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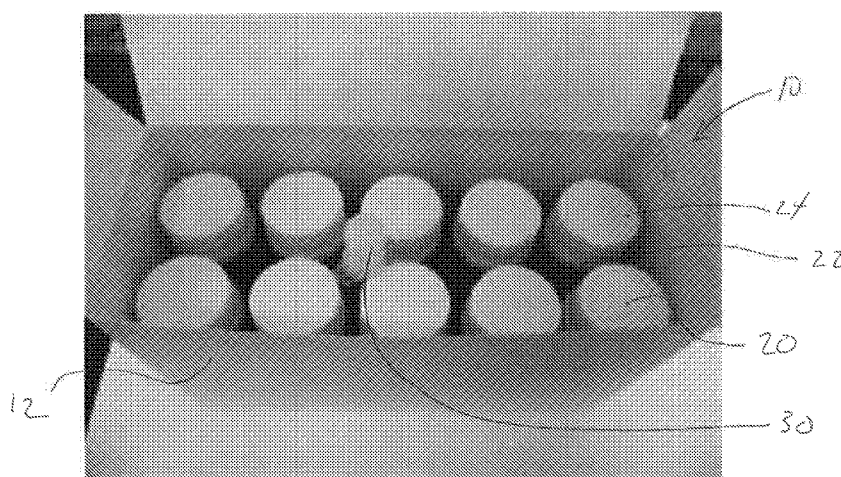


FIG 1

(57) Abstract: The present invention provides colorimetric test composition for determining the presence of a cationic active substance in a disinfectant solution having a specified amount of the cationic active, said colorimetric test composition containing an indicator solution, an anionic reagent solution, and water; wherein the colorimetric test composition has a pH below 6.0 and the ratio of the indicator, the anionic reagent and water are adjusted depending on the specified amount of the cationic active in the disinfecting composition. Also provided is a kit for testing a disinfectant solution and a method of using the colorimetric composition to test a disinfectant solution.



TEST KIT FOR DETERMINING ACTIVITY OF QUARTERNARY AMMONIUM  
COMPOUND IN SOLUTION

## RELATED APPLICATIONS

[0001] The present application is based on and claims priority to U.S. Provisional Patent application Serial No. 62/066,096, filed on October 20, 2014, which is incorporated herein by reference in its entirety.

## BACKGROUND OF INVENTION

[0002] The present invention relates to a test solution to determine whether a disinfecting composition remains active within a set tolerance.

## BACKGROUND OF THE INVENTION

Disinfectant compositions are becoming more widely used to disinfect surfaces and medical instruments. In the case of medical instruments, this is especially true when heat and other physical methods cannot be used to disinfect the medical instruments due to the sensitivity of the medical instruments to heat and physical methods of disinfecting. However, some disinfectant compositions become less effective over time. This is particularly the case where the disinfectant composition is used multiple times, for example, disinfectant compositions used to disinfect hospital equipment, such as endoscopes.

[0003] Regulations in some countries require that a disinfectant composition contain a certain percentage of an active ingredient so that the disinfectant composition remains active for its intended purpose. Therefore, in order to comply with these regulations, the disinfectant composition needs to be tested to determine if the disinfectant composition still contains an effective amount of the active ingredient so that the disinfectant composition will remain active for its intended use. Currently, methods of testing disinfectant compositions to determine whether the disinfecting composition still has an effective amount of the active ingredient includes using a titration method, which is tedious process and can be time consuming. In addition, titrations generally take highly trained personnel to complete the process. Other methods include using test strips which have a chemical reagent on a substrate. However, test strips do not always results which are accurate enough to determine

the presence of a minimum amount of the active agent in the disinfecting composition.

[0004] There is a need in the art for a quick and easy to use test method to determine if a disinfectant composition still contains an effective amount of the active ingredient. The present invention provides an answer to that need.

### SUMMARY OF THE INVENTION

[0005] In one aspect, the present invention provides colorimetric test composition for determining the presence of cationic active substances in a disinfectant solution having a specified amount of the cationic active, said colorimetric test composition containing an indicator, a reagent, and optionally water; wherein the colorimetric test composition has a pH below 7.5 and the ratio of the indicator, the reagent and water are adjusted depending on the specified amount of the cationic active in the disinfecting composition.

[0006] Another aspect of the present invention is a test kit containing 1) an outer package; 2) a container for holding a fluid; and 3) a fluid transfer device wherein the container contains the colorimetric test composition described herein.

