Automated Authentication Antigen Rapid Testing (ART) System

BACKGROUND OF THE INVENTION

Currently all the do-it-yourself (DIY) ART test kits require physical swabbers or personnel to verify the entire process and authenticate results. There are no digital track and trace system available to verify the validity of the user taking a rapid test. The results cannot be verified by others to ensure they are valid and genuine.

1. Field of the Invention

The present invention relates to an automated authentication system that can automatically read and authenticate antigen rapid tests (ART) result. It consists of a unique identifier (FIG 4001) tagged to the ART kit, a system to identify a user (FIG 6), a camera system (FIG 6002) to capture the testing process and an automated cassette reader to read and collect the test data (FIG 5)

1.1 ART is a rapid chromatographic immunoassay for the qualitative detection of specific antigens of SARS-CoV-2 present in the human nasopharynx. Typically, nasopharyngeal or oropharyngeal sample is collected and dripped into a lateral flow test cassette (FIG.4). User interprets the test results from the window of the test cassette. The test cassette is coated with two lines, the control line (FIG 1001) and the test line (FIG 1002). Depending on the lines that appear, the result can be interpreted as positive, negative or invalid as in FIG 1 to FIG 3.

1.2 Every ART test cassette has a unique identifier (FIG 4001). (This tagging process is a cross-reference to U.S. Patent Application No.: 16/362,563 filed on 22 March 2019, titled Security Systems and Methods for Electronic devices – Published on 19 September 2019 (Publication No.: US-2019-028706-A1). This provides a mean to identify every single ART kit. The ART identifier (FIG 4001) also provides an audit trail, which prevent counterfeiting, and to provide documentations to support operational and security actions.

1.3 The system also consists of a video recording camera (FIG 6002) to record the testing process of the user. The video is time-stamped. Anti-

forgery and real-time video analytic technologies can also be embedded in the system to validate the entire testing procedures.

1.4 The system also has an automated test cassette reader (FIG 5) that correctly read, interpret and collect the test results. It then disposes the test cassettes safely.

DESCRIPTION OF THE INVENTION

One key objective of the present invention is to provide track and trace of the ART result (FIG 1, FIG 2, FIG 3) to the user. The ART cassette is tagged with a unique identifier (FIG 4001) to prevent counterfeiting and fraud. The system collects the user identification with a Kiosk Terminal (FIG 6). The system then tags the user identification to this unique ART kit identifier (FIG 4001) thereby creating a one user to one test kit relationship. The test kit's unique identifier (FIG 4001) is randomly generated and hence making it impossible for one to guess or predict the unique identifier. This user-test kit relationship therefore preventing forgeries and frauds.

Another objective of the invention is to provide a method to verify that the test process is correct and done according to the ART manufacturing instructions. A video recording camera (FIG 6002) is used to record or take photo of the user conducting the test. This photographic or video record serves as the audit trail. In different embodiments, the video can be time-stamped. In other embodiments, anti-forgery and/or real-time video analytic technologies can also be embedded in the system to validate the entire testing procedures.

Another objective of the present invention is to provide an automated system for reading and interpreting the results of the ART cassette (FIG 5).

The ART cassette has two lines; Control Line (FIG 1001) and Test Line (FIG 1002). The ART result is positive (FIG 1) if a colored or faint line appears in both the Test line (FIG 1002) and the control line (FIG 1001).

The ART result is negative (FIG 2) if only a colored line appears in the Control Line (FIG 1001) and no other lines are present.

The ART result is invalid (FIG 3) if only a colored line appears in the Test Line (FIG 1002) and no line in the Control Line (FIG 1001). The ART result is also

invalid if there are no lines in either the Control Line (FIG 1001) or in the Test Line (FIG 1002).

Once the user has completed the testing process, the result will be read and interpreted by an automated reader system (FIG 5) to ensure it is tampered proof and can be validated digitally. The ART cassette (FIG 4) is inserted into loading slot (FIG 5101) of the automated reader system (FIG 5). A LED status light (FIG 5102) shows the opening and closing status of the loading slot (FIG 5101).

The automatic reading mechanism (FIG 5) consists of a rotation disc (FIG 5201) that holds a bay (FIG 5202) to align the ART cassette (FIG 4) in the correct place therein, as well as optical character recognition (OCR) reader (FIG 5301) which reads the screen image of ART cassette (FIG 4). The image is of the ART cassette is extracted, analyzed and interpreted for the test result (FIG 1, FIG 2 or FIG 3) of the ART cassette. The ART cassette (FIG 4) unique identifier (FIG 4001) is also extracted by the OCR reader (FIG 5301).

The automation reading system (FIG 5) also consists of a process programmable logic controller (FIG 5303), a computer program to determine the logic to operate the automatic reading process.

The automation reading system (FIG 5.1), is a modular system, and can be daisy chained to scale up to read more ART cassettes (FIG 4). The automatic reading system (FIG 5) is also able to integrate into any kind of kiosk device or terminal. It can also perform as a standalone ART reader device.

A rotation disc plate (FIG 5201) with cassette bay (FIG 5202) is to house all the inserted test cassettes and act as the holding or buffer for ART cassettes (FIG 4). Most of the lateral ART kits in the market has an incubation time of 10 to 15minutes before the results in the ART cassette (FIG 4) can be read. All the cassette bays (FIG 5202) are rotating in a clockwise direction on top of the disc (FIG 5201). The disc (FIG 5201) is rotated at constant speed clockwise. The rotation speed of the disc (FIG 5201) can be adjusted such that the time taken for the ART cassette (FIG 4), when first placed onto the cassette bay (FIG 5202), to reach the OCR reader (FIG 5301) is longer or similar to the incubation time. This feature ensures that ART cassette (FIG 4) has reached its incubation period before being read by the OCR reader (FIG 5301).

