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ABSTRACT

Point-of-care (POC) analysis has become a crucial method for delivering fast and convenient medical diagnostics. The use of smartphone-based solutions further enhances the accessibility and convenience of POC, facilitating efficient analysis on the go. Integrating smartphone technology with POC has led to innovative applications like the Vivoo App, which enables users to conveniently monitor various health parameters. Our research aimed to confirm the accuracy and dependability of the Vivoo mobile application for urinalysis, using a comparative approach. We compared artificial urine samples analyzed through both the Vivoo app and traditional laboratory methods, assessing a wide range of health parameters. Throughout the study, we evaluated a total of 2618 strips using Vivoo. The results showed that these strips consistently matched the expected measurement results. Moreover, when we applied a ± 1 color block acceptance criterion, 2608 out of 2618 measurements from the tested strips aligned perfectly with the expected results. Based on these findings, the 95% confidence interval for the exact match agreement proportion of Vivoo falls within $87.55\% \pm 1.27\%$ and $99.62\% \pm 0.24\%$. Consequently, our study concludes that Vivoo is a reliable and high-performing device for wellness purposes. Its ability to provide precise and timely health insights holds great promise for improving individual health management, particularly in the context of smartphones' growing role in modern healthcare.

INTRODUCTION

Point-of-care (POC) analysis is a testing approach that enables immediate examination of medical samples right at the treatment site, bypassing the need for conventional laboratory assessments (1). This method presents numerous advantages, such as quick results, cost savings, and enhanced patient outcomes (2). Recently, a noteworthy trend in POC analysis is the adoption of smartphone-based technology for diagnostic purposes, including urine analysis (3). Point-of-care technology delivers pertinent data right where treatment is administered, streamlining clinical decisions.

Urine analysis is a widely used diagnostic test in clinical practice, offering valuable insights into kidney function, urinary tract infections, and other medical conditions (4, 5). Traditional urine analysis entails laboratory-based tests, which can be both time-consuming and costly. In contrast, smartphone-based urine analysis provides a rapid and cost-efficient alternative, usually involving a disposable test strip dipped into a urine sample (6, 7). A smartphone app displays the test results visually, aiding healthcare professionals in diagnosing and treating various diseases, medical conditions, and overall health (8, 9).

This study focuses on assessing the reliability of smartphone-based POC urinalysis, specifically by employing AI and ML algorithms to analyze test outcomes. Its objective is to confirm the precision of the Vivoo urine analysis platform in measuring diverse chemical components on its test strip. Artificial urine solutions were utilized for this purpose. The integration of AI and image processing algorithms in POC urinalysis holds promise for enhancing diagnostic accuracy, speed, and accessibility, potentially making it more affordable for patients.

METHODS AND MATERIALS

1. Strip Detection and Positioning

- An object detection model used to locate the Vivoo test strip and its sensors.
- Strip positioned using box references. Strip position, distance, movement, perspective, and lighting conditions were checked.
- Ensured proper strip perspective and consistent lighting conditions.

2. Color Correction

- Color correction performed by comparing extracted reference colors with original printed reference colors.
- Root Polynomial Regression were used for color correction.

