RDTCheck: A Smartphone App for Monitoring Rapid Diagnostic Test Administration

Devesh Sarda University of Washington Chunjong Park University of Washington Hung Ngo University of Washington

Shwetak Patel University of Washington Alex Mariakakis University of Toronto

ABSTRACT

Rapid diagnostic tests are point-of-care medical tests that are used by clinicians and community healthcare workers to get quicker results at a better cost compared to traditional diagnostic tests. Distributing rapid diagnostic tests to people outside of the healthcare industry would significantly improve access to diagnostic testing; however, there are concerns that novices may administer rapid diagnostic tests incorrectly and thus be left with invalid results. In response to this concern, we propose RDTCheck - a mobile application that guides users through the instructions of Quidel's QuickVue Influenza A+B test and ensures adherence to the procedure using computer vision. RDTCheck provides users with real-time feedback so that they may either correct their mistakes or re-administer their test. In this work, we conducted findings from a pilot study that demonstrates how well RDTCheck is able to detect common mistakes and successes during the various steps of the QuickVue test. For the 7 participants we recruited, RDTCheck had an average success rate of 91.1% at giving the correct feedback during the RDT administration procedure.

CCS CONCEPTS

Human-centered computing → Ubiquitous and mobile computing systems and tools; Ubiquitous and mobile computing design and evaluation methods.

KEYWORDS

Rapid Diagnostic Tests, Computer Vision, Android application

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1 INTRODUCTION

Unlike traditional diagnostic methods that require expensive clinical equipment, rapid diagnostic tests (RDTs) allow people to test for infectious diseases like malaria [9], influenza [15], and even COVID-19 [16] in just a couple of hours. RDTs are able to achieve this feat by utilizing chemistry that transduces the presence of an analyte into a visual signal that can be interpreted by people with unimpaired vision. RDTs are relatively inexpensive (~\$2 USD) and can therefore be distributed at scale, making them particularly useful in countries that lack significant healthcare infrastructure [23]. However, this is not the only cost associated with RDTs. RDTs are normally administered by medical personnel like clinicians and community healthcare workers (CHWs), many of whom are overburdened with responsibilities. It is estimated that the opportunity cost of administering an RDT is nearly triple that of the RDT itself [6]. Furthermore, restricting RDT administration to medical personnel also limits the potential impact such tests can have for community health surveillance programs. Rather than requiring medical personnel to administer RDTs, many manufacturers are working towards getting their products certified for home use [4]. This trend will become increasingly common in the near future because RDTs can be administered with inexpensive equipment (e.g., nasal swabs, droppers, and test tubes) and the steps required to administer an RDT do not require rigorous training. Unfortunately, RDTs often have a lower effective accuracy when they are used in the field versus when they are used in lab settings [15]. Some failures in the field are due to interpretation errors, and many researchers have facilitated RDT interpretation using dedicated hardware and smartphone cameras for image analysis [10, 18, 19]. Other failures, however, are due to procedural errors that occur during the RDT administration process, such as cases when people do not gather sufficient biological samples [9] or ignore prescribed timers [20]. These errors have largely been unaddressed beyond extended training periods for CHWs [9] and product-specific features (e.g., pre-portioned liquids, instructional markings).

The human-computer interaction and computer vision communities have often used device orientation and real-time image processing to provide automated guidance during media capture. Bank check recognition for online banking is perhaps the most ubiquitous example of this approach [7, 8, 12], but smartphone apps like EasySnap [13, 22] and NudgeCam [3] apply similar methods to assist photographers as they take pictures of human subjects. In a similar vein, we propose a smartphone application called RDTCheck that supervises the RDT administration process and provides real-time corrections when mistakes are made. Using a simple 3D-printed box

that can be shipped with the RDT kit, RDTCheck uses the smartphone's camera to continuously observe the RDT administration process. RDTCheck incorporates a variety of real-time computer vision techniques that operate on-device to continuously assess how users execute each step of the process. As a proof-of-concept, we have designed RDTCheck specifically for Quidel's QuickVue Influenza A+B test¹ — a dipstick-based RDT that analyzes the contents of a nasal swab; although we do not test RDTCheck on other tests, we believe that our approach would generalize to other RDT form factors. We evaluated RDTCheck with 7 participants and found that it had an average accuracy of 91.1% across the different steps. Participants found RDTCheck to be easy to use, which motivates a future study related to RDTCheck's usability and efficacy.