[0007] In one embodiment, the colorimetric test composition comprises a solution containing the indicator, the reagent, and a solvent. In an alternative embodiment, the colorimetric test composition comprises an anionic reagent in the form of a solid. In one embodiment, the indicator can also be a solid combined with the reagent within the container. In an alternative embodiment, the indicator solution may be contained in a second container that is later mixed with the anionic reagent.

[0008] In still another embodiment of the present disclosure, the colorimetric test composition comprises a solution containing the indicator, the reagent, and water and has a pH of from about 6.0 to about 7.5, such as from about 6.2 to about 7.0. The test kit, however, contains a pH reducing agent that is separately packaged within the kit. Prior to use, the pH reducing agent is added to the colorimetric test composition so as to lower the pH to from about 2 to about 6, such as from about 2.8 to about 3.2.

[0009] A further aspect of the present invention is a method of determining if a disinfectant composition contains an effective amount cationic active substance in the disinfectant solution. The method comprises a) providing a container containing the

colorimetric test composition described herein; b) providing a fluid transfer device having fluid volume indicators to indicate the amount of fluid in the fluid transfer device; c) using the fluid transfer device to take a sample volume from a disinfectant solution containing a cationic active substance; d) adding the sample volume of the disinfectant solution to the container; e) mixing the sample volume of the disinfecting solution with the colorimetric test composition to form a test mixture; f) observing the color on the test mixture; and g) comparing the color of the test mixture to a color standard to determine if the disinfectant composition contains an effective amount of the cationic active substance.

[0010] These and other aspects will become apparent when reading the detailed description of the invention.

#### BRIEF DESCRIPTION OF THE FIGURES

[0011] FIG 1 shows a test kit of the present invention.

[0012] FIG 2 shows a fluid transfer device usable in the test kit of the present invention.

[0013] FIG 3 shows another embodiment of a test kit in accordance with the present disclosure.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0014] It has now been discovered that effectiveness of a disinfectant solution can be determined by using a colorimetric test. The colorimetric test composition is used to determine the presence of a cationic active substance in a disinfectant solution. The disinfectant solution will generally have a specified amount of the cationic active ingredient and the colorimetric test of the present invention can be used to determine if the disinfectant composition has the specified amount or an effective amount of the active ingredients.

[0015] The colorimetric test composition, in one embodiment, is a mixture of an indicator solution; an anionic reagent solution; and solvent, which is typically water or a water soluble solvent. The colorimetric test composition will have an acidic pH. The pH of the test composition is generally 6 or below and more typically in the range of 2 to about 6. An exemplary pH range is between 2.8 and 3.2. A preferred value pH value is about 3.

[0016] The amount of the indicator, reagent and solvent will be adjusted depending on the disinfectant composition being tested. Typically, the ratio of the indicator, the reagent and solvent are adjusted depending on the specified amount of the cationic actives in the disinfecting composition. Typically, the colorimetric test composition will contain for every part of the indicator solution, 5 to 50 parts of the reagent solution and 10 to 500 parts of the solvent.

[0017] In one embodiment, the colorimetric test composition can be initially formulated to have a higher pH. Prior to use, the pH of the composition can be increased in order to test disinfectant solutions. Initially formulating the composition to have a higher pH may, in certain embodiments, make the composition more stable during shipping and storage.

[0018] For example, the colorimetric test composition can initially have a pH of greater than about 6, such as greater than about 6.2, such as greater than about 6.4, such as greater than about 6.6, such as greater than about 6.8 and generally less than about 7.5, such as less than about 7.3, such as less than about 7.0, such as less than about 6.8. A pH reducing agent can then be packaged in a kit with the colorimetric test composition. The pH reducing agent can be added to the colorimetric test composition prior to use for lowering the pH into a desired range. The pH reducing agent can comprise any suitable acid or other component capable of reducing the pH. In one embodiment, the pH reducing agent may comprise citric acid or another similar weak acid or organic acid. The pH reducing agent can be in powder form and contained in a separate package within the kit. The package can then be opened for combining the pH reducing agent with the colorimetric test composition either alone or in conjunction with more solvent, such as more water.

[0019] In yet another embodiment of the present disclosure, the colorimetric test composition may comprise a solid. For instance, the anionic reagent and/or the indicator maybe provided as a solid, such as granules or a powder. When both the indicator and the anionic reagent are in solid form, both can be combined with a solvent, such as water prior to use. In an alternative embodiment, the anionic reagent may be in solid form and contained in a container, while the indicator may be in liquid form as an indicator solution. In this embodiment, the indicator and the anionic reagent can be packaged separately and combined prior to use.

