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Urinalysis Screening for Rural Communities

Dana Bren-Cardali
Santa Clara University, dbrencardali@scu.edu

Lilian Dao
Santa Clara University, ldao@scu.edu

Jeffrey Destruel
Santa Clara University, jdestruel@scu.edu

Ryan Fernandez
Santa Clara University, r2fernandez@scu.edu

SANTA CLARA UNIVERSITY

Department of Bioengineering and Computer Engineering

I HEREBY RECOMMEND THAT THE THESIS PREPARED
UNDER MY SUPERVISION BY

Dana Bren-Cardali, Lilian Dao, Jeffrey Destruel, and Ryan Fernandez

ENTITLED

Urinalysis Screening for Rural Communities

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Dr. Unyoung Kim
BIOE Thesis Advisor — date 6/10/18

Department Chair(s) (use separate line for each chair) — date 6/10/18

Dr. Silvia Figueira
COEN Thesis Advisor — date 6/12/18

Department Chair(s) (use separate line for each chair) — date 6/12/18

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By

Dana Bren-Cardali, Lilian Dao, Jeffrey Destruel, and Ryan Fernandez

SENIOR DESIGN PROJECT REPORT

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Abstract

Access to medical care and health screenings is a necessity for patients around the globe, but it can be difficult to provide this without screenings becoming costly or convoluted. In rural and underdeveloped areas, patients are often disadvantaged when it comes to finding reliable and affordable healthcare. The isolation provided by their location and the rising costs of physicians makes it impossible for most impoverished communities to attain personalized care. Because of this, treatable diseases often go unaddressed, allowing diseases to progress to a critical condition. Mortality rates have shown to be higher in communities located in rural areas and among destitute economies. Telemedicine is one solution to improve rural health care by allowing patients to have remote access to health services. Our goal for this project would be to provide simple and fast diagnosis to detect urine albumin levels, urobilinogen, nitrite, as well as pH and glucose levels combined with telemedicine to provide reliable results.

Thus far, we have completed tests for the previously mentioned parameters and have reached out to the World Health Partners in order to propose collaboration on the project. We have also reached out to the Computer Engineering team in order to normalize the images captured by the diagnostic device. Once the project reaches its conclusion, we believe that the introduction of this device into rural areas would effectively monitor patient health as well as improve the overall quality of life for those in impoverished conditions.

Key words: urinalysis, medical, mobile screening, health monitoring, mobile web application, rural, low-income, preventative medical care, telemedicine, developing world

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1 Introduction

1.1 Problem

Impoverished Communities Lack Access to Health Screening

Routine checkups allow physicians to monitor a patient's health and alert them to any potential issues that could indicate a disease. Routine health screenings allow diseases to be diagnosed in their early stages, giving patients the ability to seek treatment and prevent diseases from reaching a life-threatening condition.[1] However, patients in rural areas face certain barriers that prevent them from getting screened regularly. Patients in rural areas require access to transportation in order to reach health services as well as a means to pay for the services.[2] Because of these barriers, patients in rural areas will instead skip health screenings entirely, allowing diseases like diabetes and coronary heart disease to go untreated and reach critical conditions.[3] Lack of doctors and other medical professionals is also an issue in rural health care services. In order to have reliable health care for patients living in rural areas, it is important to have trained clinicians who can adeptly handle lab equipment and provide patients with trustworthy healthcare.[4]

1.2 Existing Solutions

Urinalysis Test Strips

[1] 9Health Fair. "Health Screening." *9Health Fair: Health Screening*, Colorado School of Public Health, 9healthfair.publichealthpractice.org/module4/1_index.htm.
[2] Rural Health Information Hub. "Rural Health Information Hub." *Healthcare Access in Rural Communities Introduction*, Rural Health Information Hub, 9 June 2017, www.ruralhealthinfo.org/topics/healthcare-access.
[3] National Rural Health Association. "NRHA." *NRHA, National Rural Health Association*, National Rural Health Association, 2016, www.ruralhealthweb.org/about-nrha/about-rural-health-care#_ftn1.
[4] Warshaw, Robin. "Health Disparities Affect Millions in Rural U.S. Communities." *AAMCNews*, Association of American Medical Colleges, 30 Oct. 2017, news.aamc.org/patient-care/article/health-disparities-affect-millions-rural-us-commun/.

Urinalysis tests are one possible solution to the improving the health of patients in rural communities. Urinalysis tests allow patients to monitor their health easily at home and can alert them when the concentration of analytes predictive of health complications fall outside of their healthy physiological ranges. Urinalysis tests can be used to rapidly detect high urine glucose, nitrite, urobilinogen, albumin, and other urine analytes that can be indicative of health risks during pregnancy.[5] These tests are also easily accessible and can be purchased at the pharmacy or over the internet without the need of a prescription. While urinalysis test strips can be used to detect health abnormalities through the detection of biological markers, they are not meant to be used for self-diagnosis.[6] Additionally, users should follow up urinalysis results with a checkup by a medical professional. The most commonly reported issues with urinalysis strips are that their results are not easily readable and that the instructions do not warn or inform patients how to avoid chemical contamination. These two factors need to be considered when interpreting urinalysis test results and when designing improved urinalysis tests.

Clinical Screening Services

Clinical screening services available in rural poor areas are a viable option for patients, however, they can become costly for those that need to schedule regular checkups. Clinical screening services also run the risk of human error because tests are analyzed by clinicians.[7] Thirdly, the screenings made available by these services may not be useful to those with non-technical backgrounds if translations of the results depends upon medical professionals.

CLINITEK Advantus Urine Chemistry Analyzer

The CLINITEK Advantus Urine Chemistry Analyzer is available for purchase and is able to evaluate over 500 tests/hour.[8] However, this device is not a practical option for patients

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[5] "Urine Test: Urinalysis." *American Pregnancy Association*, 2 Sept. 2016, americanpregnancy.org/prenatal-testing/urine-test/.

[6] "Urinalysis." *Lab Tests Online: Empower Your Health. Understand Your Tests. A Public Resource on Clinical Laboratory Testing.*, May 2016, labtestsonline.org/understanding/analytes/urinalysis/tab/test/.

[7] Naylor, C.d. "Grey Zones of Clinical Practice: Some Limits to Evidence-Based Medicine." *The Lancet*, vol. 345, no. 8953, 1995, pp. 840–842., doi:10.1016/s0140-6736(95)92969-x.

[8] "Home." *CLINITEK Advantus Analyzer - Siemens Healthineers USA*, 2017, usa.healthcare.siemens.com/point-of-care/urinalysis/clinitek-advantus-urine-chemistry-analyzer.

in rural poor areas. The device itself is bulky, making mobilization infeasible. The cost of the device (roughly $8,000) is also out of the range of the target audience.

Educational SMS Messages

Mobile phones make it possible to easily educate individuals in low- and middle-income communities about their health. Health education and resources can be shared rapidly with the patient via SMS messages.[9] Unfortunately SMS messages are limited to preventative care and health education rather than reactionary emergency care.

Mobile Clinics

Mobile clinics are able to provide healthcare services to individuals who are typically unable to access healthcare due to travel distance.[10] However, mobile health clinics are not efficient because they lack resources and often do not have accurate screening technologies.

Smartphone-Based Colorimetry

Smartphone apps with access to a camera are able to digitize colors of a colorimetric sensor array and evaluate color changes in biological samples that may otherwise be undetectable to the naked eye.[11] While smartphone-based colorimetry may be valuable in evaluating biomarkers detected in urinalysis tests, one of the major disadvantages of smartphone cameras is that they are vulnerable to changes in ambient light.[12] In order to eliminate analysis errors that may appear because of inconsistent lighting, a case must be made to hold the device and the strips that need to be analyzed in order to obtain the most accurate results for diagnosis.

1.3 Proposed Solution

[9] Lamont, Kim, et al. "Short Message Service (SMS) as an Educational Tool during Pregnancy: A Literature Review." *Health Education Journal*, vol. 75, no. 5, 2016, pp. 540–552., doi:10.1177/0017896915607910.
[10] Vavasis, Anthony. *Mobile Health Clinics in the United States* . 2013, pp. 1–36, *Mobile Health Clinics in the United States* .
[11] Hong, Jong Il, and Byoung-Yong Chang. "Development of the Smartphone-Based Colorimetry for Multi-Analyte Sensing Arrays." *Lab Chip*, vol. 14, no. 10, 2014, pp. 1725–1732., doi:10.1039/c3lc51451j.
[12] Kim, Seung Deuk, et al. "A Smartphone-Based Automatic Measurement Method for Colorimetric PH Detection Using a Color Adaptation Algorithm." *Sensors*, vol. 7, no. 17, 10 July 2017, pp. 1–13., doi:10.3390/s17071604.

Urinalysis Screening for Rural Communities

Urinalysis Screening for Rural Communities (USRC) project uses urine strip tests to perform health screenings for patients and and communicates results via a mobile application. USRC aims to give people in poor rural communities access to health screenings that are easily understood so that those with non-technical backgrounds may interpret results from urinalysis. The web application will calculate results from a urine test strip after an image of the strip is captured by an external imaging device. By mapping the colors captured from the tested strips to their respective concentrations, the results will be translated into statistical data that will make it easy for the user to understand their test results. The information will also be accessible to medical professionals and/or licensed technicians who will then be able to give a patient a formal diagnosis and treatment if needed. The application will also be able to map the medical history of patients in order to deliver the most well informed care. The current USRC initiative will build upon the progress of an iteration of the MUMS project from two years ago, which was able to successfully perform urinalysis tests for hemoglobin and glucose monitoring for maternal screening to improve detection of pregnancy complications and increase the probability of successful.