2 RDTCHECK DESIGN

In this section, we outline the design and implementation of RDTCheck, whose steps can be seen in Figure 2. We first provide background on the QuickVue test, and we then describe the 3D-printed box we add to the components of the QuickVue test to facilitate video recording during RDT administration. We then detail the computer vision software that RDTCheck uses to supervise the major steps of the QuickVue test. Throughout this section, we describe color metrics in the hue-saturation-value color space (H: 0-179, S: 0-255, V: 0-255).

2.1 QuickVue Test

Quidel's QuickVue Influenza A+B test is centered around a lateral flow immunoassay embedded in a dipstick (Figure 1, left). The kit comes with many components: a dipstick, a nasal swab, a dropper that holds 340 μ L of buffer solution, and a test tube with a capsule of freeze-dried agents. To complete the QuickVue test, the user first places the buffer solution in the tube. After swabbing the inside of their nose to collect epithelial cells onto the swab's tip, the user swirls the swab in the buffer solution and then leaves the swab in the tube for 1 minute; this process ensures that sufficient biological material is transferred to the liquid solution in the tube. The user then swirls the swab again to ensure that any remaining biological materials get transferred into the buffer. Finally, the user places the dipstick inside the tube arrow-side down and leaves it there for 10 minutes so that the liquid has enough time to flow through the immunoassay. The results on the strip appear as colored lines: one for the presence of influenza A, one for the presence of influenza B, and a control line to verify that the test results are valid.

We selected the QuickVue test as an exemplar for this research because it contains many possibilities for procedural failure that can be generalized to other dipstick-based RDTs. If the user does not properly empty the dropper of buffer liquid or does not leave their dipstick in the tube long enough, the control line will not appear. If the user does not properly deposit the biological sample from their nasal swab into the tube, the test will appear valid,



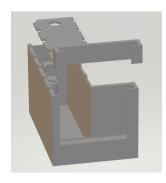


Figure 1: (left) The components in Quidel's QuickVue Influenza A+B RDT kit: a dipstick, a nasal swab, a dropper of buffer solution, and a test tube. (right) A CAD rendering of the 3D-printed box we created to house a Google Pixel smartphone and the RDT kit components.

but will likely produce a false negative. For these reasons, it is necessary to observe the entire process to understand what might have gone wrong during the procedure. RDTCheck monitors most of the aforementioned steps, with the exception of the swabbing of the nose due to privacy concerns that would arise if people were asked to record their face.

2.2 3D-Printed Box

Our goal is to support RDT administration in the most inexpensive manner possible. Given the ubiquity of smartphones, particularly amongst CHWs and people in industrialized nations [1], we believe that the requirement of a smartphone does not preclude too many people. However, we quickly discovered two challenges while conducting formative work for this system: (1) administering an RDT requires two hands, and (2) RDTs can be administered in a variety of lighting environments. With these issues in mind, we created a 3D-printed box to hold the smartphone and the RDT components (Figure 1, right). The box is designed so that the smartphone is placed upside-down along a slot on the outside so that the camera and flash within the box and the screen faces the user. At the other end of the box, there is a hole and stand for supporting the test tube that comes with the RDT. The box controls the lighting of the video recording by blocking out ambient light while the flash provides a consistent light source. Combined with the uniform background behind the tube, these features ensure visual consistency across steps. The box also controls the distance between the smartphone and the camera; the distance is short enough so that the camera can detect subtle details but far away enough to place the tube outside of the camera's focal length.