[0020] In one particular embodiment, the anionic reagent can be contained in a relatively concentrated solution and placed in a container. The solution can then be

dried removing all water. In this manner, the anionic reagent is dried onto the walls of the container for later use.

[0021] The indicator of the colorimetric test composition may be an indicator known that can effectively change color under acidic conditions and can indicate the presence of an active substance, such as a quaternary ammonium compound. An exemplary indicator is Toluidine Blue O. Other potential indicators which may be used in the present invention include, for example, thionin, astrazon orange, astrazon blue, methylene blue, acridine orange, pyronine-G, proflavine, azure A, phloxine B, cresyl violet, safranin O, thioflavin T, fast red AL, methylene green, rhodamine B, rhodamine 6G, azure B, indoine blue, brilliant cresyl blue, 4',6-diamidino-2-phenylindole dihydrochloride hydrate, acridine yellow, acriflavine, pyronin-Y, pyronin-B, meldola's blue, Nile blue, Nile red, new methylene blue, methyl violet, pinacryptol yellow and methyl green. A particular example is a 0.1% (w/v%) solution of Toluidine Blue O, which is commercially available.

[0022] The reagent used in the colorimetric test composition is an anionic reagent. A known quantity of the reagent is in the test composition and that amount is based is adjusted to the amount of the cationic active substance in the solution being tested. The higher the concentration of the cationic active substance in the solution being tested, the greater the amount of the anionic reagent is needed. Suitable anionic reagents includes, for example, a potassium poly(vinyl sulfate), a poly(vinyl sulfate), a poly(vinyl sulfonic acid), a poly(styrenesulfonic acid), poly(2-acrylamido-2-methyl-1-propanesulfonic acid), and mixtures thereof. Of these anionic reagents, a particularly useful reagent is potassium polyvinyl sulfate (PVSK).

[0023] Generally, the anionic reagent is in a solution that contains between 100 and 1000ppm of the anionic reagent. Typically, the anionic reagent is present in a concentration of about 250 ppm to about 600 ppm. A particular example is a reagent solution which contains about 400 ppm of the reagent in water. A commercially available potassium poly (vinyl sulfate) 1/400N solution which contains PVSK in a concentration at about 400 ppm in water or solvent. This reagent is commercially available from various sources.

[0024] A particular composition useable as the colorimetric test composition is a composition which contains Toluidine Blue O in a 0.1% solution; the reagent solution comprises Potassium Polyvinyl Sulfate in a 1/400N solution and the solvent is water. The pH of the colorimetric test compositions is adjusted between 2.95 and 3.05,

using hydrochloric acid and the composition contains for every part of the indicator solution, there are 5 to 50 parts of the reagent solution and 10 to 500 parts water.

[0025] In one embodiment, the colorimetric test solution is placed in a test kit for testing a cationic active solution. Referring to FIG 1, the test kit 10 for testing the presence of a cationic active substance in a disinfectant solution contains an outer package 12 for holding the other components of the test kit. Within the outer package 12 is at least one container 20 which holds colorimetric test composition. The container 20 will have a body 22 and optionally a top 24 which connects to the body 22. The colorimetric test composition is placed into the body 22 of the container 20 and is sealed with the top 24. Also contained in the test kit is a fluid transfer device 30. The fluid transfer device is use to transfer the fluid containing the cationic active solution to the container 20 for contact with the colorimetric test solution. The fluid transfer device 30 may have fluid volume indicators 32 on the device to indicate the amount of fluid in the fluid transfer device, when a fluid is present in the device.

[0026] The containers 20, in one embodiment, are prefilled with the predetermined amount of the colorimetric test solution. Generally, the containers will have a volume of 5 to 30 ml. The containers may be vials or test tubes. Preferably the containers will have a removable top or stopper to retain the colorimetric test solution within the container during shipping and during the testing of the solution to be tested.

[0027] The test kit has a fluid transfer device 30 which is a syringe, dropper, pipette such as a dual bulb pipette, or similar device which will allow a user to transfer a set amount of the solution to be tested to container 20 containing the colorimetric test solution. The outer package 12 may be a box, a bag or other similar containment device that can hold several containers 20 and the fluid transfer device. A typical test kit will contain between 1 and 25 or more containers 20, each filled with a preset volume of the colorimetric test solution. In addition. The test kit will also have one or more fluid transfer devices 30. Generally, the test kit will have a single fluid transfer device, but could have as many fluid transfer devices as containers in the outer package.