We will expand upon the previous group's accomplishments by adding parameters to extend the range of analytes detected by the device during urinalysis and target a wider demographic instead of just maternal patients. We would like our web application to be able to accurately detect the levels of analytes in urine being examined and return data that will be easy for the user to understand. When patients are able to monitor their health regularly from a remote location, complications associated with pregnancy may be detected more feasibly. Feasible detection of health complications may allow for patients to detect diseases earlier on and be able to monitor their health more frequently over time. Additionally, early detection will notify patients to seek further medical treatment if necessary.

1.4 Objectives

Reduce Mortality Rate of General Patients, Infants, and Mothers

The primary objective of the USRC project is to notify patients of potential risks to their individual health that may lead to death, or other serious complications that could easily be avoided by general screenings. The USRC project hopes to provide a device to detect diseases early on so that mothers will be informed if they are at risk for complications. Thereby, USRC will improve the prevention of both miscarriages and maternal death.

Improve General Health

Another objective of the USRC project is to improve the health of patients living in rural areas. The proposed device will be able to monitor the specified parameters of the patient in order to detect disease early on and prevent life-threatening conditions. The web application should also be able to store patient history so that patients and/or clinicians may be able to identify changes in the patient's health.

Enhance Patient Database

The web application should be able to store information regarding the patient's past urinalysis results, as previously mentioned. We hope to add further parameters for testing to the database from the previous MUMS project. Additionally, part of this objective is to create a patient database that is secure and keeps patient information confidential.

Calibrate Urine Test Strips Accurately

The web application must correctly map the colors displayed on the urine test strips to the corresponding concentrations of different parameters. The calibration algorithm must be able to translate the captured images of test strips into proper diagnoses. This will be achieved after distinguishing the spectrum of possible colors on the test strips, and mapping them to correct diagnoses based on the concentration on that particular strip.

Design a Frugal and Efficient Screening Device

The device created must be frugal and efficient in order to be accessible and reliable to our target users. When designing our device we will need to consider the materials used and portability of the device so that it can be both frugal and effective. Furthermore, we will aim to maximize the reusability of our device so that patients in poor rural communities are not

burdened by the cost of frequently purchasing new devices. The device will also need to be easily calibrated so that results are accurate and can be used to inform diagnosis.

1.5 Expected Results

We believe that our design will improve the lives of patients living in rural areas. Our device's adoption would lead to an influx of test results and patient data on our database. We also expect that there will be a decrease in the frequency of lengthy trips to mobile clinics made by patients. Our device will also reduce current redundancies in how biomarkers are measured in urine. It will also be able to accommodate other strips and be able to test for a variety of parameters: urobilinogen, urine albumin, glucose, pH, nitrite, and hCG. The levels of these parameters are often indicative of greater health problems that need constant monitoring.

Long term use of our device may be expected to increase in the number of patients in rural areas diagnosed with diabetes, kidney failure, or other general health issues, as fewer of these complications would go unreported. Our device will also lead to an decrease in misdiagnosis and unnecessary treatments that can be caused by inaccurate tests and readings.

1.6 Impact

Economic Impact It is imperative that we consider market forces as we design and implement our device. Our device must be an improvement over existing solutions otherwise it will become an obsolete product that will only be costly to taxpayers and governments.

Health and Safety The device must be accurate in determining the test results in order to prevent false positives or negatives that would confound the administration of healthcare to the patient. It must be accurate enough that the users of the device are confident in the data the device returns to them after a urinalysis test. A misdiagnosis from this device may lead to the patient pursuing costly treatment he or she does not need or not receiving treatment that they desperately need for themselves. Additionally, we must ensure that our device can be easily cleaned and has a mechanism to easily dispose of used urine strips. It is our primary concern that our device is a means of promoting health and wellness, not a means of spreading disease.

Sustainability The material of our device must be inexpensive and sustainable. We do not want to use materials that are harmful to our environment or to the environment of our target customer. The production to fabricate the materials we use must be minimally harmful to the environment, if at all. Furthermore, our device must be durable so that it is reusable and use of materials for production is minimal. Lastly, the disposal of strips and urine must be clearly defined for users so they do not release any harmful toxins into the environment.

Manufacturability The manufacturing of our device must be efficient and low cost so that we are able to produce a device that is accessible to the target audience.

Environmental Our project aims to provide patients living in rural poor communities with convenient and local means of medical screening. Therefore our device will likely reduce the distance that inhabitants of rural communities need to travel to seek medical testing. This may lower carbon emissions produced by vehicles otherwise used by these patients to travel to and from unnecessary medical appointments.

Ethical It is imperative that our project improve and not hinder healthcare. However, our device must be produced and implemented in an ethical manner. Our materials must be sourced from companies that follow good manufacturing practice (GMP) and do not harm the environment or other living beings. Our device must also be implemented in a manner that considers the sensitive nature of both the information the device collects as well as provides. Care must be taken to ensure that information reported is accurate and information collected is stored securely so that our device does not endanger the health or privacy of the patients it seeks to serve. Special care will be taken to ensure that the web-based portion of our device is secure from potentially compromising attacks.

Political Our web application will use an online database to store the medical information of patients using our device. Care will be taken to ensure that our platform and device do not violate any laws that regulate the collection of sensitive healthcare data, such as the Health Insurance Portability and Accountability Act (HIPAA). It is important that the database for the patients is only accessible to healthcare workers and/or patients and cannot be seen by others.

Social We must be aware and respectful of our target customers' culture. It is essential that our device abides by the cultural expectations of our target customers and does not harm or offend the patients that it seeks to serve. We hope to minimize this possibility by partnering with the World Health Organization.

2 Project Management

2.1 Team Management

Bioengineering Team

The bioengineering team is advised by Dr. Unyoung Kim. The bioengineering team will test six different parameters that the device will be able to detect. The biological markers being tested are: nitrite, urobilinogen, urine albumin, glucose, pH, and hCG. Four of the six parameters being tested - nitrite, urobilinogen, glucose, and pH - are being tested by using Siemens 10 SG Reagent Strips while hCG is to be tested with Wondfo Pregnancy Strips. The last parameter, urine albumin, is to be tested using a strip made by our team.

The bioengineering group will also be responsible for creating the device that the strips will be analyzed in. This device is intended to prevent contamination of the strips that could result in false positives or negatives for the user. In order for the device to be feasible for use in rural communities, it should be designed with an external imaging device that is available in such communities, such as a tablet.

Primary Computer Engineering Team

The primary computer engineering team is advised by Dr. Silvia Figuera. The primary computer engineering team will be responsible for calibrating the data that the bioengineering team obtains from the urinalysis tests so that the mobile web application can determine when abnormalities in the urine are present. The computer engineering team will implement image analysis so that our device is able to predict biomarker concentrations from the images taken of the strips. With the biomarker concentrations the computer engineering team will then design an algorithm that is able to suggest the proper diagnoses so the user knows what steps to take to maintain their health.

Secondary Computer Engineering Team

The secondary computer engineering team is also being advised by Dr. Silvia Figuera and will primarily be working on the web application. They will be responsible for designing a web application that is capable of tracking longitudinal patient data and can use these patient history data to provide statistical recommendations to the user. The data will be stored in a patient database which should be secure and only accessible to the user conducting the urinalysis tests with the device. The web page for the app should be easy to use so that the user can access the necessary information without any complications.

2.2 Back-up Plan

Should the device fail, we have a backup plan to rectify the situation. Our protocol calls for us to design a separate strip, divorced from the other strips that are available through the market. Should the device fail, we could combine both siemens and the pregnancy test with the urine albumin test into a singular strip. Rural areas could be supplied with this singular strip and given a biomarker concentration color chart to monitor their health for themselves. The previous group's device could still be marketed in the scenario that we are not able to make a marked improvement on their design, thus allowing patients to still be able to attain a somewhat accurate reading. This would not be ideal, but if it were the case then we would need to communicate the change with the primary and secondary computer engineering team in order to provide them with the necessary results.

2.3 Budget

The budget for our prototype is $1475. The majority of our funding was utilized to purchase chemical reagents to test and calibrate urinalysis strips. The cost of chemical reagents will not burden potential users of the device because they will be using either their own urine or a patient's urine. The bulk of the cost for consumers and patients will come from imaging equipment. However, we do not feel that the cost of imaging equipment is enough to disclude the device from being accessible and affordable because the equipment can be purchased for a one time fee and is reusable. The device casing will similarly be purchased for a one time fee and be reusable. The only component of our device that will be a recurring cost for patients

and/or caregivers will be the cost for a set of urinalysis strips. However, the cost for urinalysis strips is minimal and more affordable than other methods of diagnostic testing. In Table 2.3-1 the costs for both the prototype and estimation of a single device can be found.