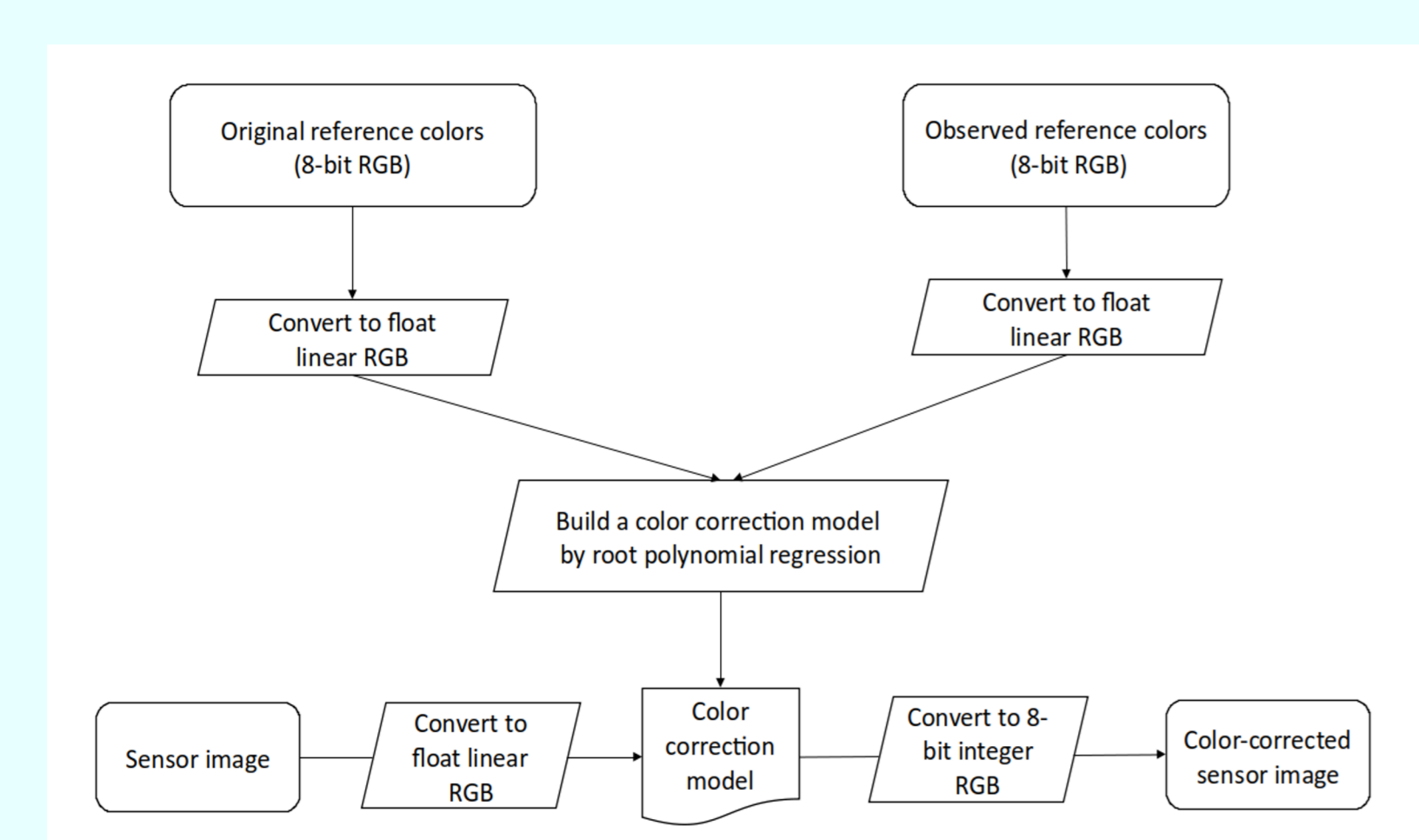


Figure 1: Color correction functioning in the Vivoo App.

