A diagnostic test reader including a test unit and a disabling unit. The test unit is configured to perform one or more tests. Each of the one or more tests employs a diagnostic assay to analyze whether an analyte is present within a sample. The disabling unit is coupled with the test unit and is configured to disable the test unit based on a selected threshold number of tests.
Fig. 1
RECEIVE ASSAY

PERFORM DIAGNOSTIC TEST

TRIGGER COUNTER UPON COMPLETION OF DIAGNOSTIC TEST

IS ACTUAL NUMBER LESS THAN THRESHOLD NUMBER?

DISABLE TEST UNIT

DISPOSE OF DIAGNOSTIC TEST READER

Fig. 2
DIAGNOSTIC TEST READER WITH DISABLING UNIT

BACKGROUND

[0001] Patient samples are often analyzed for the presence of analytes to determine if a patient is carrying a disease, has an infection, has been using drugs, etc. Analytes are typically detected with immunassay testing using antigen-antibody reactions. Conventionally, such tests have been carried out in specialized laboratories using relatively expensive reading equipment. However, the need for on-site examination at the point-of-care, such as hospitals, emergency rooms, nursing homes, physician offices, and even at the home of a patient, is growing rapidly. Due to the expense and size of many of the laboratory readers used to analyze such tests, the conventional readers are not generally suitable for use at the point-of-care.

[0002] Due to the limited sensitivity and breadth of available point-of-care tests, turn around time of clinically significant diagnostic test results typically requires three days time. More specifically, tests must be completed at a central laboratory or be transferred to the laboratory where they are placed in a queue to be analyzed on one of a first in, first out or emergency basis. The delay of clinically significant test results may result in a delay of treatment until the presence of a particular ailment or level of a particular condition has been verified. For example, in an embodiment where a patient experiences the onset of a sore throat, a streptococcus (strep) screen is typically performed. Currently available rapid diagnostic, point-of-care test kits lack the sensitivity to detect an early stage of strep, and therefore, the patient typically waits two to three days for strep throat test results. Since doctors typically will not prescribe antibiotics or other remedies until the presence of strep has been verified in the patient, the recovery of the patient will be delayed and, in the meantime, the patient may come in contact with and infect a number of other individuals. Concerns are magnified in cases involving more serious medical conditions in which delayed treatment can have devastating effects.

[0003] As noted above, conventional point-of-care test kits generally lack the sensitivity to detect conditions in early stages of their development. This lack of sensitivity is due in part to the relatively low price points required for point-of-care testing. The low price points have resulted in typical point-of-care tests being less precise and less sensitive than desired. The lack of sensitivity of such tests can result in early stages of an ailment or condition not being detected. More specifically, as the level of sensitivity of the reader decreases, the detectable level of analyte in the test fluid typically increases. As such, in early stages of diagnosis, although an analyte may be present in a patient’s system, the amount of a particular analyte within the patient may not rise to a level sufficient to trigger a positive test result in low sensitivity tests. Consequently, false negative results will be obtained further delaying treatment. This lack of sensitivity in point-of-care test kits further increases dependency upon tests analyzed in the central laboratory.

[0004] Delayed treatment may lead to additional progression of an ailment, increased contamination levels of new individuals having contact with the patient, and other undesired effects. As such, a need exists for a device and method for reading diagnostic tests that provides a level of sensitivity configured to detect relatively low levels of analytes while having a sufficiently low price point to increase the availability of such tests at the point of care. More specifically, a need exists for a test reader that is sensitive, reliable, and relatively inexpensive.

SUMMARY

[0005] One aspect of the present invention relates to a diagnostic test reader including a test unit and a disabling unit. The test unit is configured to perform one or more tests. Each of the one or more tests employs a diagnostic assay to analyze whether an analyte is present within a test sample. The disabling unit is coupled with the test unit and is configured to disable the test unit based on a selected threshold number of tests.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] Embodiments of the invention are better understood with reference to the following drawings. Elements of the drawings are not necessarily to scale relative to each other. Like reference numerals designate corresponding similar parts.

