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A Study of Automated Optical Inspection of Rapid Influenza Diagnostic Tests

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Abstract- Rapid influenza diagnostic test (RIDT) is one of the most common tools for screening patients suspected of influenza infection. The principle is to detect the surface antigen of influenza virus with known antibodies, and then to interpret it with the naked eye in the form of immune chromatographic as says. It has the advantage of obtaining speedy results (10-30 minutes) and ease of operation (which can be interpreted with the naked eye).There is a variety of rapid influenza diagnostic tests (RIDTs) available in the market, with different sensitivities and specificities depending on the design of the antibody location and reagent composition. Despite its advantages of speed and convenience, a high percentage of test results (20 to 50% or higher) do not correctly reflect the patient's status. In addition to possible misses in the specimen collection process that will affect the tests; the naked eye may not be able to distinguish the unapparent results and cause false negatives. At the same time, because a healthcare worker may not accurately grasp the time of interpretation, false positives can also occur due to excessive test times. To minimize incorrect diagnoses, we propose an interpretation system using machine vision. The system replaces the function of a healthcare worker by a camera and computer. The camera captures the image of the test piece then sent it to the computer for processing and identification; the result can provide the medical staff reference.

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Abstract- Rapid influenza diagnostic test (RIDT) is one of the most common tools for screening patients suspected of influenza infection. The principle is to detect the surface antigen of influenza virus with known antibodies, and then to interpret it with the naked eye in the form of immune chromatographic as says. It has the advantage of obtaining speedy results (10-30 minutes) and ease of operation (which can be interpreted with the naked eye).There is a variety of rapid influenza diagnostic tests (RIDTs) available in the market, with different sensitivities and specificities depending on the design of the antibody location and reagent composition. Despite its advantages of speed and convenience, a high percentage of test results (20 to 50% or higher) do not correctly reflect the patient's status. In addition to possible misses in the specimen collection process that will affect the tests; the naked eye may not be able to distinguish the unapparent results and cause false negatives. At the same time, because a healthcare worker may not accurately grasp the time of interpretation, false positives can also occur due to excessive test times. To minimize incorrect diagnoses, we propose an interpretation system using machine vision. The system replaces the function of a healthcare worker by a camera and computer. The camera captures the image of the test piece then sent it to the computer for processing and identification; the result can provide the medical staff reference.

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I. Introduction

Virus-caused influenza is one of the most severe viral respiratory infectious disease. Avian influenza of 2003 and the swine flu of 2009 have been among the cases in recent years. Once a highly contagious and lethal strain of influenza virus emerges, it often leads to a pandemic. Therefore, aside from the SARS of 2013 and COVID-19 of 2019-2020, which are also virus-caused, influenza has been the focus of international epidemic prevention and monitoring policy. Because influenza shares many symptoms with the common cold, it is often difficult for a clinician to correctly diagnose the disease in a timely fashion. The standard method for detecting influenza viruses is viral culture and molecular biology testing methods such as RT-PCR, both of which can identify subtypes. Still, both need special equipment and longer testing times. Viral culture takes at least 48 hours, RT-PCR takes 4-6 hours, so clinicians in small clinics, emergency rooms or outpatient settings cannot obtain results in a short period after the examination, resulting in incoherent diagnosis. Consequently, healthcare workers use a series of rapid influenza diagnostic tests (RIDTs) at the point of care. The principle is to detect the surface antigen of influenza virus with known antibodies, and then to interpret with the naked eye in the form of immune chromatographic as says. They are simple to execute and deliver results in less than 30 minutes. They have become an effective way to detect viruses outside the laboratory. Overall, RIDTs had a high specificity of 90-95% but only a modest sensitivity of 50-80%. Studies show the performance of RIDTs depends on the prevalence of influenza virus in the population [1,2]. A study points out RIDTs with a sensitivity of 62.3% compared to the RT-PCR method [3].In the study, RIDTs performed better in influenza A virus detection.64.6% sensitivity in influenza A compare to 52.2% in influenza B. During the 2009 H1N1 pandemic, RIDTs showed 10%-70% sensitivity compared to RT-PCR-based tests [4-7].Drexler et al. used the BinaxNOW rapid antigen-based testing, reported a sensitivity of 11.1% [8].In the early days of the pandemic, a large study from New York used the RIDTs BinaxNOW influenza A-B test (BinaxNOW), 3M Rapid Detection Flu A-B test (3MA+B) compared to R-Mix culture [9,10] with a sensitivity of 9.6% and 40% respectively. Poor sample quality and inexperience of medical staff may contribute to the low sensitivity. These researches indicate many factor scan affect the sensitivity of RIDTs. It is low in numerous cases, so this study proposes a system to improve detection sensitivity, minimize the human influence, increase efficiency and reduce the demand for screening work force.