In certain embodiments, additional buffer liquid is needed to be added to the test assay after a certain incubation period before the result is read by the OCR reader (FIG 5301). Dropper mechanism can be added in the automation process to drip buffer liquid into the test cassette's sample and buffer well (FIG 1003). The rotation speed of the disc (FIG 5201) can be controlled such that the time to add the buffer liquid adheres to the incubation period required by the assay. Once the buffer liquid is added to the cassette's sample and buffer well (FIG 1003), the disc (FIG 5201) can be controlled to turn till it reaches the OCR reader (FIG 5301). Again, the rotation speed can be controlled such that time needed to reach the OCR reader (FIG 5301) adheres to the assay requirement.

The OCR reader (FIG 5301) reads the image of the ART cassette (FIG 4) and retrieve the ART unique identifier (FIG 4001) and the results of the test. This is done by detection algorithms. One such detection algorithm works to defines a character by evaluating its lines and strokes. The OCR reader (FIG 4) recognize a line by searching for white pixel rows that have black pixels in between. Similarly, the algorithm can recognize where a line starts and finishes (FIG 7).

Once the automatic reader (FIG 5) has read the result and the unique identifier (FIG 4001) of the ART cassette (FIG 4), the data will be stored either locally or in the cloud. The kiosk system (FIG 6) software will then subsequently link the User Identification, ART unique Identifier (FIG 4001), User's testing video and the User's test result into a data string. The kiosk system (FIG 6) consists of an array of components, a housing (FIG 6001), a camera (FIG 6002), code reader (FIG 6002), LCD display (FIG 6003), and automation reading system (FIG 5).

This close loop system provides an end-to-end process to prevent any tampering of the test result and authenticate that the test is indeed done by the user. The invention provides a non-editable electronic record by having a digital means of all data, the aforesaid proof that a user has taken the test along with the recorded video or photo of that user.

DESCRIPTION OF THE DRAWINGS

FIG 1. Interpretation of ART Positive Result
Two colored lines appear. A colored line should always appear in the Control (C) region (FIG 1001) and another line should be in the Test (T) region (FIG 1002). A positive result indicates the detection of SARS-CoV-2 antigens in the sample.

FIG 2. Interpretation of ART Negative Result
A colored line appears in the Control (C) region (FIG 1001). No line appears in the Test (T) region (FIG 1002). As with the positive result, a colored line should always appear in the Control (C) region (FIG 1001) for the test to be valid. A negative result indicates that the detection threshold of SARS-CoV-2 antigens in the sample has not been reached.

FIG 3. Interpretation of ART Invalid Result
The Control line (FIG 1001) does not appear. Insufficient diluent volume or incorrect procedural techniques are the most likely reasons for the absence of the control line.

FIG 4. ART Cassette
Antigen Rapid test kits cassette, the cassette contains monoclonal antibodies against SARS-CoV-2/COVID-19 conjugated to gold nanoparticles, which bind to any SARS-CoV-2 antigen present in the sample. It comprises of the control line (FIG 1001), the test line (FIG 1002), sample & buffer well (FIG 4003) and the kit unique identifier (FIG 4001).

FIG 5. Automated Cassette Reader
The automation reader comprises a housing (FIG 5104), with a loading slot (FIG 5101), a LED status light (FIG 5102), a disc (FIG 5201), cassette holding bay (FIG 5202) with an Optical Character Recognition (OCR) reader (FIG 5301) and a programmable logic controller (FIG 5303).

FIG. 5.1 Automatic tray for cassette insertion
Illustrates the elevation of the automatic self-reading mechanism with one loading slot to insert the test cassette into.

FIG. 5.2 Automated Cassette Bay and Disc
Illustrates the holding area for the user's ART test cassette.

FIG. 5.3 OCR and Controller
Shows the cross-section of the automatic self-reading mechanism.

FIG 6. System Kiosk and Terminal
The Kiosk, the main control of this closed-loop invention system. Collecting data and sending all data to the cloud management system.

FIG 7. OCR Interpret Test Results
Interpret the test results using OCR algorithm

CLAIMS

1. The automated reader (FIG 5) technology is an integration of system and methods to automate the reading of lateral flow ART cassette (FIG 4) used in a testing kiosk. It ingeniously read, interpret, validates and allow the test results of the test cassette (FIG 4) to be authenticated after a required incubation period.

2. The system and methodology that enable user to perform ART test, validate the ART test result in a process to prevent any tampering of the test result and authenticate that the test is indeed done by the user.

3. Performing and submission of ART test results without human interference. Full end-to-end automated process from start to finish over a network of systems and methodology.

4. The testing kiosk software is the main control system for the self-test process in which the software analyze data from a cloud management protocol thereby maintaining diagnostic test results, log integrity oversight and administrative control are closed loop, summative and authentic.

5. To enable verification purposes and prevent frauds, fictitious and illicit sale of negative test results through the tagging of ART test cassettes with unique identifier.

6. The authenticity in the system and method technology creates the provision of audit trail from the user registration of each action, event and activity trigger from the system setting. No creation, alteration, modification or deletion of records are allowed. Daily volume of audit log is traceable hence the automated self-read technology. Therefore, a solution for automated tracking is good, even obligatory to have.

7. The system and method technology can protect audit trail from the origin of the log records, transparency and acts as a defense of records for compliance, record integrity and accuracy and against misuse or harm, violation of security of sensitive and vital information.