[0007] FIG. 1 is a schematic diagram illustrating one embodiment of a diagnostic test reader.

[0008] FIG. 2 is a flow chart illustrating one embodiment of a method of using the diagnostic test reader of FIG. 1.

[0009] FIG. 3 is an exploded, perspective view illustrating one embodiment of a diagnostic test reader and a sample container.

[0010] FIG. 4 is a partially exploded, perspective view illustrating one embodiment a diagnostic test reader and a sample container.

[0011] FIG. 5 is a perspective view illustrating one embodiment of a set of packaged product including a diagnostic test reader.

DETAILED DESCRIPTION

[0012] In the following Detailed Description, reference is made to the accompanying drawings, which form a part hereof, and in which is shown by way of illustration specific embodiments in which the invention may be practiced. In this regard, directional terminology, such as “top,” “bottom,” “above,” “over,” etc., is used with reference to the orientation of the Figure(s) being described. Because components of embodiments of the present invention can be positioned in a number of different orientations, the directional terminology is used for purposes of illustration and is in no way limiting. It is to be understood that other embodiments may be utilized and structural or logical changes may be made without departing from the scope of the present invention. The following Detailed Description, therefore, is not to be taken in a limiting sense, and the scope of the present invention is defined by the appended claims.

[0013] FIG. 1 is a schematic diagram illustrating one embodiment of a diagnostic test reader 10. In one embodiment, test reader 10 includes a test unit 12 and a disabling unit 14. Test unit 12 is configured to interface with and read a diagnostic test or assay. In order to keep the cost of test reader 10 below a desired level, test unit 12 is designed to be disposable with no intermediate upkeep or calibration.
Test unit 12 is configured to read only a certain number of tests, commensurate with a designed lifetime. After such usable life, failure mechanisms may cause quality or reliability effects, which may begin to degrade the sensitivity of test unit 12. To prevent use of test unit 12 after degradation, disabling unit 14 is coupled with test unit 12 and is configured to disable test unit 12 prior to degradation. In particular, in one embodiment, disabling unit 14 is configured to track the number of actual tests performed by test unit 12. In one embodiment, disabling unit 14 is configured to disable test unit 12 after a predetermined number of tests have been performed. In another embodiment, disabling unit 14 is configured to disable test unit 12 prior to degradation of the precision, reliability, or sensitivity of test unit 12 in reading the particular diagnostic test or assays associated with test reader 10. As such, a lower cost test reader 10 can be supplied that delivers the more sensitive test results desired by patients, caretakers, and other healthcare workers.

In one embodiment, unit 12 includes a diagnostic test or assay interface 20, a test processor 22, and a memory 24. Assay interface 20 is configured to receive any particular type of diagnostic assay, such as a lateral flow assay, or can be brought into the proximity of more difficult to handle assays, such as liquid form ELIZA’s performed in test tubes or microrotator plates, or other assays in which handling might interrupt the function of the assay. In one embodiment, assay interface 20 is configured to receive an assay strip, such as a lateral flow assay strip, a sample container including a diagnostic test or assay strip, or any other suitable device configured to receive at least a portion of a sample to be analyzed by test unit 12.

Assay interface 20 is coupled with test processor 22. Test processor 22 is configured to analyze the assay received by assay interface 20. Test processor 22 may include or be coupled with any suitable device for detecting the assay result, such as an opto-electronic detectors (PIN diodes, APD), cameras or other imagers, etc. In addition, test processor 22 can include post-processing of detected data as well as mechanisms for timing and/or detection of start and stop times. In one embodiment, test processor 22 is coupled with memory 24, which stores a test program 26. Test program 26 outlines a procedure for analyzing a particular assay to determine whether and/or how much of an analyte is detected by the assay being present in the fluid being tested. In one embodiment, test program 26 further instructs test processor 22 to determine how the levels of analyte detected relate to a particular ailment or condition. Accordingly, test processor 22 is configured to run test program 26 to analyze the particular assay received by assay interface 20 and the fluid tested therein.