Table 2.3-1 Prototype and Estimated Production Cost Componential Breakdown

Item	**Vendor**	**Number of Item**	**Prototype Cost**	**Estimated Production Cost**
Siemens Multistix 10 SG Reagent Strips (100 count)	Siemens	2	$111.06	$0.55/strip
Wondfo Pregnancy Strips (25 count)	Wondfo	1	$9.59	$0.19/strip
Cynmar Urine Test Strips - glucose, pH, protein, ketones (50 count)	Cynmar	1	$25.13	$0.50/strip
Human Serum Albumin (50mg)	Sigma Aldrich	1	$173.00	0
Thiazole Yellow G (5g)	Sigma Aldrich	1	$11.40	$2.28
Bromophenol Blue (25g)	Sigma Aldrich	1	$81.00	$3.25
Citric Acid	Santa Clara University	1	$42.00	$0
Whatman Filter Paper	Sigma Aldrich	1	$36.70	$0.37/paper
0.010”x21”x51” Clear Rigid Vinyl Sheet	United States Plastic Corp.	5	$5.67	$1.13
Urobilinogen (mg)	Lee Biosolutions	1	$79.00	$0
hCG	Sigma Aldrich	1	$63.00	$0
Sodium Nitrite	Sigma Aldrich	1	$45.90	$0
Glucose	Santa Clara University	1	$0	$0
NaOH	Santa Clara University	1	$0	$0

HCl	Santa Clara University	1	$0	$0
Samsung Galaxy Tab A	Amazon	1	$107	$107

Table 2.3-2 Prototype and Estimated Production Cost of Albumin Strips

Item	**Vendor**	**Number Item**	**Prototype Cost**	**Estimated Production Cost**
Thiazole Yellow (5g)	Sigma Aldrich	1	$11.40	$2.28
Bromophenol Blue (25g)	Sigma Aldrich	1	$81.00	$3.25
Whatman Filter Paper	Sigma Aldrich	1	$36.70	$0
Citric Acid	Santa Clara University	1	$0	$0.37
Clear Rigid Vinyl Sheet	United States Plastic Corp.	5	$5.67	$1.13
Total:			$176.77	$0.29 per strip

2.4 Timeline

Our schedule for the Fall quarter of our senior year has been accomplished for the most part. Our objectives for this time period was to finalize our design proposal and order materials for the testing process. We also sought to conduct a glucose test to establish a baseline similar to that of the previous group.

Winter Quarter, we are hoping to complete numerous tests and produce results that could be communicated with computer engineering groups. We also need to build the device

that will be capturing the data, improving on the previous groups design in doing so. We would also need to analyze the data to ensure it is accurate enough for the patient database.

Spring Quarter will involve the finalizing of our project. We will be finishing the testing and data collection stage of our design. We will also complete the presentation portion of our senior design project as well as our thesis. This quarter will be reserved for any last minute troubleshooting that may need to occur when working in correspondence with the Computer Engineering teams.

A further breakdown of our design process can be found in Table 2.4-1

Table 2.4-1 Year Long Design Process Timeline

Fall Quarter	Winter Quarter	Spring Quarter
Research Develop Protocol Design Device Begin Tests	Conduct Tests Build Prototype Test Device	Final Testing Finalize Design

2.5 Design Risks

Table 2.5-1 shows the risks that we may encounter with our project. Each risk listed is followed by an expected consequence, the probability of the risk, its severity, its impact, as well as a prevention measure against the possible risk. The severity of the risk is ranked on a scale of 1-10 and the impact is the product of the corresponding probability and severity.

Table 2.5-1: Potential Risks That May Be Faced During Product Development

Risk	Consequence	Probability	Severity	Impact	Mitigation Strategies
File Loss	Loss of work in progress	0.4	6	3.2	1. Backup files in separate hard drive 2. Utilize version control such as Github

Insufficient Development Knowledge	The system will not include the features as described	0.3	7	2.1	1. Seek help from online tutorials 2. Find an alternative approach
Illness	Team member(s) will be unable to work on the project	0.2	4	0.8	1. Keep up good health practices
Exposure to Dangerous Chemicals	Life threatening chemicals can affect health of team member(s)	0.3	8	2.4	1. Practice proper lab protocols and handling of lab equipment and chemicals 2. Be familiar with EHS guidelines

3 System Design

3.1 System Level Overview and Analysis

Protocols

Several protocols were written in order to test for the necessary biomarkers of the the project. These protocols involved the glucose testing, pH testing, urinalysis for nitrite, urinalysis for urobilinogen, hCG testing, and urinalysis for albumin.

Urinalysis for glucose was taken by taking a the powder form of glucose and mixing it with deionized water in order to create a stock solution. This stock solution was then used in order to create buffer solutions of 2000 mg/dL, 1000 mg/dL, 500 mg/dL, 200 mg/dL, 160 mg/dL, 130 mg/dL, 100 mg/dL, and 60 mg/dL. The strips were placed into the solution. Results were visible after 30 seconds and could be captured by the imaging device.

Testing for pH involved the use of HCl as well as NaOH and deionized H_2O. Buffer solutions with ranging from pH of 5 to a pH of 11 were created using the three above stated chemicals. A pH meter was used to verify the ranges in pH and the siemens strips were then

dipped into the buffer solutions. Results were then visible after 60 seconds and could be captured by the imaging device.

Nitrite levels were tested through the use varying nitrite solution and deionized water. Ratios were taken of the stock and nitrite until 0.08 mg/dl, 0.06 mg/dl, 0.05 mg/dl, 0.025 mg/dl dilution were made. The dilutions were then tested via the Siemens strips. Results were then visible after 60 seconds and could be captured by the imaging device.

Analysis of urobilinogen required us to create a stock solution of 8 mg/dL using 0.08 g of urobilinogen and 1 liter of deionized water. Serial dilutions of 8 mg/dL, 4 mg/dL, 2 mg/dL, 1 mg/dL, 0.2 mg/dL were made and then tested with the Siemens strips. Results were then visible after 60 seconds and could be captured by the imaging device.

Analysis of albumin required the creation of an entirely new urinalysis strip. In order to accomplish this task we used the chemicals bromophenol blue, thiazole yellow, and citrate buffer. Mixing these three chemicals together created a homogenous chromogen solution which we then immobilized onto filter paper. Once immobilized, the filter paper was adhered to a plastic sheet and cut into manageable strips. A stock solution of human albumin was then taken and diluted into dilutions of 1000, 300, 100, 30, and 10 mg/dL. The strips were placed into the solutions and allowed to sit for twenty seconds before being imaged by the device.

Pregnancy analysis required us to reconstitute lyophilized hCG to generate stock hCG solution at a concentration of 1,000 IU/ml. This stock solution was then used to generate a 6,400 mIU/ml solution which was then diluted to 3200 mIU/ml, 1600 mIU/ml, 800 mIU/ml, 400 mIU/ml, 200 mIU/ml, 100 mIU/ml, 50 mIU/ml, 25 mIU/ml, 12.5 mIU/ml, 6.25 mIU/ml, 3.12 mIU/ml, and 1.56 mIU/ml samples by a performing a series of serial dilutions. Results were then visible after 5 minutes and could be captured by the imaging device. Because Siemens strips lacked the capabilities to test for pregnancy, we instead used Wondfo strips.

3.2 Hardware

We have designed an imaging unit to be used in order to accurately evaluate biomarkers of chronic kidney disease. It was made from ¼” and ⅛” opaque acrylic in order to

reduce reflected light.[13] However there were a few issues that we encountered while using this device. The initial design, which we have improved upon, consists of a single cover, a test strip slide, tablet support arms, as well as a main body. For instance, the top of the tablet was designed in such a way as to only support iPad 4's as the primary image capturing device because of its availability and ease of use in the United States. The slide deck that would normally house the test strips is also built with only siemens multistix in mind. The test strip slide is constructed from acrylic and tape which prevents the LED lights of the device from reflecting excess light into the camera, however, this also lends itself to ease of use issues. The tape would often catch on the inside of the device preventing users from sliding the strip into the imaging compartment. There is also a gap between the strip and the bottom of the slide that causes positioning error when imaging the strip. Ideally, our final design will be able to eliminate the excess lighting as well as position the urinalysis strips consistently.

Figure 3.1-1 Top view of urinalysis device

Our main unit features a lithium battery that will be rechargeable. The main unit also houses the LED switch that controls the function of the LED lights.

[13] *Neumeyer, Joseph, et al. "Mobile Urinalysis for Maternal Screening: Frugal Medical Screening Solution and Patient Database to Aid in Prenatal Healthcare for Expecting Mothers in the Developing World." 2016 IEEE Global Humanitarian Technology Conference (GHTC), 2016, doi:10.1109/ghtc.2016.7857337.*

We have made the top casing to be interchangeable with multiple iterations so as to accommodate different tablets available to our partners in India. Removing and replacing the top casings could also be improved upon for ease of use.

The tablet support arms that acted as structural support for the original design are absent from our device in order to improve ease of use. After receiving feedback from our contact in WHP, we determined that the support arms were unnecessary for the smaller tablets available to them. As a result, the main unit is slightly wider in design as well as shorter in length in order to maintain stability when the imaging unit is mounted in place.

We have constructed multiple slide decks in order to accommodate the different sizes in test strips as well as improved the tape coating. Positioning the strip is no longer an issue and excess liquid does not remain contained in the crevice of the slide decks, making the disinfection process much easier. This is due in part to the design decision to switch the scotch tape of the original design with electrical tape.

3.3 Customer Needs

Our client, World Health Partners, is located in India. World Health Partners (WHP) is a non-profit organization that provides healthcare to underserved communities. When designing our device we have had to keep in mind the resources available to the communities that WHP works with. During our design review process, our client informed us that the tablets available in India are different than the tablets available in the United States. We therefore, have had to modify part of our hardware to accommodate different tablets. In particular, the position of the camera lens varies between tablets. We have factored this difference into our final design.

Similar to our modifications to suit the client's tablet, we have also had to consider the urinalysis strips commercially available in India. Amidst our design process, our client shared with us what the common urinalysis strips used are. The strips used in India detect for the same parameters that our team has been testing for. Therefore, our parameters are compatible with the parameters that the client desires to be diagnosed.

Other considerations that our client has shared with us are regarding the hardware component of our device. As aforementioned, our device prototype has dimensions of 29 cm x 8.1 cm x 12.9 cm and weighs 3.2 lbs. Upon review, our client informed us that the dimensions and weight suit the needs of their organization. However, they suggested we modify our power source and use lithium batteries instead of a power cord. Another hardware consideration was the strip holder. Our client asked that the strip holder be able to accommodate a variety of potential urinalysis strips.