2.3 RDTCheck Application

2.3.1 Camera Setup. Before the user begins to administer their RDT, RDTCheck goes through a number of steps to ensure that the smartphone and its camera are set up properly. RDTCheck verifies that the smartphone is placed properly into the 3D-printed box by checking the smartphone's built-in accelerometer, ensuring that the average accelerometer vector is largely in the +y-direction over

 $^{^{1}} https://www.quidel.com/immunoassays/rapid-influenza-tests/quickvue-influenza-test$



Figure 2: Screenshots from the RDTCheck app at each step of the RDT administration procedure: (left-to-right) placing the phone in the box, inserting the tube in the box, adding buffer to the tube, swirling the swab in the buffer, leaving the swab in the tube, swirling the swab again, placing the strip in tube, and leaving strip in tube.

a 1-second window. Once RDTCheck detects that the smartphone is in the correct position, it utilizes the camera's auto-focus, auto-exposure, and auto-white-balance functions to identify the optimal viewing parameters within the box. Those settings are locked while the smartphone is within the box to avoid any deviations once the user begins to administer the RDT.

For each check described in the following sections, the computer vision analysis operates under the assumption that the camera is fixed and the video frames have the same frame-of-reference. Although the box restricts the smartphone's movement, the slot is not entirely restrictive since users need room to insert and remove their smartphone without damaging it. This means that the camera can exhibit slight changes in perspective, which RDTCheck remedies using image alignment. Whenever the user advances to a new step in the procedure, RDTCheck automatically saves the first video frame as a base image that represents the box's initial state. As the user completes the step, incoming video frames are aligned relative to the base image using parametric image alignment according to the enhanced correlation coefficient (ECC) similarity metric [5]. This process can be computationally expensive, so RDTCheck significantly reduces the runtime by cropping incoming video frames around a region of interest defined by the test tube and then downsampling the images to approximately 480×640 px before aligning them.

2.3.2 Inserting the Test Tube. Detecting that the test tube has been properly inserted into the box is nontrivial since the tube is clear and reflective, without any distinguishing features. An object recognition model would have been too computationally intensive relative to the other components in RDTCheck to warrant its inclusion, and parameterized edge detection was too error-prone due to the nature of the tube's edges. Instead, RDTCheck uses image subtraction to detect the tube. RDTCheck compares incoming video frames to the first video frame of this step using grayscale image subtraction. The difference between the frames is binarized using a minimum V channel difference of 10 as the threshold, and the resulting mask morphologically smoothed using opening and closing operations. In general, the binary mask is able to detect the edges of the tube more easily than the center because of the tube's curvature; therefore, we rely on the binary mask to emphasize the outer parts of the tube rather than the entire shape. RDTCheck infers the tube's

shape by calculating the minimum enclosing rectangle that holds the significant contours in the binary mask. The tube is assumed to be in the box if it passes a series of conditions: (1) the detected bounding box's height and width exceed 75% of the expected dimensions as determined by the known scale within the box, (2) the orientation of the bounding box is within 2.5° of being completely vertical, (3) the bounding boxes detected in a 1-second window have an average intersection-over-union value of 0.9, and (4) the color difference is less than 10.

2.3.3 Adding Buffer to the Tube. Similar to the previous step, RDTCheck uses image subtraction to measure the quantity of the clear buffer liquid that has been added to the test tube. Instead of computing the minimum enclosing bounding box over multiple contours, however, RDTCheck isolates the largest contour and then calculates the interquartile range (IQR) of the contour's ycoordinates to estimate the height of the buffer in the tube. This is done because the appearance of the buffer is less consistent than that of the tube and calculating the height of the minimum enclosing rectangle often results in overestimation. Adding the buffer to the tube's freeze-dried contents produces a solution that reflects light differently depending on its homogeneity. Furthermore, droplets can appear above the buffer level if the liquid trickles down the tube's walls. To avoid false positives, RDTCheck uses the intersection-over-union and color difference calculations described in the previous step to confirm the buffer is stable and clear.

