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New Software Interface for Registering Rapid Antigen Test Results to Prevent Fraud

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Original Research

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Abstract

Donald O. Besong has already documented that the online registration of unsupervised lateral flow test results poses concerns in the case of a serious pandemic where there are not enough medics to read scans or watch videos of candidates' results (Besong *Int J Biomed Healthc Sci*. 2022;12(1):1-12). Scanning or videorecording requires a high number of available medics (Besong *Int J Biomed Healthc Sci*. 2022;12(1):1-12) in an adverse pandemic scenario. In the above study (Besong *Int J Biomed Healthc Sci*. 2022;12(1):1-12), an artificial intelligence (AI) interface with image recognition was suggested as a method to prevent cheating during the online registration of unsupervised test results. The second solution suggested was a method that obscures the meaning of the result the candidate reads from their test device so that a software interface can resolve that from a database (Besong *Int J Biomed Healthc Sci*. 2022;12(1):1-12). This is an entirely new method. In this study, the latter (entirely new) method is proposed and described in detail. Precisely, this simple but new method is all about blinding the test strips so that the candidate does not know what the face values signify. The software then connects to a database of unique strip identification numbers to determine the test result when the candidate or patient registers their results. Both strip number and the value of their test must be entered to register results. This method has never been proposed or implemented. The technique will be described in detail.

It has been found that, in emergency hospital settings, rapid diagnosis and isolation of severe acute respiratory syndrome coronavirus 1 (SARS-CoV-2) patients are required.[1] In such settings, rapid turnaround time is critical. Timely and accurate SARS-CoV-2 testing plays a crucial role in limiting the spread of the virus.[1] However, the work in Loconsole et al. is concerned only with clinical accuracy and does not deal with the reporting layer of these tests.[1]

This study fills the gap by describing a new online registration strategy for these tests. Online cheating during the registration of coronavirus disease 2019 (COVID-19) test results was first addressed in a recent study.[2] However, the study did not offer a software solution that can be readily implemented. In the following sections, the present study offers a new solution in detail.

Role of Antigen Testing in COVID-19

Different SARS-CoV-2 test procedures serve unique purposes in the current pandemic, and with no 1-size-fits-all strategy to the crisis[3] (see Table 1 below).

Antigen tests are suitable for detecting early stages of infection, with the advantages of being cheaper and quicker than polymerase chain reacton (PCR) methods. Another advantage is that the procedure can be performed by non-experts using test kits. However, their disadvantage is that antigen tests are not as sensitive as PCR tests.[3] PCR methods are nucleic acid amplification tests (*NAATs*), while rapid antigen tests are rapid diagnostic tests, or RDTs.[4] The sensitivity of antigen tests are observed to be highly variable, ranging from 0-94% but specificity is consistently reported to be high (above 97%).[4] Thanks to the extremely high specificity of antigen tests, they may be helpful in quickly identifying highly infectious individuals within a community.[4]

The clinical errors of these tests are beyond the scope of this work. The present study therefore assumes that there is sufficient clinical accuracy from antigen tests. False test reporting should not be confused with the clinical accuracy of the test itself.

The diagnostic development landscape for rapid antigen tests is dynamic, with nearly a hundred companies involved in the manufacture of rapid tests for SARS-CoV-2 antigen detection worldwide,[5] including dozens in Europe alone.[6]

Operational definitions

1. A *mild scenario* is when there are not too many rapid antigen candidates compared to the number of medics available.[2]

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Table 1. Summary of SARS-CoV-2 test methodologies

	Properties A: (target, sensitivity, and cost)	Properties B: (Turnaround, how, when)
Polymerase chain reaction (PCR) tests	Target: viral genetic material (RNA, DNA) using 1 of several PCR assays. Sensitivity: extremely high Cost: Extremely Expensive, and requires a laboratory.	Typical turnaround: a few minutes up to a week. How: multiplies genetic material exponentially. Requires laboratory/medical experts. When: useful at the early (acute) stages of infection.
Serology testing	Target: antibodies in the blood. Sensitivity: low (compared to PCR). Cost: mostly affordable (compared to PCR).	Typical turnaround: can be fast (compared to PCR). How: requires laboratory/medical experts. Uses various immunoassays or other ways to visualize the antibodies. When: useful at the later stages of infection. Not recommended for the diagnosis of acute disease.
Antigen testing	Target: antigens in various mucosae. Sensitivity: moderate (compared to PCR). Cost: cheap (compared to PCR).[3]	Typical turnaround: a few minutes (considerably fast, compared to PCR[3]). How: uses immunoassays. Can be done with or without laboratory/medical experts. When: useful at the early (acute) stages of infection (diagnosis of acute disease).