3.4 Software

The design includes the tablet being linked to a mobile application that will be able to analyze the images taken by the tablet and device in order to diagnose patients for various health risks and/or diseases. In order for the application to properly analyze test strips of unknown concentrations, it would require calibration. The activity diagram in figure 3.1-2 guides users along the calibration process.

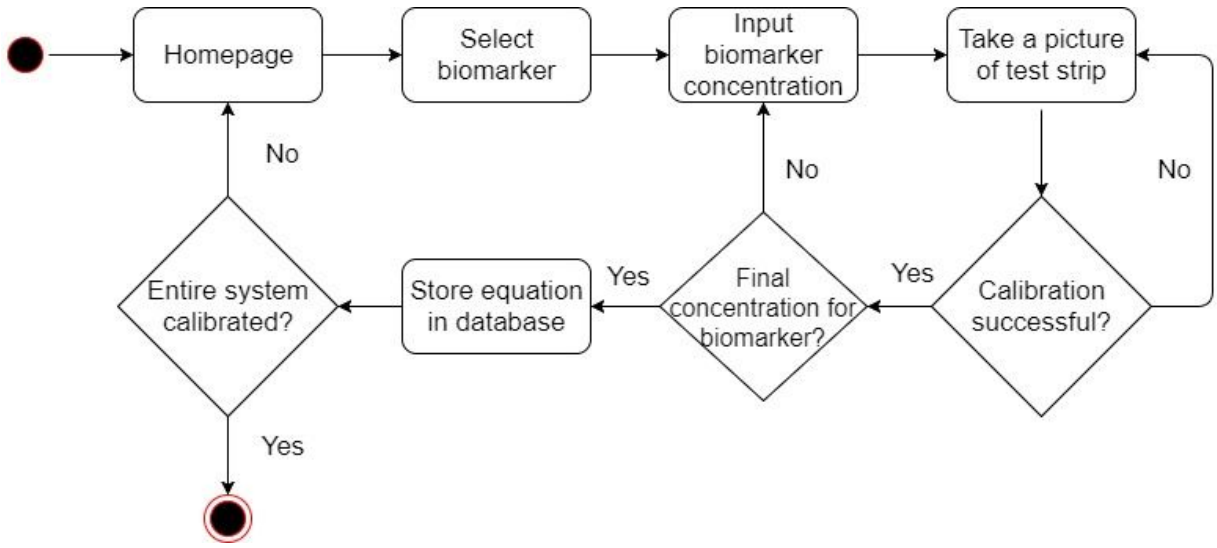

Figure 3.1-2 Activity diagram for users of the mobile application

The calibration process starts with the user selecting a biomarker and testing it specific concentrations. Using the tablet and casing, the user will then have to take a picture of the test

strip and continue testing the biomarker until a wide range of concentrations have been tested. Once images have been taken for each of the concentrations, they would each be cropped in order to isolate the reagent pad of the biomarker being tested. These cropped images would be uploaded onto Matlab, which would then run our image analysis algorithm. This algorithm analyzes each image and captures the red, green, and blue intensity values of each concentration. It then obtains the average of these values plots them onto a graph. These graphs were created in order to normalize the images captured by the strips and compared to the theoretical values proposed by the Siemens strips. The polynomial equations that make up the graph are the same equations that the mobile application will use in their image analysis algorithm to test for unknown concentrations. This process is repeated for each of the desired biomarkers.

4 Protocols

4.1 Urinalysis for Glucose

Procedure

Clinically acceptable levels of glucose in urine is usually less than 130 mg/dL.[14] Knowing this, we created several solutions that were made to simulate glucose in urine ranging from 0 mg/dL to 2000 mg/dL. Higher concentrations were used in order to better understand the limitations of the reagent test strips.

Both the Cynmar test strips as well as the Siemens Multistix were then dipped into the solutions for 60 seconds in order to attain an accurate concentration. The strips were then placed into the prototype device and photographed to record the corresponding color to the concentration. Each dilution was tested and then imaged using the device.

4.2 Urinalysis for pH Test

Procedure

In order to test the pH ranges of the strips, we created buffer solutions using deionized water as well as HCl and NaOH. A pH meter was also employed in order to validate the buffer solutions that we created for testing. The Siemens Multistix 10 SG reagent strips were expected

[14] *"Understanding Urine Tests." National Center for Biotechnology Information, U.S. National Library of Medicine, 30 Dec. 2016, www.ncbi.nlm.nih.gov/pubmedhealth/PMH0072534/.*

to be able to detect a range of pH in urine starting from a pH of 5 and ending at pH of 9, dependent on acid-base status of patient as well as diet.[15] However, our team decided to use buffer solutions ranging from a pH 5 to a pH of 11 due to the sensitivity of the Siemens Multistix. While changes in color were meant to be detected by pH 7, real changes in color were not seen until after a pH of 9, so we performed tests above the range given on the Siemens Multistix package. Three reagent strips were placed in their corresponding pH solutions and then placed in the device for imaging. A total of thirty seconds was allowed for the color to fully develop before imaging the strip.

4.3 Urinalysis for Nitrite

Procedure

A solution with a pH of 6.0 was made for the experiment by measuring out 10 mL of 1 M KH2PO4 and combining it with 90 mL of DI H2O as well as 11.2 mL of 0.1 M NaOH. The resulting reaction produced is 0.05 M of KNa2PO4

In order to generate samples containing nitrite, one milligram of sodium nitrite (ACS reagent, ≥97.0%) was dissolved into 10 dL in order to generate 0.1 mg/dL of sodium nitrite solution. From this solution we made a series of dilutions from 0.08 mg/dL, 0.06 mg/dL, 0.05 mg/dL, 0.025 mg/dl. We dipped the Siemens test strips into the dilutions and waited 60 seconds for the results to appear. Each dilution was tested and then imaged using the device. There is no acceptable range of nitrite in urine, thus the range of dilutions was miniscule.[14]

4.4 Urinalysis for Urobilinogen

Procedure

To perform the urinalysis tests for urobilinogen, we first created a stock solution of 8 mg/dL for urobilinogen in water. The stock solution would then be diluted down with DI water to test for different concentrations and tested using the siemens multistix 10 SG reagent strips.

A stock solution of 8 mg/dL of urobilinogen in water was created for the urobilinogen tests and diluted down. The acceptable amount of urobilinogen in urine was found to be 0.5-1

[15] *"Understanding Urine Tests." National Center for Biotechnology Information, U.S. National Library of Medicine, 30 Dec. 2016, www.ncbi.nlm.nih.gov/pubmedhealth/PMH0072534/.*

mg/dL.[16] As a result, we decided to test for urobilinogen concentrations between 0 - 8 mg/dL. The higher concentrations were also included in our testing because those levels of urobilinogen could be detected using the urinalysis strips that were being used to test for urobilinogen.

To test for urobilinogen, the Multistix test strip was dipped into the solution and dried of excess fluid. A photo of the result was taken after sixty seconds. Observations of these results were recorded and analyzed using the key provided with the Siemens Multistix 10 SG Reagent Strips.[17] Each concentration was tested three times following these same procedures.

4.5 Urinalysis For hCG

Procedure

To create a stock solution of hCG, we reconstituted lyophilized hCG in DI water. This provided us with a stock hCG solution at a concentration of 1,000 IU/ml. To test for pregnancy we prepared samples to generate concentrations ranging from 1.56 mIU/ml to 6400 mIU/ml. We specified this range because 25 mIU/ml to 6400 mIU/ml indicates different stages of pregnancy, but we wanted to test the sensitivity of the strips.[18]

Following the generation of dilutions, we dipped three Wondfo strips into each concentration for 8 seconds. The 8 seconds allows for the test strips to fully absorb the solution and display either a positive or negative result. After being dipped in the solution, the test strips displayed results after 5 minutes and were then imaged.

4.6 Urinalysis for Albumin

Procedure

Due to the lack of test strips commercially available for urine albumin testing, we decided to create our own strips using Bromophenol blue, thiazole yellow, and citric acid. Bromophenol Blue and thiazole yellow (1mg/ml each) were prepared separately in 0.1M citrate buffer (pH 2.49). We used 3.8497g of Citric acid and 5.8971g of trisodium citrate dihydrate in order to create the citrate buffer needed in this experiment. We then mixed 130 ul of

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[16] *"Understanding Urine Tests." National Center for Biotechnology Information, U.S. National Library of Medicine, 30 Dec. 2016, www.ncbi.nlm.nih.gov/pubmedhealth/PMH0072534/.*

[17] *www.sigmaaldrich.com/content/dam/sigma-aldrich/docs/Sigma/Product_Information_Sheet/2/g5400pis.pdf+.*

[18] *"HCG Levels." Pregnancy Birth and Baby, Jan. 2017, www.pregnancybirthbaby.org.au/hcg-levels.*

Bromophenol blue and 40 ul of thiazole yellow with 0.9mL of 0.1M citrate buffer to get a homogenous chromogen solution. Stock solution of human serum albumin (2000 mg/dL) was then diluted with deionized water in order to prepare solutions of 1000, 300, 100, 30, and 10 mg/dL.