Example, in one embodiment, test program 26 outlines a procedure for optically analyzing a lateral flow assay test for a particular change in color of or appearance of a line in the assay test, wherein a change of color or appearance of a line in the assay test indicates the presence of the analyte being tested for. In one embodiment in which test reader 10 is a pregnancy test, test program 26 outlines a method for reviewing a lateral flow assay strip for a change of color indicating the presence of human chorionic gonadotropin, or HCG, to determine whether or not a particular patient is pregnant. However, test program 26 may include instructions for performing any method of analyzing a test, such as an ELIZA test, a drugs-of-abuse test, or any other suitable analytic test.

In general, by using test processor 22 to analyze the assay, a more precise and accurate result can be determined as compared to manual reading of the assay. For example, in a typical pregnancy test, the degree of color change in an assay can vary greatly depending upon the level of HCG included in the blood or urine of the patient being tested. In early detection cases, the color change of the assay strip is relatively minor and may be undetectable to a user or may leave the user with questions regarding whether or not there was actually a color change in the assay strip. However, test processor 22 running test program 26 can more precisely analyze the degree of color change and determine a particular level of HCG within the assay. In this regard, a more definitive and sensitive test result can be achieved.

The precision and accuracy of test unit 12 is improved dramatically over manual interpretation due to the use of complex optical and electronic elements. However, the addition of more complex elements to test unit 12 generally increases the amount of maintenance used to keep the device reading correctly at the desired sensitivity levels. Therefore, the complexity of the test unit design will allow a certain level of sensitivity, however, continued use of such a test unit 12 without maintenance will have a statistical probability of failing or "drifting," which can eventually cause catastrophic failure or gradual accuracy degradation that would not overly be detected by a user. In order to statistically insure the desired level of sensitivity is maintained for test unit 12, the number of tests that test unit 12 will be allowed to perform is limited to a number configured to be completed well in advance of any statistical onset of the above-described degrading or failing mechanisms. The number of tests that can be performed is generally directly proportional to the cost of test unit 12. Accordingly, as the price of test reader 10 is lowered to increase the availability of test reader 10, the effective life span of test reader 10 typically decreases since less robust and reliable components are utilized.

In one embodiment, test unit 12 is configured to perform less than one of 100, 50, 10, 5, or any other number of tests allowable by the test unit 12. The threshold number of tests for which test unit 12 can be used depends on the particular construction, the durability of the material, electronic capabilities utilized, and safety factor for test unit 12. For example, not only may the test processor 22 and/or other electronics of test unit 12 only be configured for a limited number of uses, but mechanical tabs or other devices physically interacting with the assay or associated device break or corrode and, therefore, are also only reliable for a limited number of uses. As such, the threshold number is equal to or less than a number of tests that would result in undesirable statistical probability either electrical or mechanical degradation that decreases the test reader sensitivity to be below a desired level.

In one embodiment, test unit 12 optionally includes a display 28 for indicating the results of performing test program 26, such as whether an analyte is present and/or what levels of an analyte are present. Display 29 is any suitable indicator or information display, such as a light emitting diode (LED) light, a liquid crystal display (LCD) screen, etc.

Disabling unit 14 is coupled with test unit 12 and is configured to disable test unit 12. In one embodiment,
disabling unit 14 is configured to disable test unit after a predetermined number of tests have been performed. In one example, disabling unit 14 includes a memory storing a threshold number of tests 30, a test complete trigger 32, a counter 34, a disabling processor 36, and a disabling device 38. Threshold number of tests 30 is a number of tests that the test unit 12 has been rated to be able to perform reliably and with a particular sensitivity level desired for test reader 10.

