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A smartphone-based calibration-free portable urinalysis device

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Abstract: As one of the most common medical diagnosis methods, urinalysis is a highly demanded technique for screening tests or daily monitoring of various diseases. With the rapid development of POC (point-of-care) systems, a convenient house-using urinalysis device is widely needed. However, considering the difference of onboard systems and multiple test indicators in urinalysis, the design of such an intelligent device is still challenging. In this paper, a smartphone-based portable urinalysis system has been developed and applied for the colorimetric analysis of routine urine examination indices using an Android app. By integrating the test paper sensor in the portable device for urinalysis, our system significantly improves the instability of conventional dipstick-based manual colorimetry, and the smartphone application used for color discrimination enhances the accuracy of the visual assessment of sample strips. Using a simple operation approach that takes ~ 2 min per test, our system can be applied as rapid urinalysis for routine check-ups.

Key words: urinalysis device; colorimetry; diagnostic imaging; point-of-care; smartphone

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1 Introduction

According to cases recorded in 2017, 9.1% of the world's population is affected by kidney disease, and this number is becoming even higher in developing countries such as China [1]. Kidney disease has continued to rise in rank among leading causes of death for decades due to aging problems and the increasing risk factors of diabetes and hypertension [2]. Through early testing of some indicators (e. g., serum creatinine [3], urine album [4], etc.), kidney diseases can be prevented or alleviated to some extent. Therefore, early diagnosis and monitoring are of great significance to patients. As one of the most common medical diagnosis methods, urinalysis is a highly demanded screening test or daily monitoring for various diseases, including kidney disease [5]. Nowadays, new urinalysis technologies emerge continuously and develop rapidly, including physical properties tests, dipstick urinalysis, microscopic urinalysis, etc. [6]. Among these technologies, dipstick urinalysis is regarded as a non-invasive and rapid colorimetric test technology. Compared with the urinalysis instruments in hospitals, the dipstick urinalysis is portable, easy to use, and inexpensive, which makes it widely adopted as a routine program for physical examination [7]. However, traditional dipstick urinalysis is observed with naked eyes and judged by patients [8]. It would be unreliable and inefficient as it takes time for patients to read and

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verify the results, especially for the visually disabled. In addition, considering the different test environments which the patient is in, both the lighting conditions and psychological factors may cause incorrect results of colorimetric [9].

With the improvement of health awareness, point-of-care (POC) systems have attracted increasing attention in the healthcare industry, owing to its ability to perform routine daily examinations at home for disease prevention and monitoring [10−14]. Smartphones have a great alternative for image acquisition, result analysis, and communication in real-time, making them be the popular platform for POC systems [15, 16]. To date, many urinalysis POC devices have been developed to increase the consistency and accuracy of various types of colorimetric tests, including dipstick urinalysis [17−20]. For instance, COSKUN et al [21] demonstrated a urine albumin detection platform running on a smartphone that images and automatic analysis of fluorescence detection. LAI et al [22] designed a device that uses gold nanoparticle colorimetry to determine the content of human serum albumin in artificial urine samples. JALAL et al [23] developed a smartphone-based optical platform and a disposable paper-plastic hybrid microfluidic lab-on-a-chip device for the colorimetric measurement of urine. However, these devices remain challenging for daily urine testing; one crucial difficulty is that they can only measure a specific parameter, or they need to be specifically designed and recalibrated for users with different brands of smartphones [24, 25]. For patients who need to undergo daily urine tests, it is vital to grasp more comprehensive health information under different usage environments. As far as we know, little progress has been made in the study of solving the problem of mismatching different brands of smartphones and accurately measuring multiple urine examination indices on a single test paper. Developing an accurate smartphone-based urinalysis system that can be adapted to various smartphones and measurement environments is of great significance.