Similarly, different dilutions of albumin should also be made in urine if it is viable. Unfortunately, we were not able to make urine dilutions, but this could be an improvement that future groups can strive towards. The chromogen solution was immobilized on filter paper and dried at 30ºC for one hour in humidity free chamber for 1 hour. After immobilization and drying, the filter paper was then pasted to a sheet of polystyrene plastic and cut into 5 mm wide pieces that were 9.0 cm x 9.0 cm. The sheets of plastic were then dried in humidity free chamber for two hours and then cut into 0.3 cm x 9.0 cm pieces in such a manner that one end of the strip has the reagent pad and one end is free to handle. Strips should then be stored at room temp. in brown bottles containing silica gel bags as desiccant. Tests using the different dilutions of urine albumin can then be tested with the different concentrations of albumin.[19] For each test, the strips were dipped in the sample and an image was taken of the strip after twenty seconds.

5 Results

5.1 RGB Graphs

RGB graphs for each parameter were created for each parameter: glucose, pH, nitrite, urobilinogen, hCG, and albumin. Both glucose and pH have two graphs, one for the Siemens Multistix and one for the Precision Strips used by WHP. These graphs were constructed using MATLAB. To analyze the photos, the strip was cropped manually and evaluated using MATLAB functions to determine the intensity of the red, green, and blue of the cropped image. Depending on the concentration, the color of the strip would change accordingly. The average RGB value of all of the samples for certain concentration were found and plotted with the RGB intensity on the y-axis and the concentration of the biomarker being tested on the x-axis. An RGB graph was constructed for all of the six biomarkers that were tested. The curve

[19] *Sharma, Sandeep K, et al. "Albumin Test Strip for Quick Detection of Albuminuria in Human."Indian Journal of Chemical Technology, vol. 9, Nov. 2002, pp. 496–498., nopr.niscair.res.in/bitstream/123456789/18915/1/IJCT%209%286%29%20496-498.pdf.*

fitting function on MATLAB was used to find the equations that would later be used for calibration.

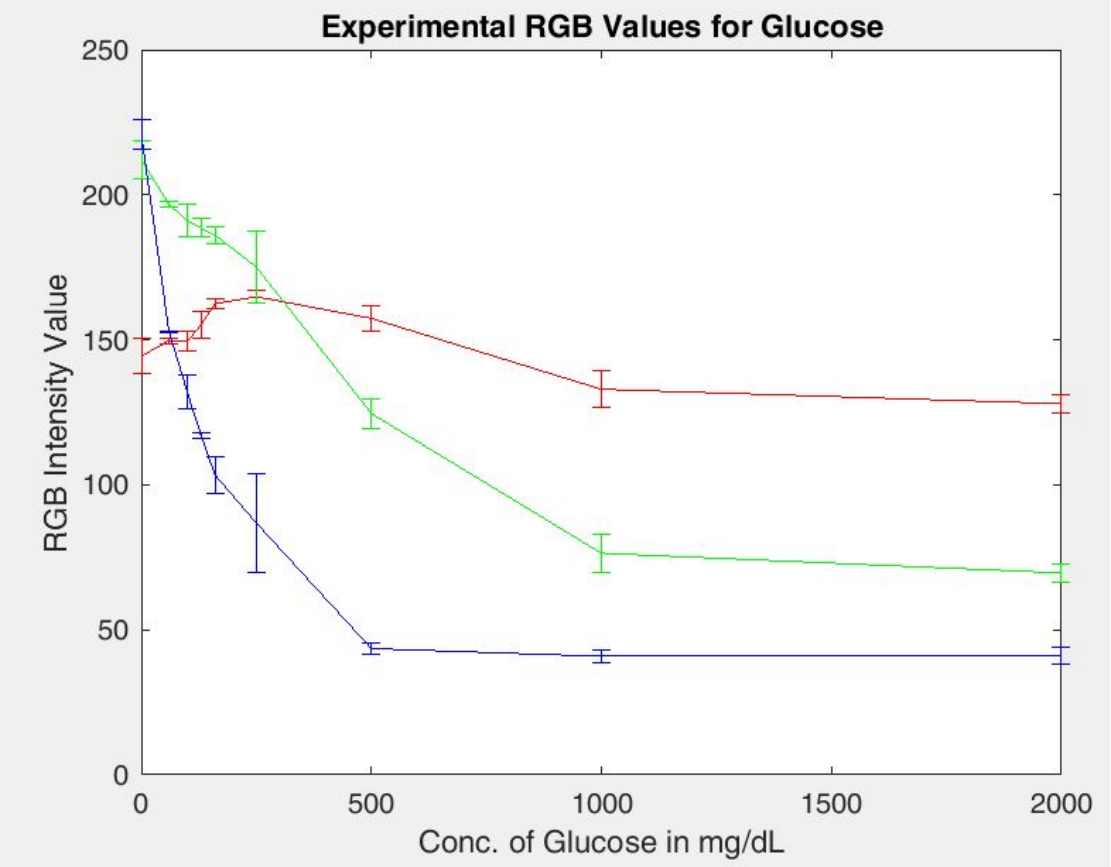

Figure 5.1-1: RGB Graph for Glucose for Siemens Multistix

Glucose was primarily tested from concentrations of 0-250 mg/dL. This is because the clinically acceptable range of glucose in a patient's urine is 130 mg/dL.[20] However, the concentration can be 180 mg/dL or higher depending on a patient's condition like in Type 1 and Type 2 diabetes.[21] Tests were also conducted beyond 250 mg/dL depending on the detection ability of the strips.

[20] *"Understanding Urine Tests." National Center for Biotechnology Information, U.S. National Library of Medicine, 30 Dec. 2016, www.ncbi.nlm.nih.gov/pubmedhealth/PMH0072534/.*
[21] *IQWiG. "Type 1 Diabetes: Measuring Sugar Levels in Blood and Urine Yourself." Advances in Pediatrics., U.S. National Library of Medicine, 29 June 2017, www.ncbi.nlm.nih.gov/pubmedhealth/PMH0072521/.*

Figure 5.1-1 shows the RGB graph that was obtained for glucose. The graph depicts the changing intensity of the red, green, and blue on the Siemens Multistix 10 SG Reagent strips as the concentration of glucose increased. The strips were tested for concentrations of glucose ranging from 0-2000 mg/dL because that was the capability of detection given on the Siemens Multistix package. Based on the graph, the RGB values obtained can be used to predict the concentrations below 1000 mg/dL. This makes it possible for the app to alert patients of increasing glucose levels and allows clinicians to advise patients to seek treatment.

Figure 5.1-2: RGB Graph for Glucose for Precision Strips

Figure 5.1-2 above shows the RGB graph obtained for the glucose tests using the Precision Strips used by WHP. The strips were tested from concentrations of 0-3000 mg/dL because they had a wider range of detection than the Siemens Multistix. Comparison between the two graphs show that they have differing RGB intensities depending on the concentration and thus the equations obtained by these graphs cannot be used interchangeably. The RGB graph for the Precision Strips show that the blue intensity is almost flat. This makes the red and

green equation that will be obtained by the graph far more important when creating the algorithm.

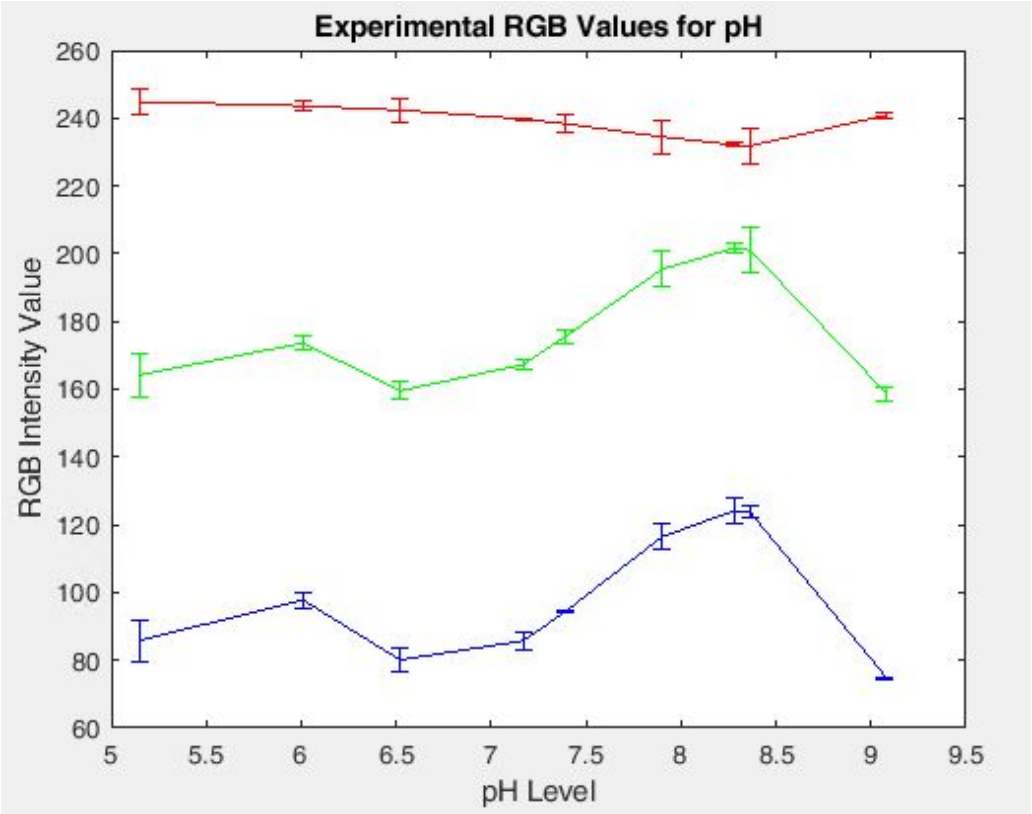

Figure 5.1-3: RGB Graph for pH for Siemens Multistix

pH is an indicator of how acidic or alkaline a patient's urine is and can predict the likelihood of kidney stones in a patient. [22] The average pH level of urine is 6, but the level can fluctuate depending on a patient's diet or health condition. [23] If a patient's urine is acidic, less

[22] *Healthline. "Urine PH Level Test: Purpose, Procedure & Side Effects." Healthline, Healthline Media, www.healthline.com/health/urine-ph.*

[23] *Healthline. "Urine PH Level Test: Purpose, Procedure & Side Effects." Healthline, Healthline Media, www.healthline.com/health/urine-ph.*

than 6, this can indicate certain conditions such as kidney stones, dehydration, diabetes, and starvation. If a patient's urine is alkaline, higher than 6, then it is indicative of conditions such as kidney failure, kidney tubular acidosis, or urinary tract infection.[24] pH levels in urine can range anywhere from 5.1-8. [25] The tests were conducted for pH used pH levels of 5-9. However, Siemens Multistix failed to have a significant color change and tests above a pH of 9 were conducted using the Multistix.