[0028] Fig. 3 illustrates an alternative embodiment of a test kit in accordance with the present disclosure. Like reference numerals have been used in order to indicate similar elements. Referring to Fig. 3, the test kit can include an outer package 12, at least one container 20, and a fluid transfer device 30. In this embodiment, the test kit 10 further includes a second container 40. The second container 40, for instance,

may optionally comprise a pouch containing the pH reducing agent. In an alternative embodiment, the second container 40 may contain an indicator solution for combining with the reagent in the form of a solid contained in the first container 20.

[0029] As described above, in one embodiment, the colorimetric test composition may comprise a solution. In other embodiments, however, the colorimetric test composition may comprise a solid. For instance, the test kit may contain in the container an anionic reagent in solid form. The indicator may also be a solid and can be combined with the anionic reagent. Prior to use, a solvent, such as water, can be added to the dry composition prior to use. The amount of water added can be based on the desired pH of the colorimetric test composition and the type of disinfecting composition being tested.

[0030] For example, the container may hold the anionic reagent, which may comprise potassium polyvinyl sulfate, in a solid form. In one embodiment, for instance, the test kit may contain one or more doses of the anionic reagent. Each dose can weigh from about 1mg to about 10 mg, such as from about 2 mg to about 5 mg, such as from about 3 mg to about 4 mg. In one embodiment, for instance, each dose may comprise about 3.6 mg in dry form. As described above, the indicator may also be in solid form or can be in a solution. When contained in a solution, the indicator may be present in a separate container from the anionic reagent. Prior to use, the indicator solution can be combined with the anionic reagent for forming a colorimetric test composition. The amount of solvent combined with the indicator can be such that the final pH of the composition is within desired limits, such as from about 2 to about 6, such as from about 2.8 to about 3.2. In one embodiment, for instance, the indicator solution may contain the indicator in an amount of from about 50 ppm to about 150 ppm, such as from about 70 ppm to about 90 ppm.

[0031] In another embodiment of the present disclosure, the colorimetric test composition may comprise a solution, but at a higher pH than desired during testing. The solution, for instance, may contain the indicator and the anionic reagent combined with a solvent, such as water, at a pH of generally greater than about 6. By maintaining a higher pH prior to use, the colorimetric test composition may remain more stable during storage and shipping. In order to lower the pH prior to use, the test kit can be packaged with a pH reducing agent. The pH reducing agent, for instance, may comprise an acid, such as a weak acid and/or an organic acid. In one embodiment, for instance, the pH reducing agent may comprise citric acid. The citric

acid may be contained in the test kit in a separate container from the colorimetric test composition. In one embodiment, the citric acid may be present as a dry product, such as a powder. For instance, the pH reducing agent can be contained in a pouch that is opened and the entire contents of the pouch are combined with the colorimetric test composition prior to use. The amount of pH reducing agent included in the test kit can depend upon various factors including the initial pH of the colorimetric test composition, the amount of the colorimetric test composition being used in the test, and the desired resulting pH. In one embodiment, for instance, the test kit may contain citric acid in an amount of from about 0.02 to about 0.25 grams.

[0032] The test kit of the present invention is used in a method to test the presence of an effective amount a cationic active substance in a disinfectant solution. The method of using the test kit includes removing a container 20 from the test kit, where the container 20 is prefilled with predetermined amount of the colorimetric test solution. The fluid transfer device 30 is provided in the test kit and is removed from the test kit. The fluid transfer device 30 is used to take a sample volume from a disinfectant solution containing a cationic active substance. The sample volume taken from the disinfectant solution will generally be fairly small and will be generally in the range of 1 to 10 drops of the fluid. (25 drops is 1 ml).

[0033] Once the sample volume of the disinfecting solution is in the fluid transfer device, the sample volume is added to the container containing the colorimetric test solution. Once added to the container, sample volume is mixed with colorimetric solution forming a test mixture. The color of the test mixture is observed and compared to a color standard to determine if the disinfectant composition contains an effective amount of the cationic active substance. Alternatively, the user is advised of colors that are acceptable and colors which are not acceptable.