In this study, we report a smartphone-based urinalysis POC device that can rapidly acquire test results and greatly reduce the difficulty of operations in conventional urinalysis. Based on the utilized real-time colorimetric algorithm and the miniaturized design of detection components, the designed urine analysis device is portable, reliable, and user-friendly. Our device exhibits many superior functionalities such as convenient operation, fast colorimetry (only a few seconds after inserting the test paper), versatility to different smartphones, measurement environments, and high accuracy (only 7.6% accuracy error). We believe that the smartphone-based portable urinalysis system constructed in this study makes it possible to conduct comprehensive and accurate home urine tests, helping to promote the initial screening and daily monitoring of patients with kidney diseases.

2 Design of urinalysis system

2.1 Design of detection device

We design the portable detection device by following some basic requirements, including a stable light source and appropriate detection equipment layout. First, for the portable urinalysis device, a favorable environment with a stabilized light source is needed for the measurement to increase the accuracy of the obtained RGB data sets. When the light source is unstable, the illumination will vary on the test paper, which will affect the RGB value of the sample and is prone to error in color measuring [26]. Second, the scattering of the internal housing surface should be minimized during the measurement process [27]. The detection box is composed of 54 mm×54 mm×76.5 mm (width×length×height) 3D printed box, two pieces of LED (light-emitting diode), light bars (3 diodes in 1 part), a GP 12 V A23 battery, a 12 V battery holder, and a push-button switch (Figure 1).

A hole with diameter of 6 mm was reserved for CMOS (complementary metal oxide semiconductor) chip or the smartphone camera. This design ensures

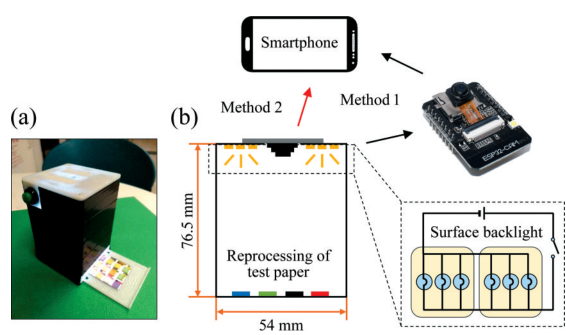


Figure 1 Portable urinalysis system: (a) Shell of urinalysis device; (b) Internal structure of shell

an enclosed environment and stable light source during the entire measurement process. In addition, a slot is reserved for detecting the prepared test paper (the detailed design process is in Section 2.2) with urine. The users only need to insert the sampled test paper into the pre-designed slot and operate it on the smartphone to complete the measurement.

2.2 Test paper

Traditional colorimetric test strips are mostly long strips in shape, which increases the difficulty of imaging with high quality in a single shoot [28]. Minimizing the size of the test strip in a single photo is not only conducive to the rapid detection of multiple indices but also conducive to the portability of the POC device. A mini-size test paper can be easily carried anywhere, and a urinalysis test can be conducted in different locations. In our study, we select Medi-test Combi 11 urinalysis test strip (Macherey-Nagel Company) and redesign a new square test paper. The new test paper contains both the test zone and the reference color zone and can test 11 indicators, including bilirubin (Bi), protein (Pro), nitrite (Nit), ketone (Ket), leukocytes (Leuk), glucose (Glu), urobilinogen (Ur), pH, density (Den), ascorbic acid (Aa), and blood (Bl). As shown in Figure 2, the test paper is divided into multiple squares according to the designed location to fit the device's size. The area of the test paper is 30 mm× 30 mm, which is square instead of a long strip, benefiting the image capturing process. To match with the base of the urinalysis box, the top-right corner of the test paper is designed as a trapezoid. It helps to fix the position of the test paper when the user is operating the urinalysis device. A configuration that minimizes the distance between the reference zone and test zone will approximate the lighting conditions of the two areas and improve accuracy. As for the positioning of the test paper after insertion, the black square spot on the top-right corner can help to align and adjust the position of the test paper in the camera. The black square spot has a fixed length of the side and helps to align the position of the test paper in the camera. Thus, the number of black pixels at this spot is related to the actual size of the black spot. We carefully arrange our reference zone and test zone so that the locating of each zone can be calculated by the number of pixels. Under such arrangement, no matter which brand of smartphone is selected for testing, the positioning is based on the actual number of pixels of the black point, rather than the camera's hardware (resolution, lens focal length). The optimized test paper ensures the portable size of the device, realizes the approximation of the lighting conditions, and avoids the shooting error caused by the uncoordinated size ratio.