Figure 5.1-3, shows the RGB graph of pH as the pH level increases. Of the graphs constructed, the pH showed the most difference from the theoretical change in color described on the Siemens Multistix 10 SG Reagent Strips. The test ranges described on the label were listed for pH levels from 5 to 9. However, our tests showed a significant change only occurring when the pH levels were above 9. This would become very important when calibrating the device and later creating the algorithm for the web application.

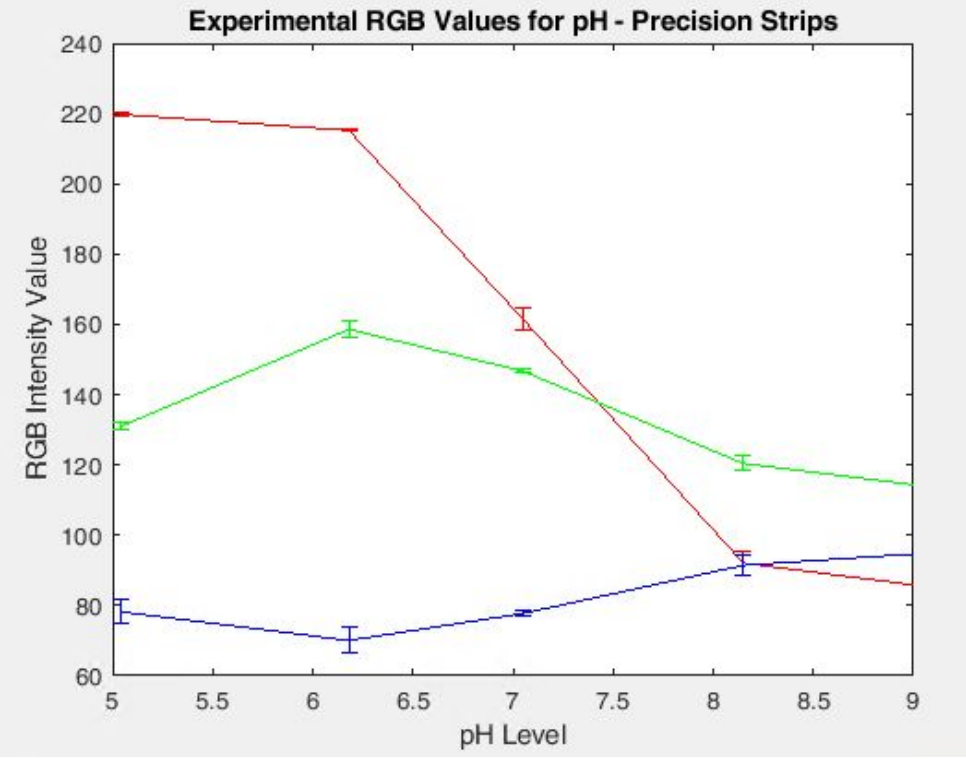

Figure 5.1-4: RGB Graph for pH for Precision Strips

[24] *Healthline. "Urine PH Level Test: Purpose, Procedure & Side Effects." Healthline, Healthline Media, www.healthline.com/health/urine-ph.*
[25] *RENCEUS. "Urine PH." Urine PH, RNCEUS, www.rnceus.com/ua/uaph.html.*

Figure 5.1-4 displays the RGB graph for the Precision Strips with differing concentrations of pH. Like the Siemens Multistix, these tests were conducted from pH levels of 5 to 9. As seen on the bottle of the Precision Strips, there is a drastic change in pH from around 6 to 8 pH. This differs from the Siemens Multistix, which only has a drastic change after the pH reaches a level of 9. From our tests, Precision Strips display a higher sensitivity when the pH level changes.

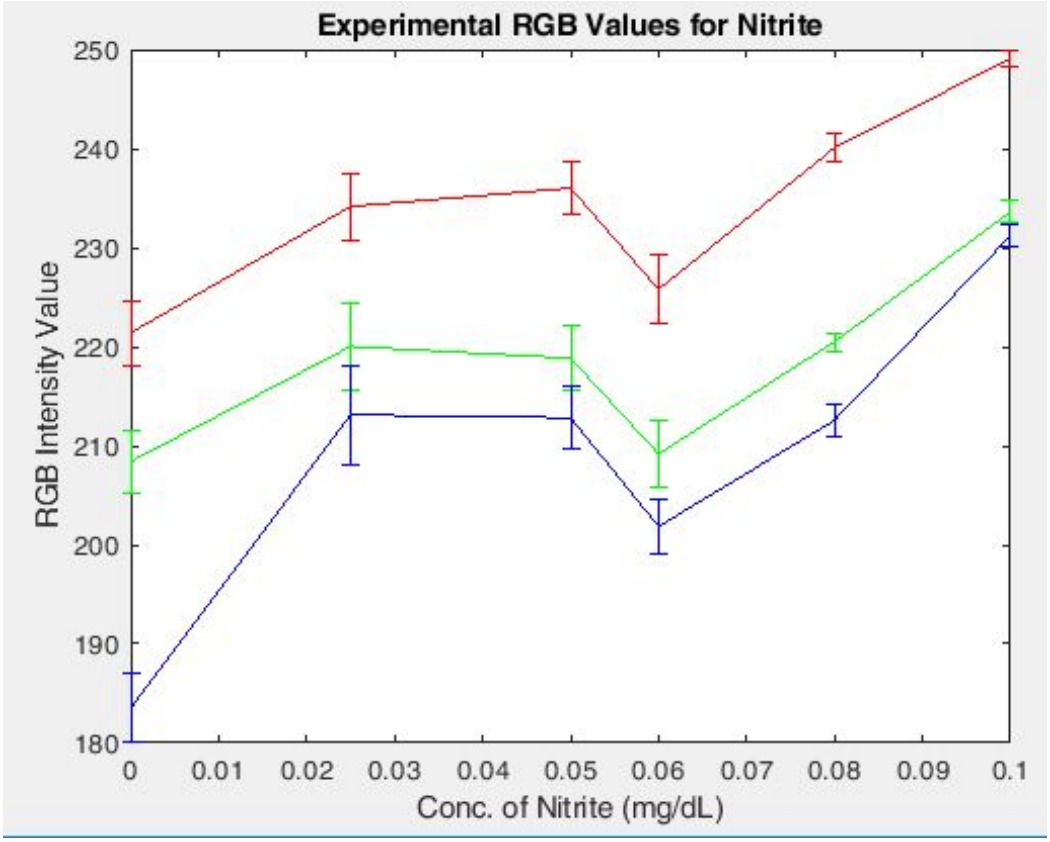

Figure 5.1-5: RGB Graph for Nitrite for Siemens Multistix

While nitrate can be found in urine, nitrite should not be present in a patient's urine at all.[26] Nitrate in urine can be transformed into nitrite if there is bacteria present, which can occur if a patient has urinary tract infection.[27] Because nitrite should not be found in a patient's urine at all, we conducted nitrite testing for very low concentrations of nitrite in DI water.
The RGB graph constructed for the different concentrations of nitrite, which can be found in

[26] *Healthline. "Nitrites in Urine: Causes, Symptoms, and Treatments." Healthline, Healthline Media, www.healthline.com/health/nitrites-in-urine#1.*
[27] *Healthline. "Nitrites in Urine: Causes, Symptoms, and Treatments." Healthline, Healthline Media, www.healthline.com/health/nitrites-in-urine#1.*

Figure 5.1-5. The intensity of the red, green, and blue fluctuate the same way for each color as the concentration of nitrite increases in all of the cases that were tested. The tests were conducted for concentrations of nitrite from 0-0.1 mg/dL because nitrite should not be found in urine at all, so we hoped the strips would have significant changes in color with small increases in nitrite concentration. However, the nitrite strip results dip down back near the original RGB intensities seen at 0 mg/dL. As of right now, we have determined that this information can be used to predicted the presence of nitrite in urine, but further tests must be conducted in order to see if it is possible to obtain an algorithm that will be able to predict the concentration of nitrite in a patient's urine.