II. Problem Statement

Figure 1 illustrates the procedures for taking an RIDT: (a) Collect the patient's nasopharyngeal specimen through a swap, b. Flush it in a solvent provided by the manufacturer, c. Suck up the fluid using a pipette, then drop it to a specified place on the test pad.

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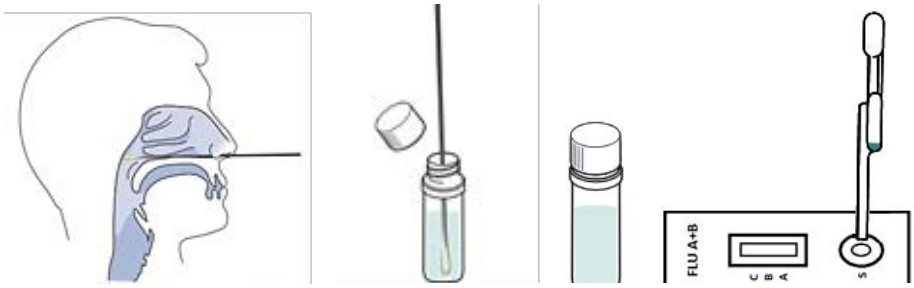
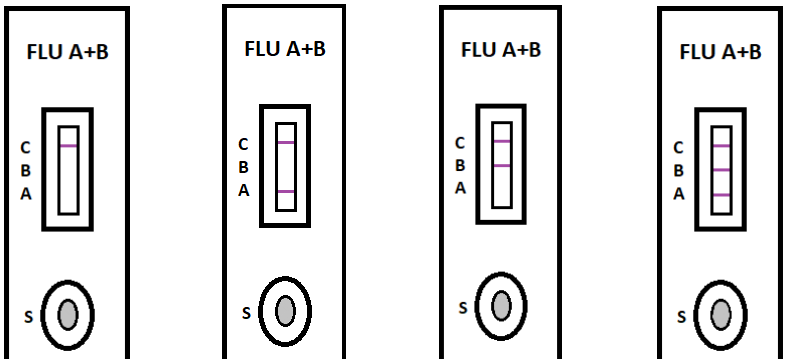


(a) (b) (c)

Figure 1: Procedures for Taking a Rapid Influenza Diagnosis Test

After 15 minutes at room temperature, determine whether there is influenza and influenza type (A or B) based on the stripes displayed on the pad, as shown in Figure 2, provided that the control line appears at the same time. If the control line at C does not appear, it is an invalid detection, repeat the test until a control line shows up.



(a) Negative (b) Type A (c) Type B (d) Type A+B

Figure 2: Test Results

The test procedure requires the healthcare worker to make a diagnosis if a stripe, no matter how faint it is, appears at the designated position as long as the control line is also visible. In clinical practice, however, there may be cases too vague for the human to make a definite judgment. Figure 3 displays some examples with faint stripes. Even if one makes a diagnosis, it is nearly impossible to be consistent. This can explain the high false positives during the peak of the influenza season and high false negatives during the low season.

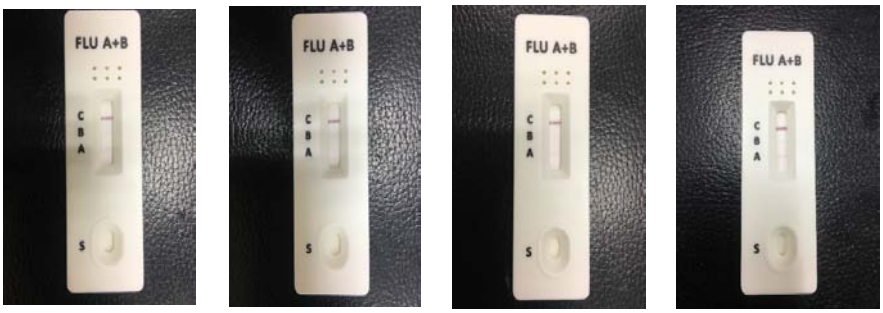


Figure 3: Some test examples with faint stripes

This study applies machine vision technology to develop an automatic interpretation system for RIDTs to assist healthcare workers in the conduct of influenza virus testing, improve the correctness and efficiency, save workforce, and reduce the risk of misjudgment. Other medical tests currently dependent on the naked eye can also implement similar techniques.