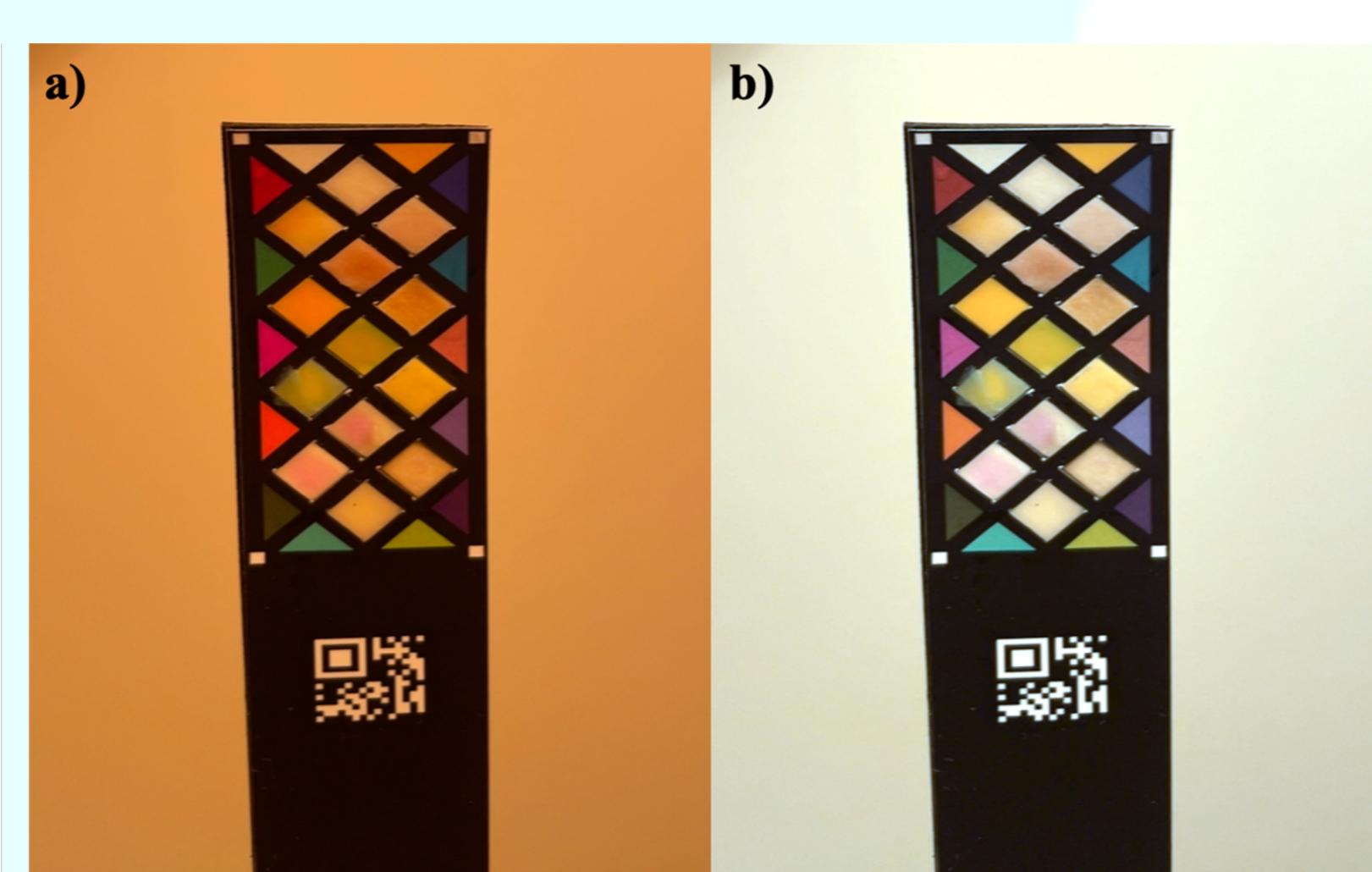


Figure 2: Color correction. (a) The detected Vivoo urine test strip, (b) the Vivoo urine test strip after color correction.

3. Sensor Value Prediction

- Sensor models were developed for each sensor using Convolutional Neural Networks.
- Models were trained with lab images from established urine samples.
- Models automatically learned key features for differentiating sensor values.

4. Vivoo App Validation

- Analytical validation of Vivoo App were performed using artificial urine samples.
- Different factors were used during analysis such as ambient light, image resolution, and shading.

5. Preparation and Verification of Urine Solutions

- Artificial urine solutions were prepared for validation experiments.
- Artificial urine solutions were verified using appropriate analytical methods.