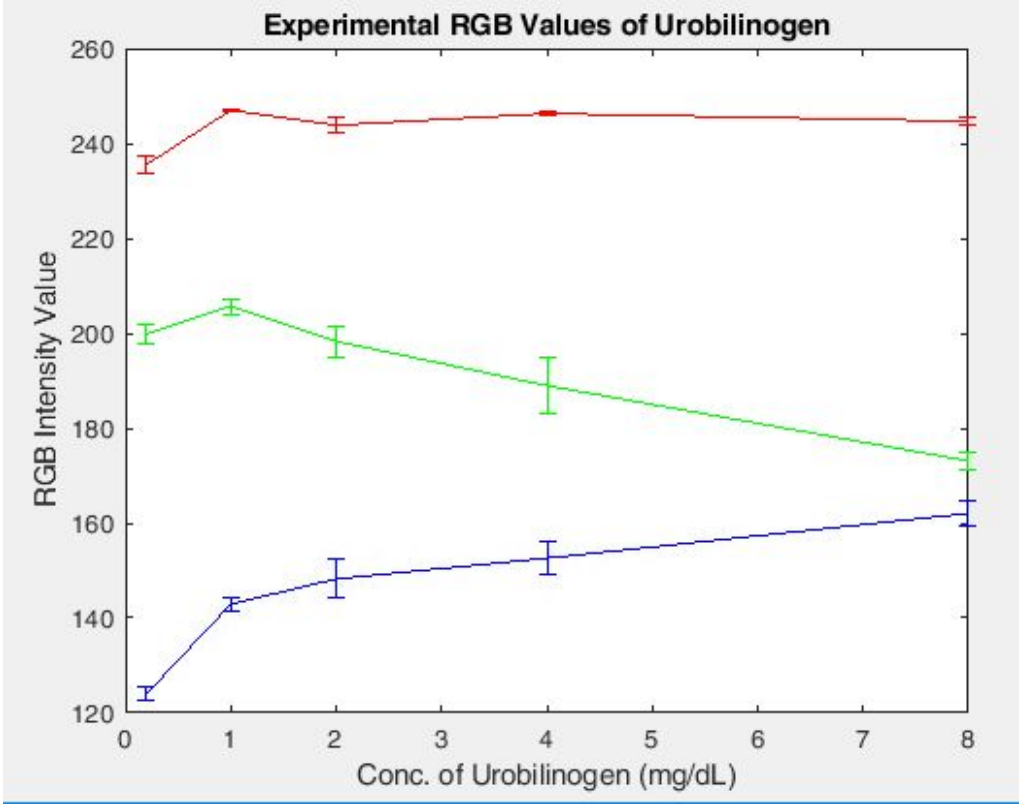

Figure 5.1-6: RGB Graph for Urobilinogen for Siemens Multistix

Urobilinogen is a compound that can be found in trace amounts in urine and is typically observed to find liver problems.[28] The clinically acceptable concentration of urobilinogen in a patient's urine is considered to be <1 mg/dL, but it can range anywhere from 0-8 mg/dL, which

[28] *MedlinePlus. "Urobilinogen in Urine: MedlinePlus Lab Test Information." MedlinePlus, U.S. National Library of Medicine, 22 Sept. 2017, medlineplus.gov/labtests/urobilinogeninurine.html.*

is the range we tested for in our experiments.[29] Too little urobilinogen, is indicative of liver blockage or issues with liver function while high concentrations of urobilinogen indicate health conditions like hepatitis, cirrhosis, or liver damage.[30]

Figure 5.1-6 displays the plot of the RGB intensity as the levels of urobilinogen in urine increase as found through our experiments. As seen in the graph, the intensity values for the blue and green color of the strip are more drastic than that of the red color, which means that those values will be far more valuable in constructing the algorithm needed for the app. The changes in RGB are more significant below the 4 mg/dL concentration of urobilinogen, so the RGB values will be helpful in predicting the concentration of urobilinogen in a patient's urine as it increases.

[29] Marchione, Victor. "What Does Urobilinogen in Urine Mean? Causes, Symptoms, Tests, and Treatment." Bel Marra Health - Breaking Health News and Health Information, Bel Marra Health, 6 Dec. 2017, www.belmarrahealth.com/urobilinogen-urine-mean-causes-symptoms-tests-treatment/.

[30] Marchione, Victor. "What Does Urobilinogen in Urine Mean? Causes, Symptoms, Tests, and Treatment." Bel Marra Health - Breaking Health News and Health Information, Bel Marra Health, 6 Dec. 2017, www.belmarrahealth.com/urobilinogen-urine-mean-causes-symptoms-tests-treatment/.

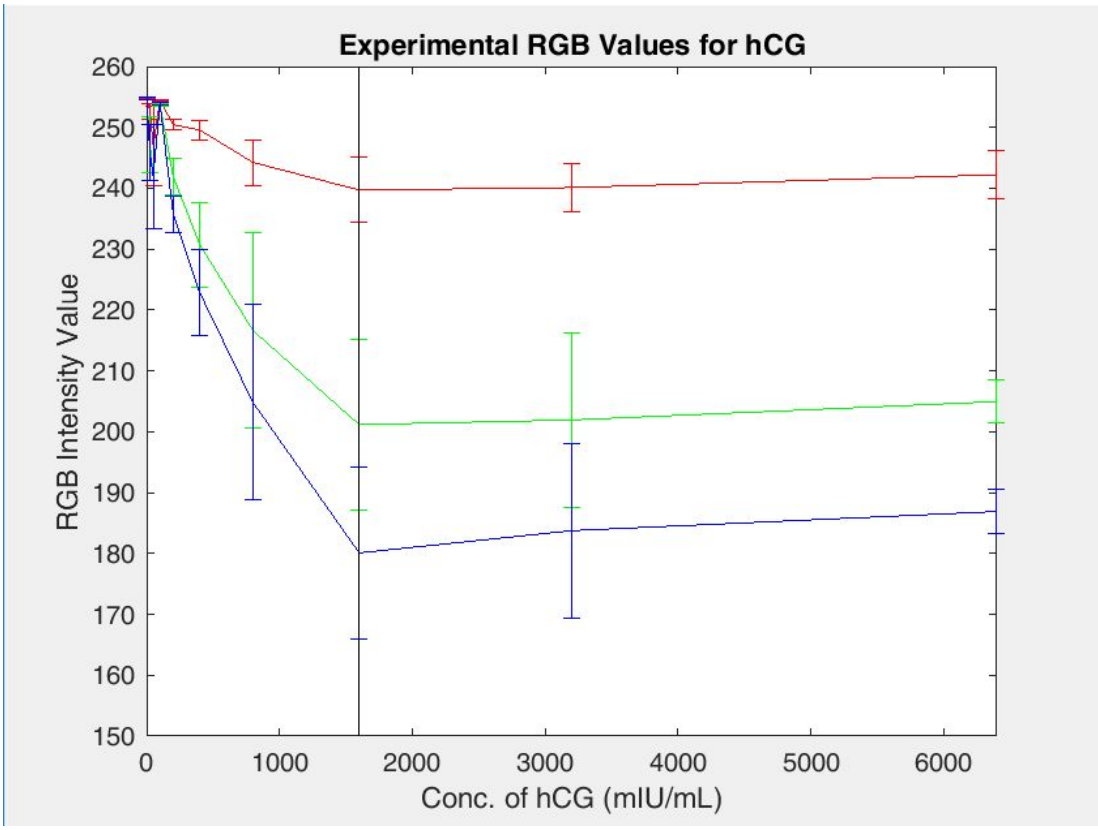

Figure 5.1-7: RGB Graph for hCG

hCG is a hormone present in urine when a woman becomes pregnant. The Wondfo strips can only detect after two weeks of a woman's pregnancy, but we tested a range of 0-6400 mIU/mL to determine if we could obtain equations to predict a patient's stage of pregnancy. Because it is critical to determine a patient's pregnancy as soon as possible, we focused on testing from ranges of 0-1600 mIU/mL, which is the normal concentration of hCG during 0-3 weeks of pregnancy.[31]

Figure 5.1-7 displays the RGB graph that were obtained for hCG. Unlike the Siemens Multistix 10 SG Reagent strips, the Wondfo strips that were used to detect hCG only confirm the presence of the biomarker rather than giving an estimate of the concentration of the biomarker as well as confirming the presence or absence of it in urine. As a result, the RGB graph for hCG lacks the curves seen in the other RGB graphs for the other parameters that used

[31] *Advanced Fertility Center of Chicago. "Advanced Fertility Center of Chicago." PGD Costs | How Much Does Preimplantation Genetic Diagnosis Cost?, Advanced Fertility Center of Chicago, www.advancedfertility.com/earlypre.htm.*

Siemens Multistix 10 SG Reagent strips for testing. Instead there is a sharp change in slope after the 1600 mIU/mL concentration where the graph has a very shallow slope, indicating a positive pregnancy. As a result, the information taken from this graph would only allow the algorithm to confirm that a patient is pregnant rather than predicting how many months pregnant a patient is.