III. Hardware Setup

A typical optical inspection system includes a camera, a computer, a light source, and other necessary mechanical and electrical components. Figure 4depicts a CAD model of the one for RIDT. Figure 5(a) shows the actual mechanism. A groove is

cut in the bedplate to contain the test specimen, as shown in Figure 5(b). Figure 5(c) shows the optical apparatuses in a position to capture the specimen image. The device connects with a computer.

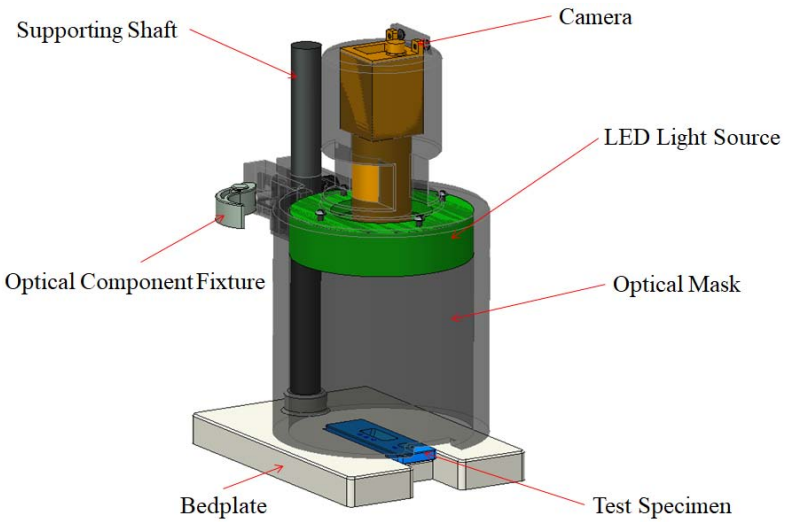


Figure 4: A CAD model of the RIDT inspection system

(a) (b) (c)

Figure 5: The developed RIDT inspection system

IV. Image Processing

The captured image, shown in Figure 6, is transmitted to the computer, which analyzes the stripes of the test specimen. The following subsections discuss the image processing techniques employed by the computer program.

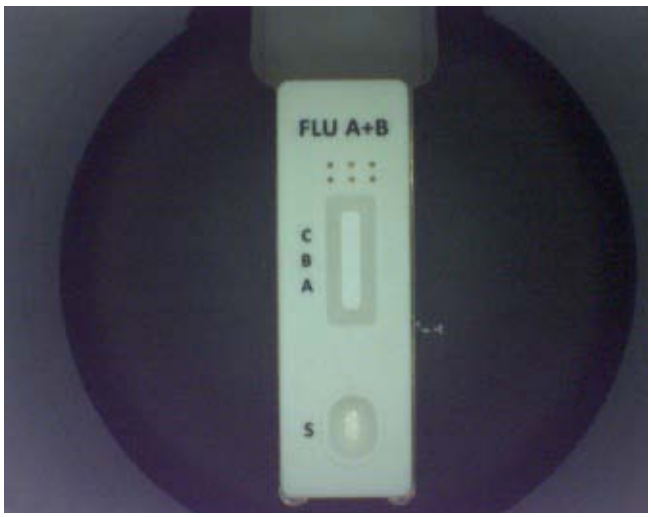
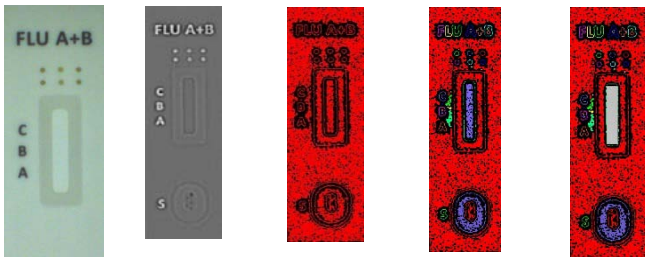


Figure 6: The captured image of a test specimen

a) Image Pre-Processing

First, the test pad and the area showing the test lines are identified by image pre-processing. The specimen is overall much brighter than its background. The program separates them by a binary threshold, Figure 7(a). To find the region where the test lines may appear, the image is then processed by the Laplace-of-Gaussian (LoG) operator, Figure 7(b). The edges of possible features are found by the zero-crossing operation, Figure 7(c).The components are joined by the connection operation, Figure 7(d). The software finds the test region by selecting the one with the rectangularity between 0.9 and 1, and an area larger than 5000 pixels, Figure 7(e).