2. An *adverse scenario* is when urgent unsupervised tests are needed for mass evacuation and isolation, attending work and meetings or travel. In this case, there would be too many testing candidates for medics to handle.[2]
3. *A blind strip* is a test strip where the internal structure is reversed in 1 group but all the faces remain the same in both. In that way, test providers would be able to catch half of the fraudsters if equal quantities from each group are in each test kit. The only way to cheat would be through guesswork.
4. *A transparent strip* is a strip whose internal configuration is identical to the external one in all the strips. These are the strips currently in use.

Methods

Ethical clearance was not needed in any of the methods presented in the present study.

How Rapid Antigen Tests Work

After collecting the respiratory specimen and applying it to the test strip, results are read by the operator within a few minutes with or without the aid of a reader instrument.[4]

The devices (ie, test strips) manufactured by the clinical companies listed by the European Commission[6] are generally based on the same principles and methods. Therefore, in the present study's brief description of how rapid antigen tests work, it refers only to a document from Abbott Rapid Diagnostics.[7]

Like all other test devices, Abbott's Panbio™ COVID-19 Ag Rapid Test Device contains a membrane strip where the line labeled *T* is precoated with immobilized anti-SARS-CoV-2 antibodies, while the label *C* is precoated with the chromatographic control assay.[7] *T* is the test line, while *C* is the control line. For clinical details, and how to perform these tests, the reader should read the referenced manuscript or the manual enclosed in the test kit of any recognized manufacturer,[6] as those details are not relevant for the purpose of the present study.

Consider Figure 1 below,[7] where each rectangle represents the face of the test strip.

It is well-known that these tests are standard, accepted, and clinically reliable for their intended application. The innovation posited in the present manuscript applies only to the registration of test results by the remote user (ie, the candidate).

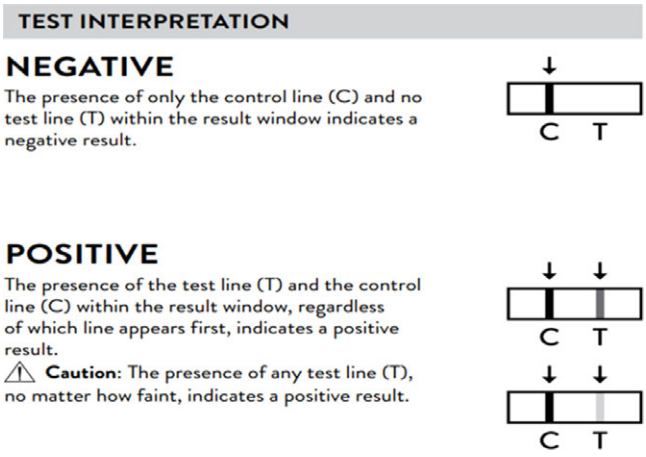

Figure 1. Lateral flow test interpretation, courtesy of Abbott.[7]

How Test Results Are Currently Registered

The present study will first illustrate how the current method for registering test results online during an adverse pandemic scenario actually works as well as the risk it poses. Figure 2 shows the candidate's steps during the registration of results.

The scenario that poses opportunities for online cheating is the adverse case of mass testing and isolation in a serious pandemic,[2] where the number of medics is insufficient to deal with videos and scans. This study refers to this as the adverse scenario. In Figure 2, the candidate can register any result irrespective of the outcome in step 4. That is where the current method is open for online cheating.

When the COVID-19 lockdowns were lifted, the registration procedure shown in Figure 2 was used by the Hospital Corporation of America (HCA) and Healgen for us to get back to the office.[2,8,9] There was no mechanism to detect fraud. Please see Figure 2 above.