[0034] The test kit may also contain a color chart having the color standard used to determine if the test solution color is within a range that is acceptable for having an effective amount of the cationic active substance. The color chart may be printed or located on the outer container 12, on an inner surface or on an outer surface. Alternatively, the color chart may be located on a separate insert which is placed in the container. As an alternative to the color chart, the user may be provided with instructions as to which colors are acceptable and which colors are not acceptable. In addition, there may be instructions provided on an insert or printed or located on the container on an inner surface or an outer surface. These instructions may also

provide which colors are acceptable and which colors are not acceptable from an effectiveness standpoint.

### EXAMPLES

Preparation of the Colorimetric Test composition.

[0035] A colorimetric test solution is prepared by mixing 8 ml of 0.1% solution of Toluidine Blue O with 260 ml of a potassium polyvinyl sulfate 1/400N solution and 732 ml of water. The contents are mixed and the pH is determined. Hydrochloric acid is added to the solution until a pH of 3.0 is reached. The contents are then shaken to mix.

Preparation of the test kit

[0036] The colorimetric test solution prepared above was placed in 10 ml containers with a screw tight top. Each container had 9 ml of the colorimetric test composition placed therein. Once filled, the screw tight top was placed on the container filled with the colorimetric test composition.

Disinfecting Solution Testing

[0037] A disinfectant solution containing about 1.0 % of N,N Bis(3-aminopropyl dodecylamine) and 1.0% Didecyl methyl polyoxyethyl ammonium propionate was provided and a 0.16 ml sample was taken from the solution. The 0.16 ml sample of the test solution was placed into a container containing the 9 ml colorimetric test described above. The screw tight top was placed onto the container and container was tipped upside down and returned to the upright position. The color of the composition in the container is observed. The color of the composition was a blue color and it was determined the color of the disinfecting composition is within accepted tolerance.

Comparative Test.

[0038] A disinfecting solution out of specification containing about 0.5% of N,N Bis(3-aminopropyl dodecylamine) and 0.5 % Didecyl methyl polyoxyethyl ammonium propionate was provided and a 0.16 ml sample was taken from the solution. The .16 ml sample of the test solution was placed into the container containing the 9 ml colorimetric test solution. The screw tight top was placed onto the container and

container was tipped upside down and returned to the upright position. The color of the test composition in the container is observed. The color of the test composition was a pink color and it was determined the color of the disinfecting composition is outside of the accepted tolerance.

[0039] While the invention has been described above with references to specific embodiments thereof, it is apparent that many changes, modifications and variations can be made without departing from the invention concept disclosed herein.

Accordingly, it is intended to embrace all such changes, modifications, and variations that fall within the spirit and broad scope of the appended claims.

What is claimed is:

1. A colorimetric test composition for determining the presence of a cationic active substance in a disinfectant solution having a specified amount of the cationic active, said colorimetric test composition comprising
  - a) an indicator;
  - b) an anionic reagent; andwherein the colorimetric test composition has a pH of less than 7.5 and the ratio of the indicator, the reagent and optionally a solvent are adjusted depending on the specified amount of the cationic active in the disinfecting composition.
2. The colorimetric test composition according to claim 1, wherein the composition contains a solvent comprising water.
3. The colorimetric test composition according to claim 1, further comprising a pH reducing agent.
4. The colorimetric test composition as defined in claim 1, wherein the anionic reagent comprises a solid.
5. The colorimetric test composition as defined in claim 1, wherein the indicator and the anionic reagent are solids.
6. The colorimetric test composition according to claim 1, wherein the indicator is in an indicator solution and the anionic reagent is in an anionic reagent solution and wherein for every part of the indicator solution, there are 5 to 50 parts of the anionic reagent solution and 10 to 500 parts water.
7. The colorimetric test composition according to claim 1 or 6, wherein the indicator solution comprises Toluidine Blue O.
8. The colorimetric test composition according to claim 1 or 6, wherein the reagent solution comprises Potassium Polyvinyl Sulfate.
9. The colorimetric test composition according to claim 8, wherein the anionic reagent contains the potassium polyvinyl sulfate in a concentration of about 400 ppm.
10. The colorimetric test composition according to claim 7, wherein the indicator solution comprises a 0.1% solution of Toluidine Blue O.