[0022] The threshold number of tests 30 may be selected with any factor of safety desired to generally disable test unit 12 prior to any statistical probability of either electrical or mechanical degradation that decreases the test reader sensitivity to be below a desired level. In particular, threshold number of tests 30 is determined via calculations and/or experimentation in which a number of test units 12 are tested during periods of repeated use. The number of uses at which particular components of test unit 12 begin to fail or the sensitivity levels of the test fall below a desired level are determined. The threshold number of tests 30 stored in disabling unit 14 is generally a number significantly lower than the number of tests determined to cause degradation or an undesired decrease in the sensitivity or reliability of test unit 12. The desired level of sensitivity varies depending upon the test being run with test unit 12. For example, pregnancy tests may require less sensitivity or may allow higher error rates than a test for an infectious disease where test errors may have a more detrimental effect on the patient or others.

[0023] In one embodiment, the threshold number of tests 30 is selected based upon a mean time to failure (MTTF) number of tests completed. The MTTF occurs when half the units will give incorrect test results when performing the MTTF number of tests. The threshold value may be adjusted or decreased in appropriate orders of magnitude to achieve an acceptable error rate for a particular type of test. Acceptable levels to determine threshold numbers may be based on such confidence levels and/or economics of test production. However, any other suitable method of determining threshold number of tests 30 may also be utilized.

[0024] For example, in one embodiment in which test unit 12 was continually found to be electrically and/or mechanically degrade sensitivity to less than acceptable levels at or around fifty tests, threshold number of tests 30 is determined to be a fraction of the fifty tests given a particular safety factor. For example, threshold number of tests 30 may be determined to be forty tests given an 80% safety factor. By using a safety factor or guard band, the threshold number of tests 30 is positioned well below the actual number of tests that cause test unit 12 to degrade, thereby, guarding against failure or decreased sensitivity of test unit 12 prior to reaching the threshold number of tests 30. Given the particular unit and the cost points of that unit, the threshold number of tests 30 can range anywhere from 1 to 500 tests. Notably, in one embodiment, threshold number of tests may be selected to allow some sensitivity degradation of test unit 12, but is selected to prevent use of test unit 12 below a predetermined level of sensitivity.

[0025] Test complete trigger 32 is configured to recognize when test unit 12 has completed analysis of an assay. Trigger 32 is coupled with counter 34. Counter 34 receives notification of trigger 32 that a test has been completed. Upon such notification, counter 34 increments the actual number of tests stored by counter 34 by one. In this manner, counter 34 includes an up-to-date tally of the number of tests that test unit 12 has actually performed.

[0026] Trigger 32 can be any trigger suitable to determine when a test has been completed by test unit 12. In one embodiment, trigger 32 detects when an assay has been loaded into test unit 12, which, in turn, starts a timer in one of test unit 12 and disabling unit 14. When the timer indicates that a particular time period has passed, which corresponds with a completion of the test, trigger 32 notifies counter 34. In other embodiments, trigger 32 may sense a physical movement of the assay into or out of assay interface 20, may optically and/or electronically sense the introduction of a sample fluid to the assay strip or assay interface 20, may detect a color change or other indicator of the assay strip, and/or may detect any other suitable action or occurrence indicating that a test has begun or has been completed. In one embodiment, triggers conventionally used to begin a test or analysis are used as at least a part of trigger 32. In one example, a button may be included on the device to manually trigger counter 34. In one embodiment, trigger 32 is automatically activated during performance of a diagnostic test and does not require a separate action by the user to trigger the device.

[0027] Disabling processor 36 is any suitable processor configured to compare threshold number of tests 30 to the actual number of tests performed as determined by counter 34. In particular, following each use or otherwise periodically, disabling processor 36 is configured to compare the number of actual tests performed from counter 34 to threshold number of tests 30 to determine if the number of tests that have actually been performed is equal to or greater than threshold number of tests 30. If the actual number of tests performed is found to be below the threshold number of tests 30, the disabling processor 36 does nothing further. However, if the disabling processor 36 determines the actual number of tests performed to be equal to or greater than threshold number of tests 30, disabling processor 36 notifies disabling device 38 to disable test unit 12.