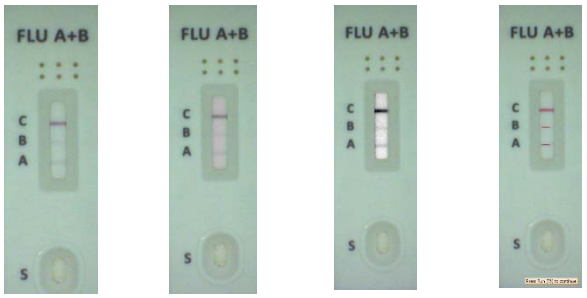


(a) (b) (c) (d) (e)

Figure 7: Image pre-processing of the test specimen

b) Identification of Diagnosis Line

The camera takes the image of the test specimen every minute. The suggested time for RIDTs inspection is 15 minutes. Figure 8(a) is the image taken after 15 minutes. The test region is identical to the previous step, as shown in Figure 8(b).The gray value is then spread from 0 to 255 to enhance the image. Figure 8(c) portrays the enhanced image. The program identifies lines on the image by using partial derivatives of a Gaussian smoothing kernel; and shows the extracted lines in red, as in Figure 8(d).



(a) (b) (c) (d)

Figure 8: Specimen Image Processing after 15 minutes

c) Gray-value Calculation

The program also calculates the gray changes of the test region. It averages the values of each row in the test region, and subtracts the initial numbers from those of later times. Significant changes in gray value indicate test lines, as illustrated in Figure 9. The horizontal axis represents the row position of the test region, as 0 being the top-most row. The vertical axis denotes the difference of gray values between the initial specimen and the specimen after 15 minutes. Three peaks appear in positions that correspond to the three stripes.

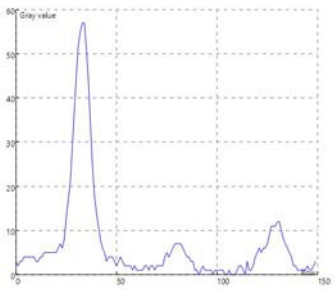
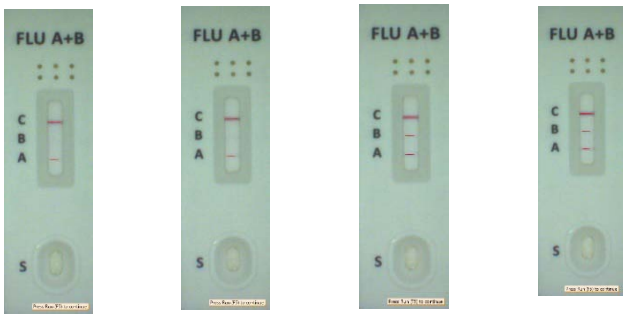


Figure 9: Gray value variations of the test specimen after 15 minutes

From Figures 8 and 9, healthcare workers can easily see the test results. The program can also provide the identification result of the specimen at any specified time. Figure 10 shows the results at (a) 5 minute, (b) 10 minute, (c) 15 minute and (d) 20 minute.



(a) 5 minute (b) 10 minute (c) 15 minute (d) 20 minute

Figure 10: Specimen identification results at different times

The identification results can then be stored and analyzed. Figure 11 shows the changes in gray values from 1to 20 minutes at A, B, and C positions, respectively. It can provide a basis for accessing the test results.

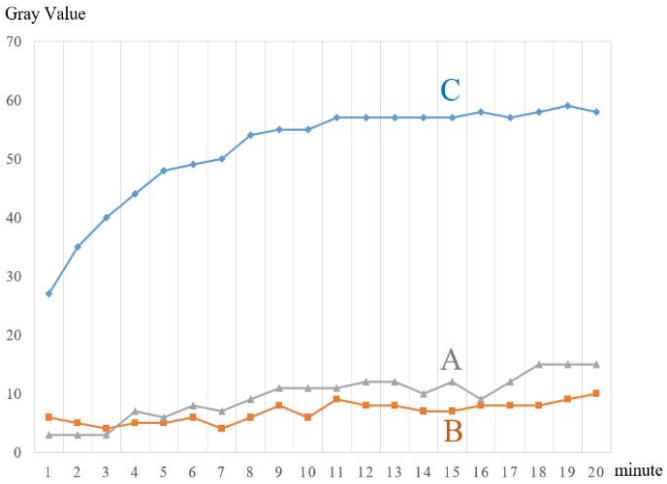


Figure 11: Gray value changes along time at A, B and C line positions

V. Conclusion

This research studies the implantation of optical inspection in RIDTs and development of a working system. The experimental results show that it can provide useful assistance to the healthcare workers. With more clinical cases, its consistency and sensitivity can be examined. One may also extend the method to similar rapid tests in medical practices, e.g., COVID-19 diagnosis tests. A proper application of optical inspection techniques will reduce the medical staff's workload and possible human errors, in the meantime, increase test sensitivity and consistency.

Acknowledgment

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