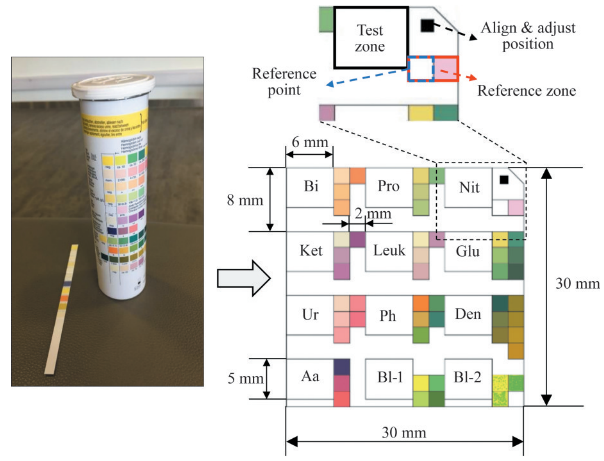


Figure 2 Schematic illustration of the design of the test paper (In the re-designed test paper, the black square is used to align/adjust the position. It can detect 11 indicators, including bilirubin (Bi), protein (Pro), nitrite (Nit), ketone (Ket), leukocytes (Leuk), glucose (Glu), urobilinogen (Ur), pH, density (Den), ascorbic acid (Aa), and blood (Bl). Each indicator's test region contains a test zone of 6 mm×5 mm and multiple reference zones of 2 mm×2 mm)

2.3 Recognition algorithm

The development of the recognition algorithm is conducted on Eclipse, which is an integrated development environment (IDE) mainly for Java. The simulations are run on MacBook Pro (13-inch 2017), and they are performed on Eclipse before implementing into a smartphone application. First, a database with the coordinate of the test zone and reference points is built, which is used to match the recognized RGB values. The database included the coordinate of the test zone and reference points on the test strip. The standard set of coordinates was based on the figure shown below. The coordinate had to be changed based on the size of the photo taken. The sizes of the photo are 1200×1600 for testing the housing without ESP32-CAM, while the sizes for testing the housing with ESP32-CAM are

1600×1200. The corresponding meanings of the RGB value were also listed in the database. The extraction of RGB values is conducted by the built-in function of Eclipse, i. e., "getRGB(x, y)". It is used to extract the pixel value of the specified coordinate on the image. "(p>>16) & 0xff", "(p>> 8) & 0xff" and "p & 0xff" are used to separate the pixel value to get R/G/B value respectively. And the coordinate used in "getRGB()" was referring to the database. Here, the half-cut method is used to match the recognized data of the test zone. It adopts the concept of "round-off" in this method, and the cut-off interval is determined by the mean of the RGB values of two adjacent reference points, which can be expressed as:

$$P_n^{\text{cut-off}}(R,G,B) = \frac{P_n^{\text{ref}}(R,G,B) + P_{n+1}^{\text{ref}}(R,G,B)}{2} \quad (1)$$

where $P_n^{\text{cut-off}}(R,G,B)$ is the vector with one row and three columns made up of the cut-off point n's RGB values; $P_n^{\text{ref}}(R,G,B)$ and $P_{n+1}^{\text{ref}}(R,G,B)$ express the RGB values of reference point n and reference point n+1, respectively. After the determination of the cut-off point, we can set the RGB range for each chemical concentration. The range would be determined according to the RGB value of the previous point and the next point. Specifically, for the first reference point,