11. The colorimetric test composition according to claim 1, wherein the pH is between 2 and 6.
12. The colorimetric test composition according to claim 11, wherein the pH is between 2.8 and 3.2.
13. The colorimetric test composition according to claim 6, wherein the indicator solution comprises toluidine blue O; the anionic reagent solution comprises potassium polyvinyl sulfate; the pH is between 2.8 and 3.2; and for every part of the indicator solution, there are 5 to 50 parts of the reagent solution and 10 to 500 parts water.
14. A test kit for testing the presence of a cationic active substance in a disinfectant solution comprising a
  - 1) outer package,
  - 2) a container for holding a fluid,
  - 3) a fluid transfer device having fluid volume indicators to indicate the amount of fluid in the fluid transfer device, when a fluid is present in the device;wherein the test kit contains an indicator, an anionic reagent, and optionally a solvent and wherein the container and the fluid transfer device are located within the outer package.
15. The test kit according to claim 14, wherein the fluid transfer device is a syringe.
16. The test kit according to claim 14, wherein the fluid transfer device has fluid volume indicators to indicate the amount of fluid in the fluid transfer device.
17. The test kit according to claim 14, further comprising a color chart.
18. The test kit according to claim 14, further comprising instructions.
19. The test kit according to claim 14, wherein the container contains a colorimetric test composition comprising the indicator and the anionic reagent in a solution, the solution having a pH of from about 7.5 to about 6.0 and wherein the test kit further includes an pH reducing agent contained in a second container, the pH reducing agent for reducing the pH of the colorimetric test composition prior to use.

20. The test kit according to claim 19, wherein the pH reducing agent comprises citric acid, the citric acid comprising a powder.
21. The test kit according to claim 14, wherein the anionic reagent comprises a solid and is contained in the container, the indicator being present in a solution contained in a second container, the indicator solution for combining with the anionic reagent prior to use.
22. The test kit according to claim 14, wherein the container contains a colorimetric test composition comprising the indicator and the anionic reagent, the colorimetric composition comprising a solid.
23. A method of testing the presence of an effective amount cationic active substance in a disinfectant solution comprising
  - a) providing a container containing the colorimetric test composition according to any one of claims 1-13;
  - b) providing a fluid transfer device having fluid volume indicators to indicate the amount of fluid in the fluid transfer device;
  - c) using the fluid transfer device to take a sample volume from a disinfectant solution containing a cationic active substance;
  - d) adding the sample volume of the disinfectant solution to the container,
  - e) mixing the sample volume of the disinfecting solution with the colorimetric test composition to form a test mixture;
  - f) observing the color on the test mixture;
  - g) comparing the color of the test mixture to a color standard to determine if the disinfectant composition contains an effective amount of the cationic active substance.

