded housing 12... [t]he housing includes an optional removable, friction-fitted or snap-on protective cap 22 adapted to fit over open end 16 of housing 12..."; see fig. 1) with a test strip housed within said sample tube (col 8 lines 11-13: "Housing cavity 14 includes therein on the bottom surface a lateral-flow test strip 28 adapted to detect the presence of an analyte..."; see fig. 1) wherein the test strip has at least one control zone and at least one test zone (col 8 lines 26-29: "Support strip 30 includes... stationary-phase membrane 36, which includes test zone 38 and control zone 40 for the analyte to be detected..."; see fig. 1). Therefore, it would have been obvious to combine the teachings of Saul and Markovsky and form a single unit assay comprising a sample housing, an extraction material within the sample housing, a test strip within the housing, the test strip comprising a glass fiber membrane including at least one control zone and at least one test zone, as disclosed by Saul, wherein the sample housing comprises a sample tube having a releasable cap, as disclosed by Markovsky, in order to form an assay where the test strip can be contacted more readily with the sample (by removing it from the housing) instead of having to conform the sample so it can be applied to the test strip confined in the housing, as disclosed by Saul (col 9 lines 47-49: "When sample, including dilution buffer, was applied to the sponge it expanded within the confines of the housing...").

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

Notes to Application:

Claims 2-3 and 15-16 are unclear insofar as the use of a trademark ("Fusion 5") to characterize a product, rather than a source of the products. See PCT ISPE, paragraph 5.39 ("Trademarks and similar expressions characterize the commercial origin of goods, rather than the properties of the goods (which may change from time to time) relevant to the invention. Therefore, the examiner should invite the applicant to remove trademarks and similar expressions in claims, unless their use is unavoidable"). Therefore, the term "Fusion 5" in claims 32-3 and 15-16 have been interpreted to broadly mean a hydrophilic, single layer, glass fiber membrane (see "Whatman FUSION 5" to Whatman Inc., page 1 features and benefits).