2.3.4 Swirling the Nasal Swab in the Tube. One of the biggest concerns from RDT manufacturers is that people do not sufficiently agitate their nasal swab in the buffer solution, which directly correlates with how much biological material is transferred to the buffer [17]. We initially tried to use optical flow [11] to track the motion of the swab within the tube; however, the varied motion of the liquid within the tube complicated this approach. Instead, we rely on a spatial reliability tracker (CSRT) [14] to continuously track the swab's motion. The tracker is initialized by identifying large contours with V channel values above 200. The CSRT is able to use assumptions on spatial continuity to make swab tracking more accurate than continuous color detection. Frames where the swab tip is above the buffer line are ignored since they represent cases when the swab is not completely immersed in the liquid. For the remaining frames, RDTCheck estimates the speed of the swab

using the IQR of the swab's horizontal position within a 1.5-second window. The higher the IQR, the faster the swab tip is moving through the buffer and thus the more agitation that is occurring, so RDTCheck assumes that the swab is being swirled if the IQR of the window is at least 15% of the tube's width. In those cases, a progress meter is updated based on the time difference between the current timestamp and the timestamp of the last frame. The progress bar fills up when the user has swirled for a total of 4 seconds, which typically takes 5–11 cyclical motions depending on how quickly the user is moving the swab.

2.3.5 Detecting the Orientation of the Test Strip. Despite the fact that there are arrows indicating which end of the dipstick should be inserted into the tube first, some people may not notice those indicators and insert their dipstick upside down. To confirm the dipstick's orientation, RDTCheck detects an arrow near the bottom of the tube using multi-scale template matching [2]. In short, this approach entails scanning a template image of a single arrow across the video frame and computing a cross-correlation coefficient at each position; we use a minimum threshold of 0.6 (range: 0–1) to confirm the presence of an arrow in the tube. Although detecting multiple arrows would be more robust, it can only be assumed that at least one arrow will be present due to how the fiducials are printed on the dipsticks.

2.3.6 Leaving Kit Components in the Tube. Throughout the procedure, there are multiple steps during which the user is required to leave kit components in the tube for a prescribed duration. The swab is left in the tube for 1 minute to allow for additional biological material to transfer to the buffer solution, while the test strip is left in the tube for 10 minutes to allow for the strip to soak up the solution. One of the additional benefits of using a smartphone is that it can actually facilitate the swab agitation process. The 3D-printed box is light enough that the smartphone's vibration motor can shake the entire structure, thereby disturbing the tube and its contents. RDTCheck vibrates the smartphone for the first 15 seconds of the wait time to agitate the tube without annoying the user or draining their battery for too long.

For both the swab and the test strip, RDTCheck continues to use their respective detection algorithms — the white color detector for the swab and the arrow detector for the strip — to ensure that the components remain in the tube. Note that for the swab, we are able to utilize the computationally efficient color detector rather than the object tracker since the swab does not need to be tracked while the buffer liquid is moving. If the kit component in question is missing from the tube for at least 1.25 seconds, the user is warned to return the item back to the tube.

3 EVALUATION

We conducted a pilot study to quantify RDTCheck's ability to detect mistakes and successes during the RDT administration process. We also gathered preliminary feedback regarding RDTCheck's usability from our participants. In this section, we describe the study procedures and present the results of our study.

3.1 Participants and Procedure

We recruited 7 participants (4 male and 3 female) between the ages of 25 and 42 for our study. All of the participants use a smartphone on a regular basis, and none had ever administered an RDT before the study. This study was approved by the Institutional Review Board at the University of Washington, and social distancing measures were applied in response to the COVID-19 pandemic.