$$P_X(R,G,B) \leqslant RP_X \leqslant P_{X+1}(R,G,B) \quad (2)$$

where RP_X is the covered range of reference point X; $P_X(R,G,B)$ and $P_{X+1}(R,G,B)$ are respectively the RGB values of point X and point X+1. And for the last reference point, the covered range of point X can be expressed as:

$$P_{X-1}(R,G,B) \leqslant RP_X \leqslant P_X(R,G,B) \quad (3)$$

For the reference points, which are not the first one and the last one, the covered range of point X is presented as:

$$P_{X-1}(R,G,B) \leqslant RP_X \leqslant P_{X+1}(R,G,B) \quad (4)$$

In the calculation, the values of red, green, blue are calculated separately and stored in a matrix (n*4). A range is set for each concentration of the chemicals. When the R/G/B value was within the range of the specific concentration, one mark would be given to that concentration. This score is used for matching the most suitable reference point.

3 Operational protocol and detection principle

The smartphone-based urinalysis device is designed as a POC device with simple operation. As shown in Figure 3, after collecting the urine sample on the test paper, the patients only need to insert the test paper into the paper slot and turn on the system's switch.

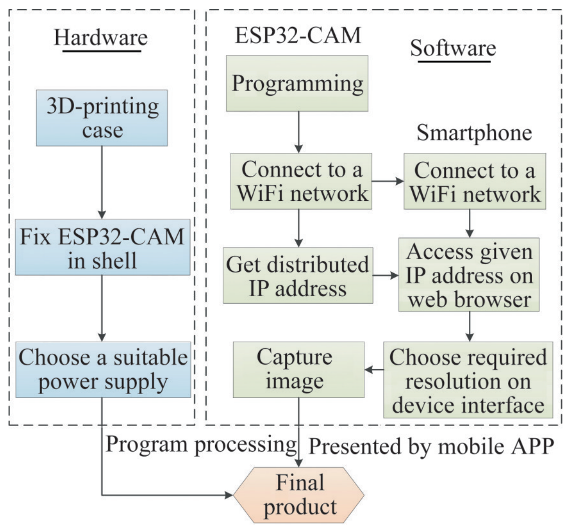


Figure 3 Flowchart of operational protocol of urinalysis system

Next, the test paper to be detected was uniformly illuminated by the built-in LED light source, and the RGB image is captured by a CMOS camera for further analysis. Lastly, the software program will perform sample analysis according to the designed colorimetric algorithm: 1) it aligns and adjusts the test paper position according to the pre-designed black square spot; and 2) it compares the RGB values of the target zones and reference zones to classify the results.

As shown in Figure 4, through the control of the ESP32-CAM motherboard, the data of the target zone together with the reference zone can be transferred via the Bluetooth module to the smartphone application. The collected RGB data for both target zone and reference zone are stored in the smartphone and further analyzed by a recognition algorithm. Lastly, the urine test report is presented on the screen of the smartphone. The entire experiment takes about 2 min from sampling to the results from the smartphone application. After further comparison with the hospital's clinical test

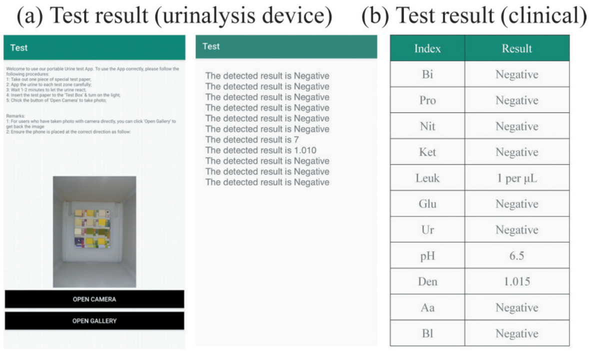


Figure 4 (a) The developed smartphone application for Android software with the proposed method: capturing the image and displaying the test results of the urinalysis device; (b) Standard clinical test results (for comparison)

results, they are found to be basically consistent with the test results of our urinalysis device.