Consider Figure 3 below, which analyses the current solution. The test strip is represented by a rectangle.

The first rectangle (green) represents the internal composition of the test strip, that is, the position of the assays. All test strips are identical. C is the chromatographic control assay, while T is the chromatographic test immunoassay that reacts with COVID antigens.

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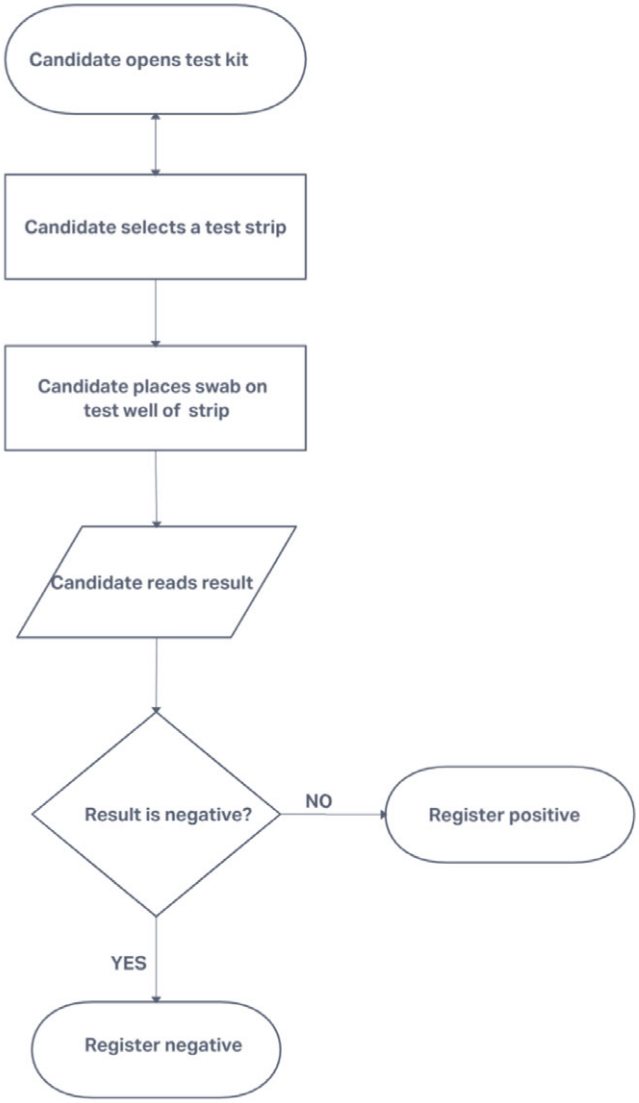

Figure 2. Lateral flow test – Registration of Results

Internal structure	External structure	Result the candidate sees on the face of the strip	What the candidate registers in the portal	How the software should interpret the registered result
C T	C T	C T	Negative	Negative
		C T	Positive	Positive
		C T	Neutral	Neutral

Figure 3. Illustration of how unsupervised tests are currently reported – transparent test strips.

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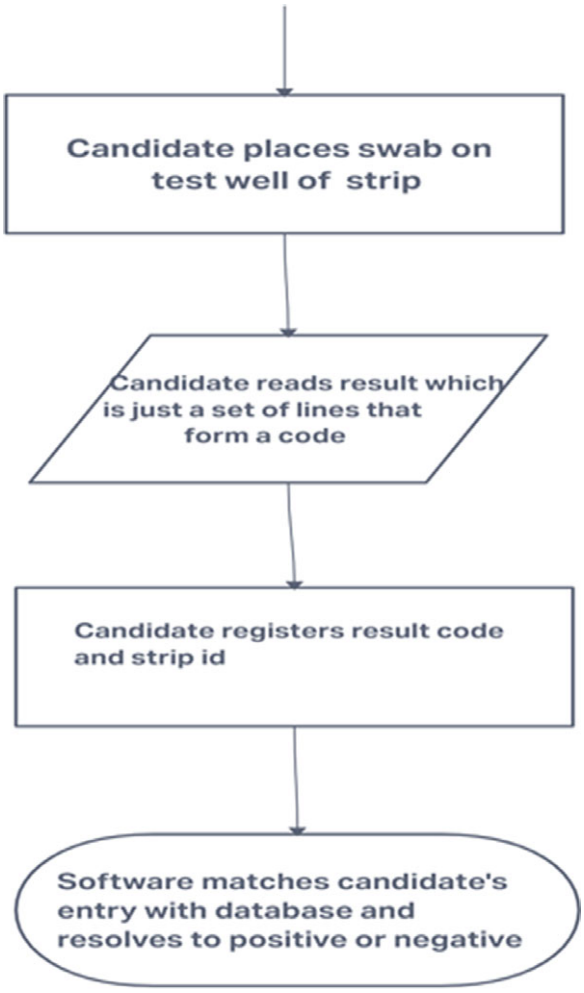