[0028] Disabling device 38 can be any device configured to effectively disable or de-activate test unit 12 to substantially prevent use of test unit 12 to perform any further diagnostic tests. In one embodiment, disabling device 38 is coupled with memory 24. In this embodiment, disabling device 38 is configured to erase memory 24 of test program 26 upon instruction from disabling processor 36. As such, once test program 26 is deleted from memory 24, test processor 22 cannot analyze subsequent assays placed within assay interface 20 since it no longer has instructions for how to perform such analysis. As such, no subsequent diagnostic test can be performed by test unit 12. In another embodiment, disabling device 38 is configured to burn or otherwise de-activate a fuse within test unit 12, thereby, preventing use of test unit 12 to diagnostically access an assay received by assay interface 20. A fuse may be configured to deprive test unit 12 of power, to disrupt communication between assay interface 20 and test processor 22, and/or to disrupt communication between test processor 22 and memory 24. However, any other suitable disabling device 38 is also acceptable.

[0029] In one embodiment, in which test unit 12 is configured for only one use before being disposed, trigger 32...
may be directly coupled with disabling device 38. As such, when trigger 32 senses completion of the first use, trigger 32 notifies disabling device 38 to disable test unit 12. In such an embodiment, threshold number of tests 30, counter 34, and disabling processor 36 may be eliminated. In one embodiment, all of disabling unit 14 or any portions of disabling unit 14 may be realized mechanically, electrically, and/or optically.

In the above description, test unit 12 and disabling unit 14 are described as separate units in view of their function for clarity. However, in one embodiment, test unit 12 and disabling unit 14 are formed to utilize or share components. For example, a single processor may serve as test processor 22 and disabling processor 36, etc.

In this respect, test reader 10 is specifically configured to prevent use of the test reader 10 beyond a particular number of predetermined uses. For example, a unit that has only been rated for use with ten tests generally cannot be used to perform an eleventh test. Therefore, even if a particular patient, or caregiver believes the test reader 10 to be reliable for a number of tests greater than threshold number of tests 30, the patient or caregiver cannot continue to use a test reader 10. It is important to substantially prevent use of a test reader 10 beyond the threshold number since any subsequently performed tests would generally have an increased chance of error or decreased sensitivity, or under an economic motivation, to prevent use of test reader 10 for unpaid services.

Prevention of use for more than the threshold number of tests is particularly important in practice areas where users do not generally believe that test readers 10 are disposable. In particular, in more complicated diagnostic tests, the test readers are generally believed by healthcare workers and others to be expensive pieces of equipment that are not generally disposable. As such, healthcare workers or other individuals having this general belief may not be comfortable with disposing of a test reader 10 that still appears to working properly. Therefore, disabling unit 14 protects against undesired or unreliable uses of test reader 10. Furthermore, use of disabling unit 14 allows inexpensive parts to be used with test unit 12 without a worry that such parts will degrade and lead to unreliable test results or a desensitivity of the test results.

FIG. 2 illustrates a method of using test reader 10 generally at 50 with reference to FIG. 1. At 52, test reader 10 receives a diagnostic assay via assay interface 20. At 54, the diagnostic assay is read and analyzed by test unit 12. Upon completion of the diagnostic analysis, counter 34 is triggered at 56. For example, as described above, the triggering of counter 34 may be caused by a passing of a predetermined period of time, a mechanical interaction, an optical interaction, an electrical interaction, or other sensor interaction. In one embodiment, counter 34 is triggered by the removal of assay strips 78 from test reader 10 following completion of a test.

At 58, it is determined if the actual number of diagnostic tests performed by test unit 12 is less than threshold number 30 stored in disabling unit 14. If the actual number of tests performed is less than threshold number 30, then additional tests may be performed by test reader 10 and steps 52 through 58 are be repeated accordingly with new assays. However, if the actual number of diagnostic tests performed is not less than threshold number 30, then the method 50 continues to operation 60.