4 Results and discussion

4.1 Comparison of light source

A stable and uniform lighting environment is essential for all kinds of colorimetric tests. For manual and machine vision colorimetric tests, any slight changes in illumination may affect the final results. Considering the influence of ambient light, we design a fully shading black box with a built-in light source to block the ambient light. The black opaque box eliminates changes in ambient lighting conditions, thereby providing a calibration-free platform for capturing sample images. To validate the effectiveness of the design, we conduct a large number of repeated test experiments on each index in the test paper and analyze the relative percent range in the captured RGB value:

$$\sigma_{\text{error}} = \frac{V_{\text{max}} - V_{\text{min}}}{V_{\text{mean}}} \times 100\% \tag{5}$$

where σ_{error} is the precision percentage error; V_{max}, V_{min}, and V_{mean} are respectively the maximum value, minimum value, and mean value.

Comparisons are made between the RGB values of the images captured by the same camera. As shown in Figure 5, for the test carried out in the housing of the designed box, the relative percentage range of most test regions was much smaller than the relative percentage range under the random ambient illumination outside the box. The overall relative percentage range of the device with housing was 7.6%, while that of without housing was 26.9%. This result proves that our design can effectively eliminate the influence of illumination on measurement in different environments.

4.2 Smartphone-based urinalysis

Although the smartphone-based device has some shortcomings such as illumination, distance, and different CMOS chips, they are considered an essential part of the next generation of POC devices that integrates data collection, communication, and calculation. Therefore, it will be necessary to introduce the design of a smartphone-based urinalysis device into our urinalysis system. To demonstrate the effectiveness, we conduct the experiments to compare the measurement results when using the built-in camera (ESP32-CAM) and the smartphones. As illustrated in Figure 6, the RGB values of all the 11 urine analysis indices are collected by a smartphone camera (Nokia 8) and compared with the device with a built-in camera (ESP32-CAM). According to the result, when the smartphone camera is applied, the relative percentage error is basically the same as that of a built-in camera with a housing box. When replacing the ESP32-CAM with the smartphone camera, the overall relative percentage error increased from 7.6% to 11.5%, which is acceptable for a POC urinalysis system. Therefore, these results further prove the stability of our system.

In view of the problem that different smartphones require specialized calibration before testing, we specially design the test paper and colorimetric algorithm. Because the designed detection box has a fixed height and stable light source, the influence of illumination and imaging distance can be eliminated. In addition, we combine the reference zone and the test zone on the same test paper so that the entire colorimetric process is under the same conditions, eliminating the errors that may be caused by different brands of smartphones. To illustrate that, we compare the analysis results of photos taken by three types of smartphones (iPhone 12, HUAWEI Enjoy20 SE, and Mi 8) based on the same urine test data. As shown in Figure 7, their test results are basically consistent. The identification method used in this device is compatible with different types of smartphones, which further promotes its widespread popularity in future use.