Figure 4. Lateral flow test – Proposed method for registering results.

The second rectangle (blue) represents the assay labels as the layman (the candidate) sees it. Observe that in all the current strips, the internal configuration is identical to the external one.

The third column shows test strips with all possible results we can get from a test. However, for brevity, we shall keep this entire discussion focused on the negative result, which the candidate usually desires.[2] The fourth column shows what the candidate reads as results, and the fifth is what the portal reports for the candidate.

In Figure 3 above, the candidate already knows the face value of the test script that implies a negative (or positive) result. Therefore, the candidate can log their desired result onto a Web portal irrespective of their actual result. Consequently, even if their result was actually positive, or they did not take the test at all, they could still register a negative outcome with 100% success. This success rate in cheating is because the interior configuration is identical to the external design. Let us term such test strips as *transparent*.[1]

How to Prevent Fraud in the Registration of Results

In Figures 2 and 3, the present manuscript illustrates how the adverse scenario is currently managed. During the COVID pandemic, some candidates cheated with a 100% success rate since they could simply register their desired result without being caught. AI/image recognition can take the place of medics.[2] However, the present study will propose and develop a simpler solution here.

All steps in Figure 4 are identical to those in Figure 2 until the registration of the results, where instead of the candidate registering positive or negative, they register only a code and a strip ID, which only the software interface can resolve as positive or negative. This is achieved by having 2 groups of test strips where the internal structure is reversed in 1 group but all the faces remain the same in both. That way, test providers could catch half of the fraudsters because the only way to cheat would be by guessing. We will describe these strips as *blinded*.[2] It is important that each test strip has a unique number and that test strips from each group are in equal proportion in every kit that is shipped out. The test provider should save all strip numbers and their corresponding internal configuration in a database. When the candidate or patient registers their strip number and the value of their test result onto the Web portal, the software will match this with the database and then resolve to the correct human-readable result, that is, positive or negative.

How is this achieved? Consider that instead of all test strips being identical as in the current solution, we create 2 groups of test strips S1 and S2.

Figure 5 below shows how the test strips will be configured and how the software interface will interpret the results after step 4 in Figure 4 for the S1 set.

Similarly, Figure 6 below shows how the test strips will be configured and how the software interface will interpret the results after step 4 in Figure 4 for the S2 set.

That way, test providers could catch half of the fraudsters because one can only cheat through guesswork. The probability of correctly guessing a negative result would be 1/2 since a negative would be (1,0) in half of the strips and (0,1) in the rest. This would already be enough to deter cheating. The principle behind this is simple: switch the assays denoted by C and T in half of the test trips, but keep the external labels unchanged.

Comparison Between the Current Method and the Proposed Technique

Table 2 below is what we shall now achieve, compared with the current way of doing things.

Results and Conclusions

Ethical clearance is not required for any of the results presented in the present study.

The way in which unsupervised rapid antigen tests are registered is a major concern for the adverse scenario. This paper describes a new and creative feasible solution that entails using blind strips from 2 different groups configured differently on the inside. The technique requires 2 types of test strips, which should be identical on the outside, while in 1 group, the internal configurations are reversed. One set (S1) will be constructed as described in Figure 5, and the other set (S2) will be as in Figure 6. If each test kit has equal quantities from both groups S1 and S2, then a cheat can only succeed 50% of the time.