At 60, disabling device 38 is triggered by disabling processor 36 to disable test unit 12. In one embodiment, disabling test unit 12 at 60 includes at least one of deleting test program 26 from memory 24, burning a fuse in test unit 12, or any other suitable method of disabling test unit 12, which guards against future use of test unit 12. In one embodiment, after being disabled, test unit 12 is substantially useless. At 62, test reader 10 is disposed of accordingly.

FIG. 3 illustrates one embodiment of a particular diagnostic test system 70 including a diagnostic test reader 72 similar to test reader 10 of FIG. 1. In this embodiment, diagnostic test system 70 further includes a sample collection cup 74 and a diagnostic lid 76. Sample cup 74 is configured to receive test fluids, such as urine, blood, etc. from a patient. Lid 76 is configured to interface with an open end of cup 74 to substantially enclose the sample fluid within cup 74. In one embodiment, lid 76 includes one or more diagnostic assays 78. For example, as illustrated in FIG. 2, lid 76 is subsequently transparent and includes a plurality of lateral flow assay strips 78 that are generally visible through lid 76.

Test reader 72 is configured to interface with sample cup 74, more particularly, with lid 76 of sample cup 74. In one embodiment, test reader 72 is adapted to optically analyze assay strips 78 in lid 76. In one embodiment, test reader 72 is formed of two parts, namely, an inner housing 80 and an outer housing 82. Outer housing 82 is configured to coaxially receive inner housing 80.

In one embodiment, circuitry 88 of inner housing 80 is mounted to a top surface of inner housing 80. In one example, circuitry 88 includes test processor 22 (FIG. 1), a timer, an opto-electronic camera positioned within inner housing 80, and/or disabling unit 14 (FIG. 1). In one embodiment, test reader 72, in particular, inner housing 80, includes a connection device 90 to a computer processing unit or other device, in one embodiment, connection device 90 is a universal serial bus (USB) connector.

Test reader 72 is configured to be aligned with and pushed down and at least partially over lid 76 to secure test reader 72 to lid 76. Upon coupling of test reader 72 with lid, in one embodiment, a camera included in circuitry 88 is positioned to optically capture assay strips 78 through lid 76. To facilitate coupling in one embodiment, inner housing 80 includes tabs 84 circumferentially spaced around an open periphery of inner housing 80. Tabs 84 are bent toward lid 76 during use to grasp lid 76 locking test reader 72 to lid 76. In one embodiment, bending or unbending of tabs 84 may trigger test reader 72 that a test has been performed. In one example, springs 86 interact with inner and outer housings 80 and 82 and facilitate decoupling of test reader 72 with lid 76.

In one embodiment, lid 76 includes a cavity 92 including an aliquot plunger, and test reader 72 includes an index member 94. After inner housing 80 is positioned on lid 76, outer housing 82 is pushed toward inner housing 80, thereby, moving index member 94 down into cavity 92. Index member 94 interacts with the aliquot plunger causing sample fluid in cup 74 to be aliquot to assays 78.

In one embodiment, once inner housing 80 grasps lid 76, the timer begins a countdown of the predetermined time period required to complete the analysis of assay strip 78 in lid 76. In particular, in one embodiment, the opto-electro camera (not pictured) of inner housing 80 views
assays 78 through transparent lid 76 to determine whether or not a particular analyte is present by analyzing any color change of test strip 78. At the end of the predetermined time period, if no analyte is detected, then the test is negative. Regardless of whether or not the analyte was detected, the test is generally complete upon the expiration of the predetermined time period. Therefore, in each embodiment, the expiration of the time period serves as the test complete trigger 32 (FIG. 1) and notifies counter 34 (FIG. 1) to increment the tally of the actual tests performed by one.