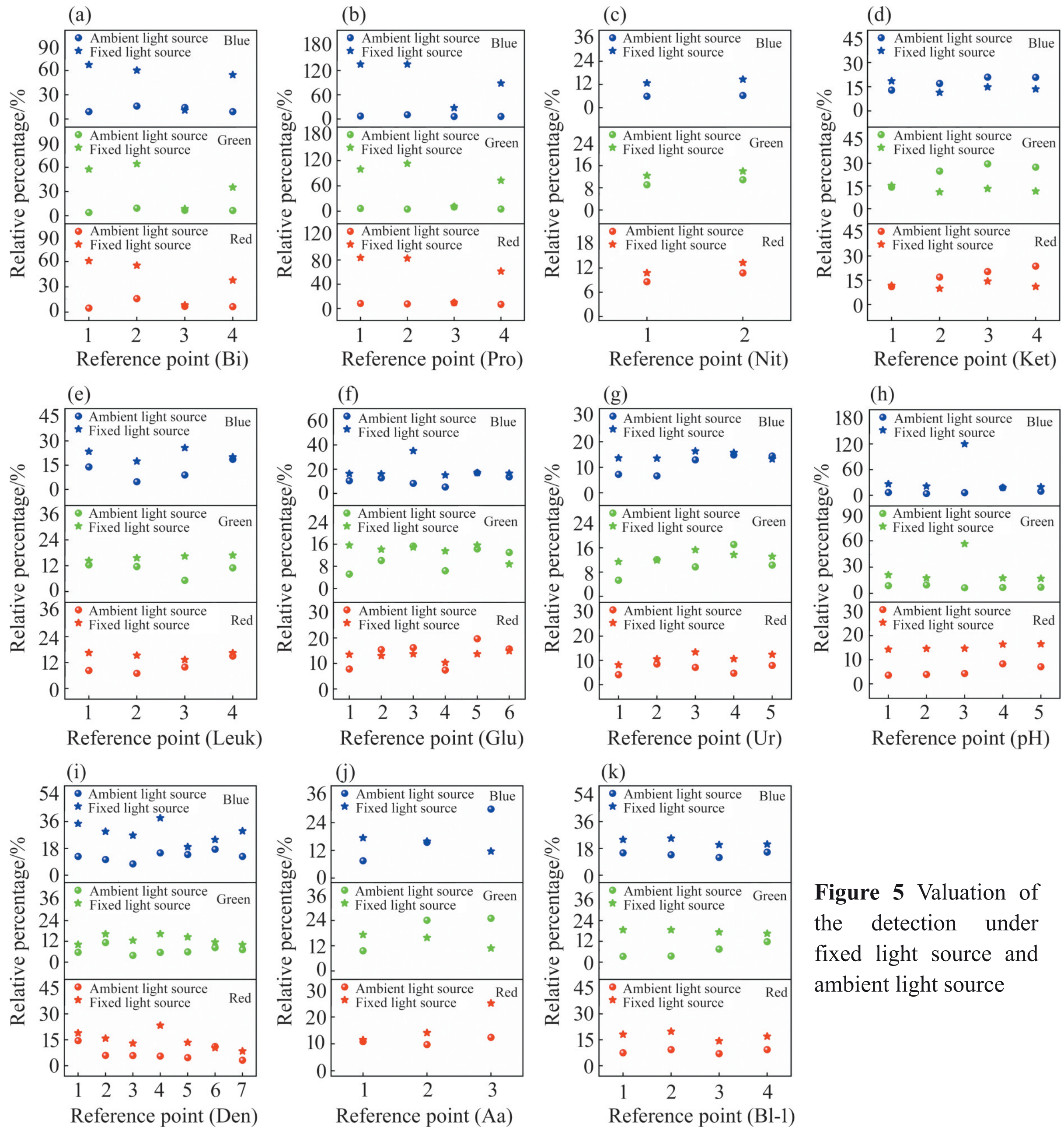