[1]This term, *transparent, has* never been used to describe test strips.

[2]The use of the term *blind* to describe test strips does not yet exist in the literature. Blind test strips have not yet been produced as well.

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Table 2. Conclusion and comparison

	Current solution	Proposed solution
Description	All test strips are identical. Neither a database nor software interface is needed to know if a test is negative. This paper describes such strips as transparent.	There are 2 types of test strips, which are externally identical, but in 1 group the internal configurations are reversed. Both a database and a software interface are needed to know if a test is negative. Test strips are described as blind.
Negative result	All strips as in Figure 3.	See Figure 5 for S1 and Figure 6 for S2.
Implication	Candidate is free to cheat and will succeed 100% of the time.	If each test kit has equal quantities from both groups S1 and S2, then a cheat can only succeed 50% of the time.

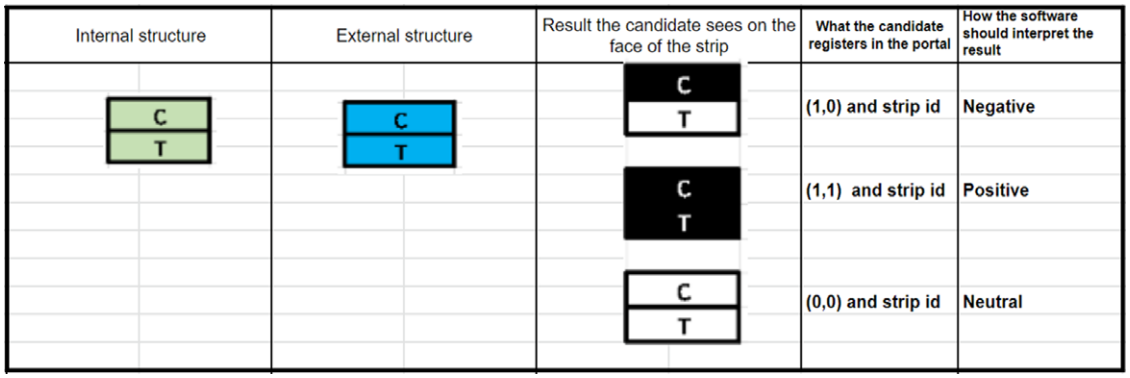

Figure 5. Lateral flow test – interpretation of blind test strips S1.

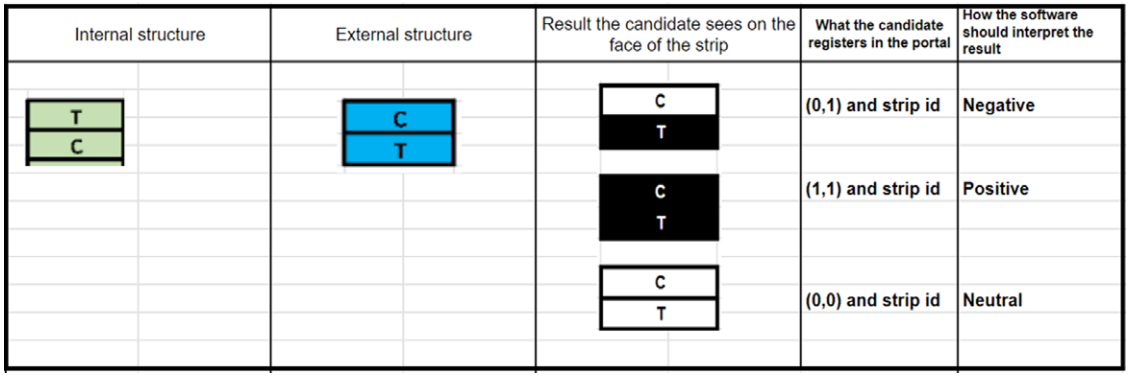

Figure 6. Lateral flow test – interpretation of blinded test strips S2.

Novel terminology often emerges with new operational definitions. The new terms that come with this paper are *mild scenario*, *adverse scenario*, *blind strip*, and *transparent strip*.

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