6. Experimental Procedure and Statistical Analysis

- Artificial urine solutions are used to test Vivoo App accuracy.
- Multiple replicates were conducted for each test.
- All results saved in a datasheet and statistical analysis using IBM SPSS Statistics Version 26.

RESULTS

In our study, our goal was to confirm the precision of Vivoo urine analysis app in measuring 13 distinct chemical components present on its test strip. To assess accuracy, artificial urine solutions were employed to evaluate Vivoo performance in measuring bilirubin, ketones, leukocytes, nitrites, pH, specific gravity, protein, magnesium, sodium, calcium, creatinine, vitamin C, and MDA. The results conclusively demonstrate Vivoo capacity to deliver precise measurements for all tested chemical components.

Table 1. Confidence intervals results of Vivoo App.

Chemical Component	test variable	frequency	n	proportion	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound	Standard Error of the Estimate	±
Total	True/False (Exact Match)	2292	2618	87.55 %	86.28 %	88.81 %	0.65 %	1.27 %
	True/False (± 1 Color Block)	2608	2618	99.62 %	99.38 %	99.85 %	0.12 %	0.24 %
Bilirubin	True/False (Exact Match)	188	200	94.00 %	90.71 %	97.29 %	1.68 %	3.29 %
Ketone	True/False (Exact Match)	169	200	84.50 %	79.48 %	89.52 %	2.56 %	5.02 %
Leukocyte	True/False (Exact Match)	177	200	88.50 %	84.08 %	92.92 %	2.26 %	4.42 %
pH	True/False (Exact Match)	165	207	79.71 %	74.23 %	85.19 %	2.80 %	5.48 %
	True/False (± 1 Color Block)	203	207	98.07 %	96.19 %	99.94 %	0.96 %	1.88 %
Specific gravity	True/False (Exact Match)	179	203	88.18 %	83.74 %	92.62 %	2.27 %	4.44 %
Protein	True/False (Exact Match)	180	200	90.00 %	85.84 %	94.16 %	2.12 %	4.16 %
Magnesium	True/False (Exact Match)	158	204	77.45 %	71.72 %	83.19 %	2.03 %	5.74 %
	True/False (± 1 Color Block)	198	204	97.06 %	94.74 %	99.38 %	1.18 %	2.31 %
Sodium	True/False (Exact Match)	179	204	87.75 %	83.25 %	92.24 %	2.30v	4.51 %
Calcium	True/False (Exact Match)	163	200	81.50 %	76.12 %	86.88 %	2.75 %	5.38 %
Creatinine	True/False (Exact Match)	149	200	74.50 %	68.46 %	80.54 %	3.08 %	6.04 %
Vitamin C	True/False (Exact Match)	186	200	93.00 %	89.46 %	96.54 %	1.80 %	3.54 %
MDA	True/False (Exact Match)	199	200	99.50 %	98.52 %	100.00 %	0.50 %	0.98 %

These findings support the notion that Vivoo urine analysis app is highly accurate when it comes to quantifying various chemical components in urine. The use of artificial urine solutions ensured controlled testing conditions, ruling out external influences on the results. It is important to note that this study effectively validated Vivoo's accuracy in measuring chemical components in artificial urine solutions, indicating its potential effectiveness in analyzing real human urine samples.

CONCLUSION

Smartphone-based POC urinalysis is rapidly advancing and could revolutionize health monitoring. Smartphones, with their sensor capabilities, can conduct medical tests with a urine sample. A key application is detecting biomarkers in urine for health insights and disease risk.

Despite progress, challenges remain for widespread adoption. Standardizing methods and addressing user errors are vital, requiring protocols for consistency. Validation is necessary for accuracy and reliability, even though the Vivoo App shows huge promise.

The future holds exciting possibilities, including AI-driven analysis for precision and personalized health recommendations.

In summary, smartphone-based POC urine analysis Vivoo App has transformative potential in healthcare.

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