[0042] As described with reference to FIG. 1, disabling processor 36 compares the actual number of tests completed as determined by counter 34 with a threshold number of tests 30 previously stored to test reader 72. If disabling processor 36 determines that the actual number of tests completed by test reader 72 is equal to or greater than the threshold number of tests 30, disabling device 38 is notified, and disabling device 38 subsequently deletes test program 26 from memory 24, thereby, disabling test reader 72. Since test reader 72 is disabled, a patient or healthcare worker is more likely to dispose of the test reader 72 and will not generally reuse the test reader 72 for additional tests beyond the number of threshold tests 30.

[0043] Although described in the embodiments above as being a sample cup 74 with assay strips 78 in lid 76, in one embodiment, the lateral flow assay strip is directly configured to receive the sample fluid being tested, such as urine, blood, etc. such as in a pregnancy test. In those embodiments, the above described test reader 72 functions in a similar manner wherein placement of the lateral flow assay test into the pregnancy reader triggers a test or performance of a test of a lateral flow assay mechanically, electrically, or otherwise indicates to the trigger 32 that a test has been complete and notifies counter 34 to increment by one the number of actual tests completed.

[0044] For example, FIG. 4 is a schematic diagram of a diagnostic test system 110 including a test reader 111, which functions similar to test reader 10. Accordingly, test reader 111 includes a test unit 112 and a disabling unit 114 similar to units 12 and 14, respectively. A lateral flow assay strip 116 is received by assay interface test unit 112. Receipt of assay strip 116 or some subsequent event triggers disabling unit 114 to track the actual number of assay strips 116 that have been analyzed by test reader 111. In a similar manner, as described above with test readers 10 and 72, disabling unit 114 is configured to disable test unit 112 when a predetermined threshold number of assay strips 116 have been analyzed.

[0045] FIG. 5 illustrates one embodiment of packaged diagnostic test system at 150. In one embodiment, packaged diagnostic test system 150 includes a container or packaging 152, a test reader 10, and a plurality of test strips or assays 154. In one embodiment, the number of assays or test strips 154 packaged with a single test reader 10 is equal to the threshold number of tests 30 (FIG. 1). For example, where threshold number of tests 30 is ten, a single test reader 10 is packaged with ten test assays 154. As such, packaging 152 can be used in addition to or as an alternative to counter 34 (FIG. 1) to determine when diagnostic test reader 10 has performed threshold number of tests 30. For example, a test reader 10 is used with all diagnostic assays 154 packaged therewith. Upon the use of all diagnostic assays 154 packaged with test reader 10, test reader 10 is disposed of and a new diagnostic test system product package 150 is opened and used. As such, such packaging can be used in and of itself to monitor the use of test reader 10 and/or can be used a secondary or visual device indicating the number of diagnostic assays remaining that may be completed on a particular test reader 10 including disabling unit 14 (FIG. 1). In one embodiment, the threshold number of tests may be set slightly differently than the number of assays 154 to allow for inclusion of spare assays 154 in packaged system 150, or for a few additional uses if a user unintentionally triggers the counter or otherwise so requires.

[0046] The embodiments described above provide relatively low cost diagnostic test readers configured to analyze immunoassays with a desired level of sensitivity. The low cost of the test readers increases availability of such test readers at non-laboratory locations, such as at the point of care. In addition, the disabling unit included within the test readers polices use of the test readers, substantially preventing use of the test readers to perform tests after a threshold number of uses and well before statistical probability of either electrical or mechanical degradation of the test reader or before the legal life of the test unit has expired. As such, a sensitive diagnostic test can be performed at the point of care for a relatively low price.

[0047] Although specific embodiments have been illustrated and described herein, it will be appreciated by those of ordinary skill in the art that a variety of alternate and/or equivalent implementations may be substituted for the specific embodiments shown and described without departing from the scope of the present invention. This application is intended to cover any adaptations or variations of the specific embodiments discussed herein. Therefore, it is intended that this invention be limited only by the claims and the equivalents thereof.