Each participant was given a Quidel QuickVue RDT kit, our 3Dprinted box, and a Google Pixel (12.3 MP back-facing camera) with the RDTCheck app. The app provided on-screen instructions that mirrored those found in Quidel's printed instructions when possible. Because mistakes are infrequent but important to detect, we decided against asking participants to go through the instructions to the best of their ability since it would not guarantee full testing coverage of RDTCheck. Instead, we instructed participants to follow a specific procedure in which they were told to deliberately make certain mistakes in the process and then later correct them. The list of test cases is given in Table 1. The instructions were specific enough so that people understood which actions to perform, but general enough that people would still perform those actions in their own idiosyncratic manner. RDTCheck's response to each action was recorded so that we could assess its accuracy at identifying mistakes and permitting people to continue through the RDT administration process. After each step, we also asked participants to provide feedback on RDTCheck's usability for future iterations of our design. The swirling steps were repeated multiple times for a couple of reasons: (1) the instructions that come with Quidel's QuickVue test suggest that users should swirl their swab before and after adding it to the test tube, and (2) swirling a swab has the most variation across people. We did not explicitly ask people to swirl their swab an excessive amount since more swirling is generally better; however, we did penalize situations when people swirled for more than 11 cyclical motions since those situations indicated failures in swab tracking.

3.2 Results

3.2.1 System Performance. Although there has not been any prior work that documents the frequency of different errors in RDT administration, a mistake anywhere along the procedure can lead to invalid or questionable diagnostic results. Therefore, we consider each step with equal importance for the sake of our analysis. As shown in Table 1, RDTCheck was able to achieve an average accuracy of 91.1% per step and a median accuracy of 85.7% across all steps of the study procedure. RDTCheck was particularly accurate for the steps that involved opaque kit components: the nasal swab and the test strip. One notable observation was the fact that participants had a higher success rate with the swirling steps as they repeated that task during the procedure, which indicates that participants learned how to satisfy RDTCheck's expectations on proper swabbing technique from trial and error. Participants sometimes thought they were moving the tip of the swab in the buffer solution, but they were actually only were moving the stem of the swab; the tip of the swab was stuck in place at the bottom of the tube, using it as a pivot point and thus not moving through the liquid. The lack of movement by the progress bar eventually led the participants to

Table 1: The study procedure that participants followed to emulate mistakes and successes while administering Quidel's Quick-Vue test, along with RDTCheck's success rate at detecting those cases.

Step	Test Case	Detection Success Rate
Tube in box	Tube partially inserted into the box at an angle	7/7
	Tube partially inserted into the box vertically	5/7
	Tube inserted in into the box vertically	6/7
Buffer in tube	Tube removed from the box	7/7
	Too little buffer added into the tube (75% of prescribed amount)	5/7
	Too much liquid added into the tube (125% of prescribed amount)	6/7
	Correct amount of buffer solution poured in the tube	5/7
Swirl swab in tube	Insufficient swab speed	27/28
	Swab not near the bottom of the tube	14/14
	Progressing with limited swirling (<3 cyclic motions)	14/14
	Progressing with sufficient swirling (5–11 cyclic motions)	10/14
Swab wait timer	Swab removed from the tube	7/7
	Swab returned to the tube	7/7
Strip in tube	Strip inserted into the tube upside down	7/7
	Strip inserted into the tube correctly but away from camera	6/7
	Strip inserted into the tube correctly and facing camera	6/7
Strip wait timer	Strip removed from the tube	6/7
	Strip returned to the tube	6/7
Overall		151/168

adjust their technique so that the tip of the swab moved through the buffer, which is the ideal technique for agitation.

RDTCheck was most error-prone during steps that involved clear objects (i.e., the tube and the buffer liquid). These failures could sometimes be attributed to slight movement of the smartphone or the objects themselves, which led to misaligned measurements that were not properly compensated by the periodic image alignment. In other cases, the transparency of the objects and the ways they reflected the light in the tube caused RDTCheck to miss the edges that are crucial for specifying the extent of those objects. Regardless, none of the test cases failed for more than 2 participants.