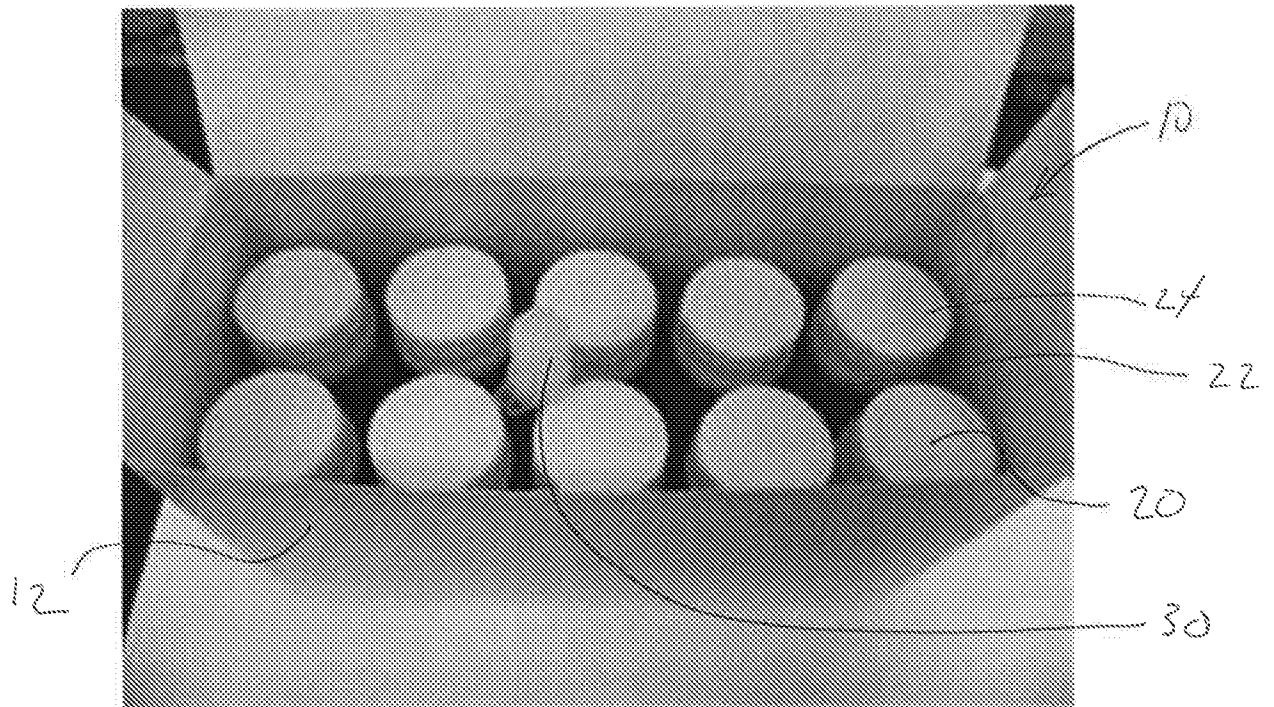


FIG 1

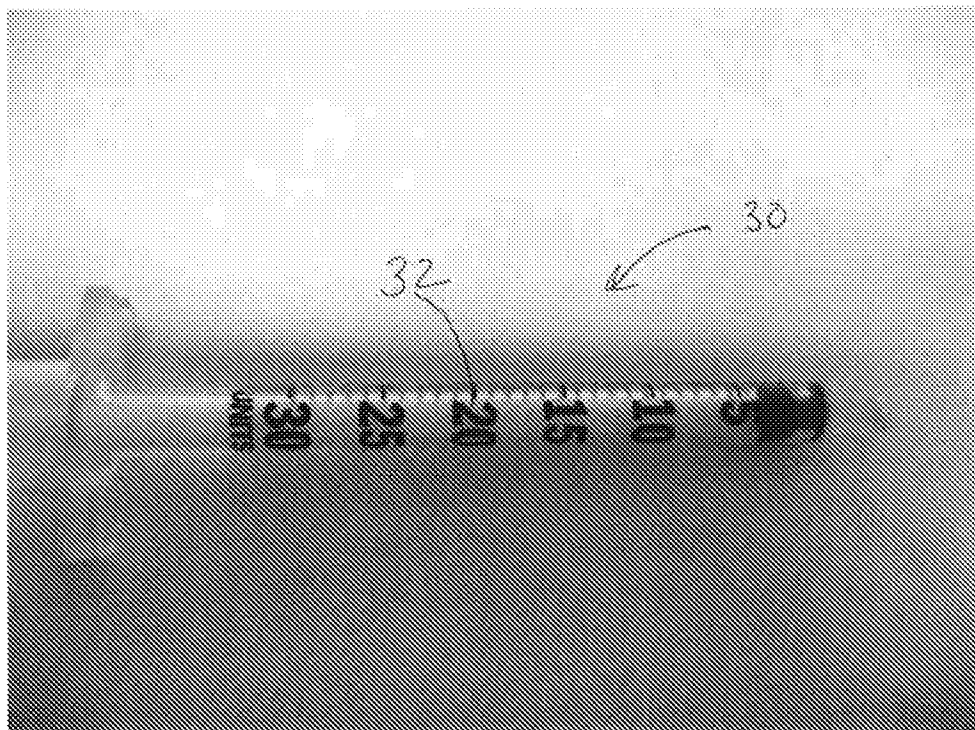
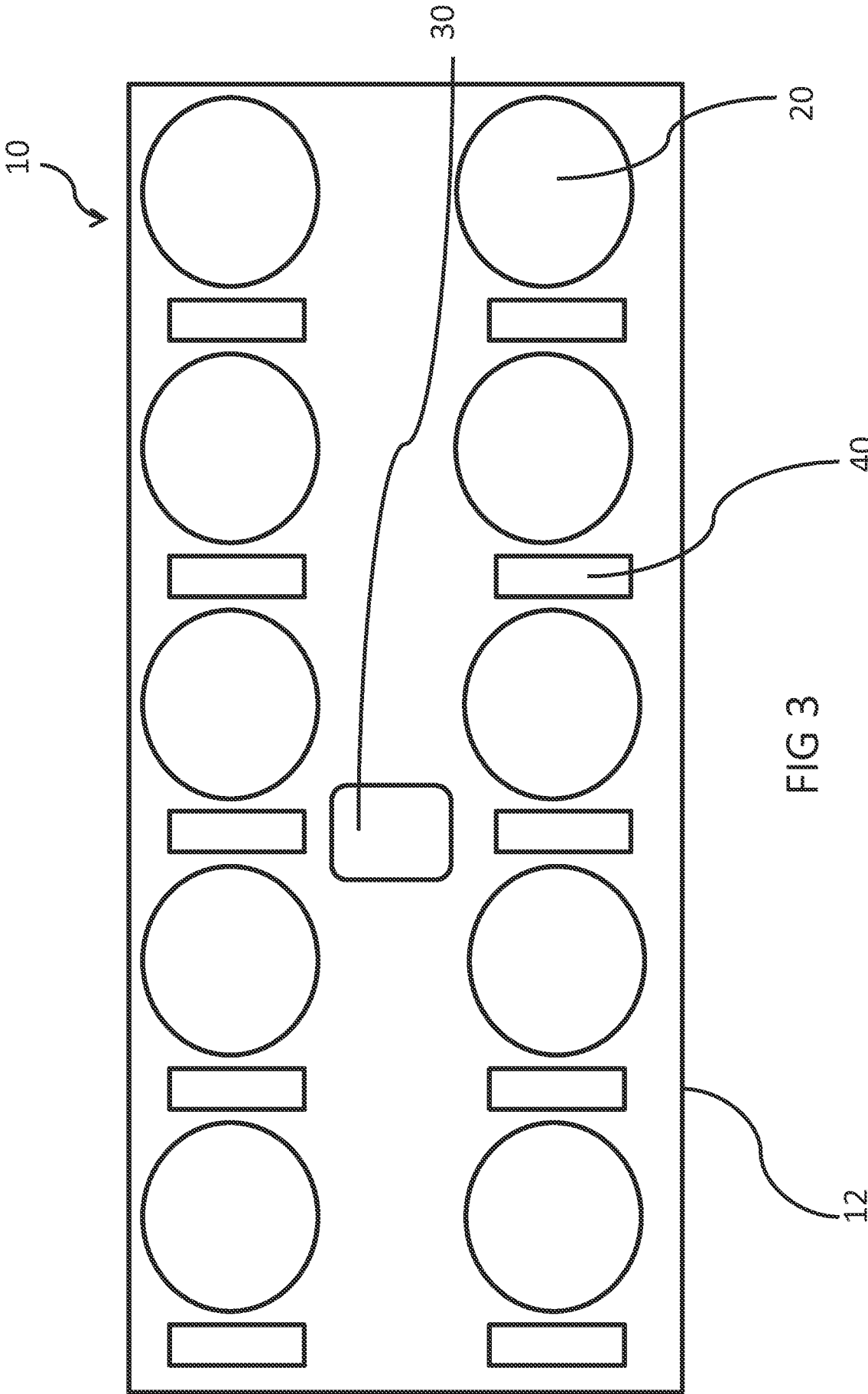