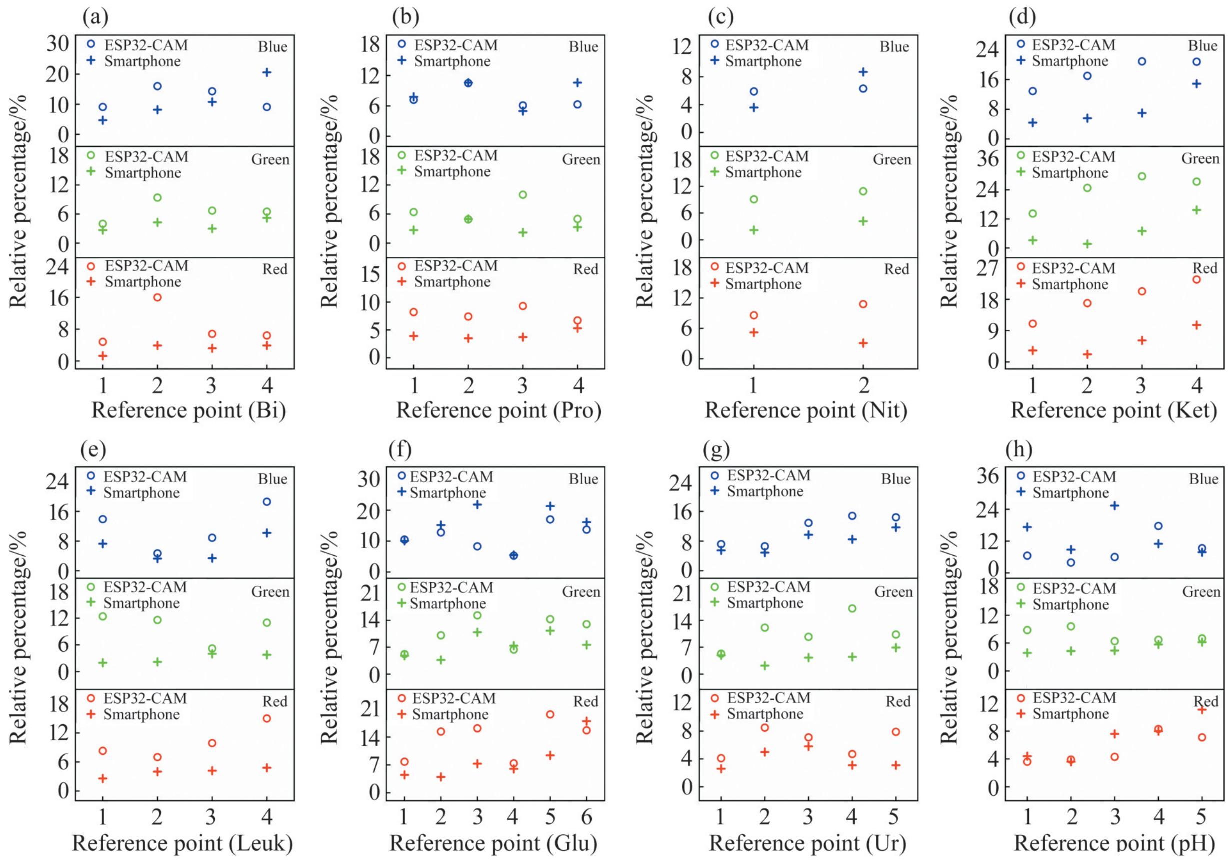