3.2.2 Usability. Most participants commented that RDTCheck was helpful in explaining the RDT administration process. Three participants (P4, P5, P7) pointed out that RDTCheck made them feel confident that they were using the RDT correctly, especially during the steps that involved the buffer and the swab. P5 remarked that RDTCheck eliminated the need for them to switch between paper instructions since the on-screen instructions became integrated with the rest of the test components. Participants did encounter some challenges while using RDTCheck. Four participants (P3, P4, P6, P7) were confused when the progress bar did not increase when they felt that they were vigorously swirling the swab. As mentioned earlier, some of these cases were due to improper swirling technique, while others were due to lapses in swab tracking. Such issues could be remedied with targeted user feedback, but some participants also recommended that we provide a video demonstration of the ideal swirling technique. Lastly, P6 noted that while having the app auto-advance was a helpful feature, they also wanted to know how far along they were in the RDT administration process.

This information is easier to glean from written instructions since people can see all the steps at once, so we intend on transferring that feature to RDTCheck.

4 DISCUSSION AND LIMITATIONS

The foremost motivation of our work was to develop a system that would correct procedural errors that are made when nonexperts administer RDTs. The results of our study demonstrate that RDTCheck is able to reliably detect and correct such errors with reasonable accuracy, and we found that supervising the administration process helps non-experts feel more confident that they are carrying out the procedure properly. RDTCheck not only provides benefits to people who are administering RDTs, but also people who oversee community testing. For example, many global health organizations rely on supervisors to manage groups of CHWs who work in the field. The supervisors periodically train their CHWs on proper CHW administration practices [9]. Once those CHWs go into the community, they can make unintentional mistakes, regress to poor habits, or take shortcuts, all which can go unchecked until the next training session. A system like RDTCheck would not only correct these mistakes at the time of RDT administration, but would also provide data that supervisors can examine to identify common mistakes that can be corrected in the next training session. In fact, RDT manufacturers could also utilize this data since common failures may compel them to improve their products.

Our current implementation of RDTCheck is not without its limitations, one of which is the fact that RDTCheck does not currently supervise users as they swab the inside of their nose. Although

collecting a sufficient biological sample is a critical step in the diagnostic accuracy of the RDT, our formative work demonstrated that it was challenging to identify proper swabbing technique without knowing how far the swab was inside the user's nostril. Getting that information requires knowing how much of the swab is outside of the nose, which can only be visually determined with a privacy-invasive video recording that includes the user's face. We plan to explore alternative sensing approaches that compare the swab before and after it has been inserted into the user's nose to determine whether the swab has a sufficient biological sample. Another limitation is the 3D-printed box we require to be used in conjunction with the RDTCheck app. The packaging of Quidel's kit comes with a cardboard cutout for holding the tube within the box, so we are hopeful that a similar modification could be made to hold a smartphone at the other end of the box. The packaging would need to be adaptable to different smartphone models, which would impose additional manufacturing costs for a product that is designed to be inexpensive. Lastly, RDTCheck is currently designed specifically for Quidel's QuickVue Influenza A+B test, but many of RDTCheck's procedural checks will generalize to other RDTs. Most dipstick-based RDTs (e.g., Crystal VC RDT² and the Pregnancy Urine Dip-Strip³) require filling a clear tube with liquid and leaving the dipstick in the tube for a prescribed amount of time. RDTCheck's nasal swab checks would also be useful for emerging COVID-19 RDTs [21].

5 CONCLUSION AND FUTURE WORK

As more and more RDTs become approved for at-home use, we argue that proactive measures need to be put into place to ensure that the RDTs are used correctly administered and that the diagnostic test results they provide are reliable. In light of that goal, we demonstrated that a smartphone app with on-device computer vision routines can be used to detect mistakes made during the RDT administration process. Motivated by these findings, we aim to conduct a usability study in which we discover critical steps where people commonly make mistakes in the RDT administration. Furthermore, we can compare people's experience with Quidel's paper instructions versus RDTCheck, where we capture both quantitative and qualitative data to measure RDTCheck's efficacy. If we achieve compelling results in that study, we hope to engage in a broader deployment to see if Quidel's QuickVue RDT can achieve comparable effective accuracy in the field relative to its observed accuracy in lab settings once paired with RDTCheck.

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²https://www.cdc.gov/cholera/crystal-vc.html

³https://www.cliawaived.com/cliawaived-inc-pregnancy-urine.html