What is claimed is:
1. A diagnostic test reader comprising:
   a test unit configured to perform one or more tests, wherein each of the one or more tests employs a diagnostic assay to analyze whether an analyte is present within a sample; and
   a disabling unit coupled with the test unit, the disabling unit configured to disable the test unit based on a selected threshold number of tests.
2. The diagnostic test reader of claim 1, wherein the disabling unit includes:
   a counter configured to determine an actual number of tests that have been performed by the test unit,
   a memory configured to store the threshold number, and
   a processor configured to compare the actual number of tests to the selected threshold number.
3. The diagnostic test reader of claim 2, further comprising a trigger coupled to the counter and configured to be activated after a test has been performed by the test unit, wherein the counter increments the actual number each time the trigger is activated.
4. The diagnostic test reader of claim 2, wherein the selected threshold number is commensurate with a predetermined sensitivity level range.
5. The diagnostic test reader of claim 2, wherein the selected threshold number is based on a probable sensitivity of the diagnostic reader.
6. The diagnostic test reader of claim 1, further comprising:
a trigger configured to be activated after a test has been performed by the test unit, wherein the activated trigger is configured to instruct the disabling unit to disable the test unit.

7. The diagnostic test reader of claim 6, wherein the trigger is mechanically activated.

8. The diagnostic test reader of claim 6, wherein the trigger is electrically activated.

9. The diagnostic test reader of claim 6, wherein the trigger includes a timer that begins when the test begins, and wherein the trigger is activated when the timer reaches a predetermined time.

10. The diagnostic test reader of claim 1, wherein the test unit includes:

an assay interface configured to receive the diagnostic assay,

a memory configured to store a program for analyzing the diagnostic assay, and

a test processor configured to execute the program and analyze the assay.

11. The diagnostic test reader of claim 10, wherein the disabling unit is coupled to the memory and is configured to disable the test unit by deleting at least a portion of the program from the memory.

12. The diagnostic test reader of claim 1, wherein the disabling unit is configured to electrically disable the test unit.

13. The diagnostic test reader of claim 1, wherein the analyte is human chorionic gonadotropin and the diagnostic assay is a lateral flow assay.

14. The diagnostic test reader of claim 1, wherein the analyte indicates drug use by a patient who provided the sample being tested.

15. A diagnostic test system comprising:

a diagnostic test reader including:

a test unit configured to perform one or more tests, wherein each of the one or more tests employs a diagnostic assay to analyze whether an analyte is present within a sample, and

a disabling unit coupled with the test unit, the disabling unit configured to disable the test unit based on a selected threshold number of tests; and

a number of diagnostic assays equal to the threshold number, wherein the diagnostic test reader and the plurality of diagnostic assays are packaged together.

16. A diagnostic test reader comprising:

means for performing one or more tests, wherein each of the one or more tests uses a diagnostic assay to analyze whether an analyte is present within a sample received from a patient; and

means for disabling the diagnostic test reader when a threshold number of tests have already been performed, wherein a disabled diagnostic test reader is unable to perform additional tests.

17. A method of performing one or more tests employing a disposable diagnostic test reader, the method comprising:

performing one or more tests employing the disposable diagnostic test reader including determining with an assay if an analyte is present in a sample introduced to the assay; and

preventing use of the diagnostic test reader based on a selected threshold number of tests performed with the disposable diagnostic test reader.

18. The method of claim 17, further comprising:

determining the threshold number of tests that can be performed at a desired sensitivity level.

19. The method of claim 17, further comprising:

determining the number of tests performed with the disposable diagnostic test reader; and

comparing the number of tests performed to the threshold number,

wherein preventing use of the disposable diagnostic test reader occurs based on the comparison of the number of tests performed to the threshold number.

20. The method of claim 17, wherein preventing use of the disposable diagnostic test reader includes one of deleting a test program from the disposable diagnostic test reader and electrically disabling the disposable diagnostic test reader.

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