Figure 5 Valuation of the detection under fixed light source and ambient light source

5 Conclusions

A smartphone-based calibration-free urinalysis system with a unique test paper designed and a colorimetric detection algorithm has been proposed for the self-service urine test at home or a low-resource area. The simplicity and robustness of the proposed test paper and algorithm will benefit the development of the next generation of smartphone-based POC devices. The urinalysis system successfully demonstrated accurate real-time colorimetric detection and convenient operation, thereby enhancing the accuracy and reducing the difficulty of operation and measurement variability inherent in conventional urinalysis. The utilization of the smartphone application as a data collector and processor made the system more convenient and reliable. Further, we also design a smartphone-based version and solve some inherent problems of traditional smartphone POC devices, such as the difference in imaging results caused by the difference in smartphone hardware. The experimental results demonstrate that the proposed system can accurately perform measurement regardless of whether the built-in camera or the



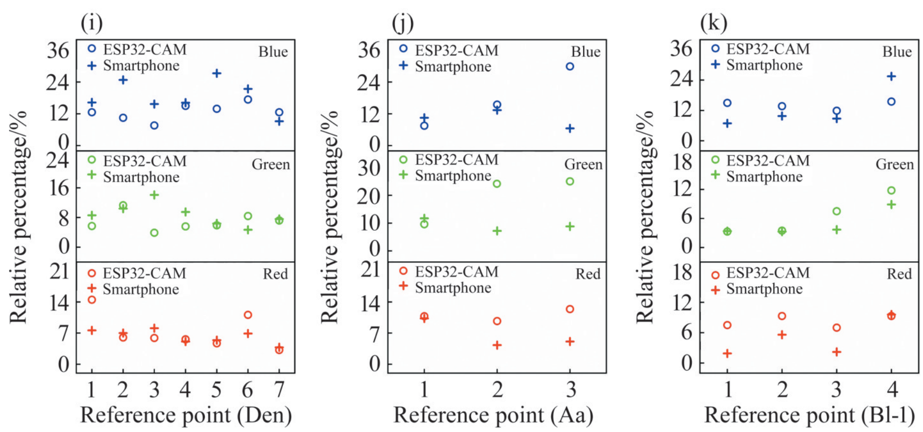


Figure 6 Evaluation of the detection based on ESP32-CAM and smartphone

Test result (urinalysis device)

iPhone 12

Index	Result
Bi	Negative
Pro	Negative
Nit	Negative
Ket	Negative
Leuk	Negative
Glu	Negative
Ur	Negative
pH	7
Den	1.010
Aa	Negative
Bl	Negative

HUAWEI Enjoy20 SE

Index	Result
Bi	Negative
Pro	Negative
Nit	Negative
Ket	Negative
Leuk	Negative
Glu	Negative
Ur	Negative
pH	7
Den	1.005
Aa	Negative
Bl	Negative

Mi 8

Index	Result
Bi	Negative
Pro	Negative
Nit	Negative
Ket	Negative
Leuk	Negative
Glu	Negative
Ur	Negative
pH	7
Den	1.010
Aa	Negative
Bl	Negative

Figure 7 Evaluation of the detection based on ESP32-CAM and smartphone

smartphone is used for detection. These advantages make our device suitable for the early screening test and daily self-monitoring. Meanwhile, it is acknowledged that compared with the traditional urine test in the hospital, the test-paper-based device has less precision than the sophisticated urine testing equipment. However, for daily home testing, the proposed device has possessed sufficient accuracy, which is used to give a rough qualitative assessment. In addition, the development of this device is still in a primary stage; in future work, we will carry out more tests to ensure that it has enough accuracy and stability to serve as the universal household equipment. We will also try to improve the design and pay more attention to the user experience, such as how to deal with the residual taste after multiple tests, etc. Overall, this study, to a certain extent, sheds new light on overcoming the existing limitations and more general POC applications in colorimetric detections fields, including but not limited to food safety detection, water quality monitoring, and virus detection.

Contributors

GUO Dong and SHEN Ya-jing provided the concept. GUO Dong and LI Gen conducted the literature review and wrote the first draft of the manuscript. GUO Dong and MIAO Jia-qi analyzed the measured data. All authors replied to reviewers' comments and revised the final version.

Conflict of interest

GUO Dong, LI Gen, MIAO Jia-qi, and SHEN Ya-jing declare that they have no conflict of interest.

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中文导读

基于智能手机的免校准便携式尿液分析设备

摘要：作为最常见的医学诊断方法，尿液分析是一种用于筛查测试或日常监测各种疾病的高需求技术。随着POC (point-of-care) 即时医疗系统的快速发展，人们广泛需要一种方便的家用尿液分析设备。然而，考虑到机载系统的差异以及尿液分析中的多项测试指标，这样智能设备的设计仍然具有挑战性。在本文中，开发了一种基于智能手机的便携式尿液分析系统，并将其应用于Android程序进行尿液常规检查中的指标比色分析。通过在便携式尿液分析设备中集成试纸传感器，我们的系统显着改善了传统基于试纸的手动比色法的不稳定性，用于颜色辨别的智能手机应用程序提高了样品条视觉评估的准确性。以简单的操作方法和每次约2 min的测试，我们的系统可应用于尿液的常规检查和快速分析。

关键词：尿液分析装置；比色法；诊断成像；即时医疗；智能手机