FIG 2



## INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2015/056326

A. CLASSIFICATION OF SUBJECT MATTER  
INV. G01N31/22  
ADD.

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)  
G01N

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 practicable, search terms used)

EPO-Internal, WPI Data, BIOSIS, EMBASE, FSTA, INSPEC, MEDLINE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages                                                                    | Relevant to claim No. |
|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| X         | EP 0 611 966 A1 (MILES INC [US])<br>24 August 1994 (1994-08-24)                                                                                       | 1-22                  |
| Y         | Section: Field of the invention;<br>page 1<br>page 4, line 48 - page 5, line 6<br>page 9, lines 35-48<br>page 10, lines 25-32<br>page 12, lines 32-58 | 23                    |
| X         | EP 0 539 175 A2 (WAKO PURE CHEM IND LTD<br>[JP]) 28 April 1993 (1993-04-28)                                                                           | 1-8                   |
| Y         | pages 3-5<br>claims 1-6                                                                                                                               | 9-23                  |
|           | -----<br>-/--                                                                                                                                         |                       |



Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

7 January 2016

Date of mailing of the international search report

18/01/2016

Name and mailing address of the ISA/

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## INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2015/056326

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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| Y         | page 2, paragraphs 1, 2<br>Second embodiment, steps 1-5;<br>page 5<br>-----                  | 9-23                  |

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Information on patent family members

International application No

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