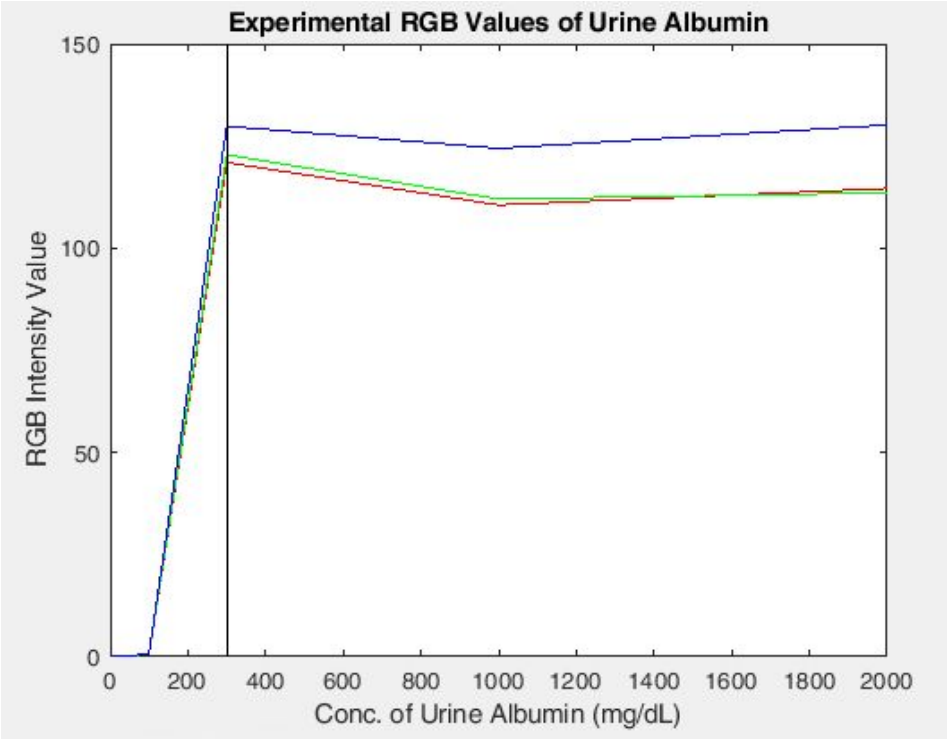

Figure 5.1-8: RGB Graph for Albumin

Albumin is a protein that can be found in urine and can be observed to determine if a patient has kidney disease.[32] The clinically acceptable range of albumin in urine is 30 mg/dL and a patient is considered to have albuminuria if the concentration of albumin in urine is greater than 300 mg/dL.[33]

Figure 5.1-8 above shows the RGB graph for the urine albumin strips that

[32] *National Institute of Diabetes and Digestive and Kidney Diseases. "Albuminuria: Albumin in the Urine." National Institute of Diabetes and Digestive and Kidney Diseases, U.S. Department of Health and Human Services, 1 Oct. 2016*

[33] *National Institute of Diabetes and Digestive and Kidney Diseases. "Albuminuria: Albumin in the Urine." National Institute of Diabetes and Digestive and Kidney Diseases, U.S. Department of Health and Human Services, 1 Oct. 2016*

manufactured in lab. The concentrations that were tested ranged from 0-2000 mg/dL, which is far above the normal 300 mg/dL that is found in patients with albuminuria. This is because we wanted to determine if the strips constructed would be able to detect albuminuria in a patient. As seen in the graph, our strips can successfully determine if a patient has high enough levels of albumin in their urine to indicate albuminuria, which is shown to the left of the black line on the graph. Our tests also show that the strips are able to determine the concentration of albumin in a patient's urine from concentrations of 160-300 mg/dL, alerting patients to take steps in preventing albuminuria from occurring.

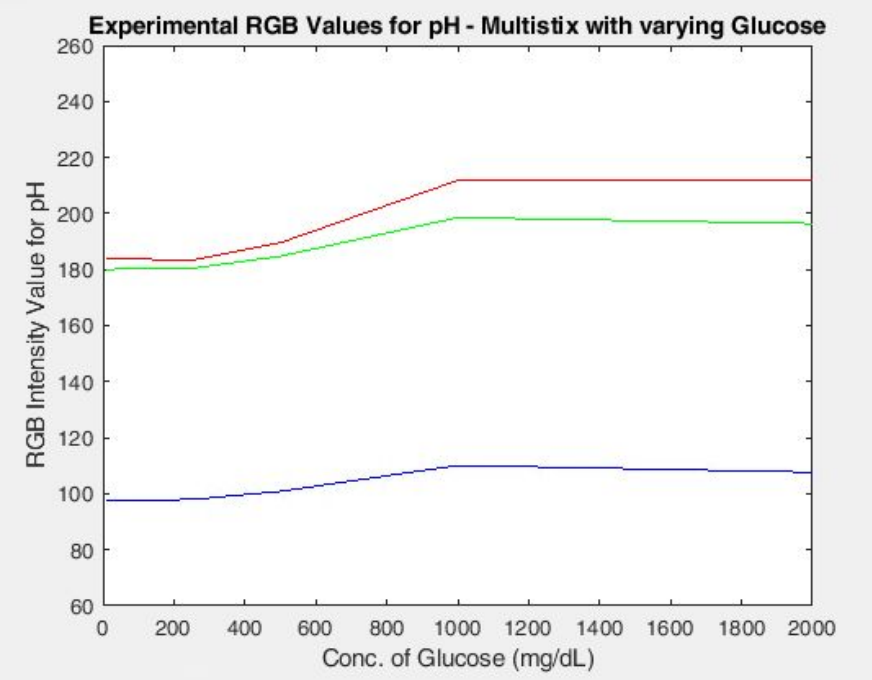

Figure 5.1-9: RGB Graph for pH for Siemens Multistix in Varying Glucose

We also conducted tests with multiple parameters to determine whether the presence of additional biomarkers would affect the biomarker being observed. Figure 5.1-9 above displays the results of one of these combination parameter tests where we observe the RGB of the pH reagent pad of the Siemens Multistix. Because only glucose is varied, the expected graph should have a flat line because pH is unchanging. As Figure 5.1-9 shows, the RGB intensity does vary slightly as glucose is increased, particularly between glucose concentrations of 0-1000 mg/dL.

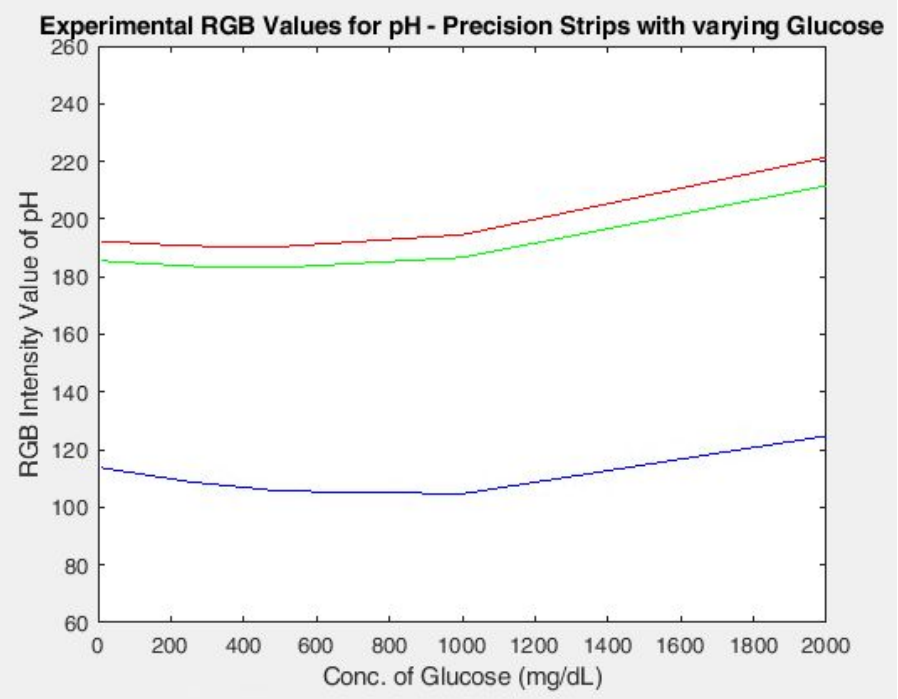

Figure 5.1-10: RGB Graph for pH for Precision Strips for Varying Glucose

We also constructed a similar RGB graph for the Cynmar Precision Strips that observed the RGB of pH as the concentration of glucose was increased. Figure 5.1-10 displays the result, showing how the RGB intensity of pH changes as glucose is added to the sample. Compared to the Siemens Multistix, the Precision Strips are much more sensitive to change when additional parameters are present, suggesting that Siemens Multistix may be more accurate in monitoring a patient's health because the color change is not as drastic even when multiple biomarkers are present in the sample.

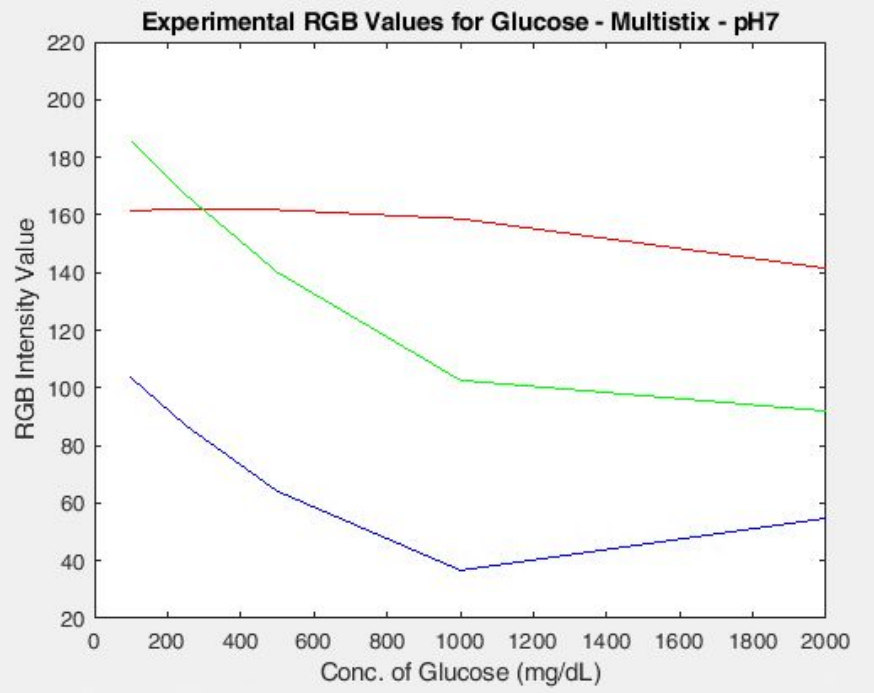

Figure 5.1-11: RGB Graph for Glucose for Siemens Multistix with Constant pH of 7

During these same combination tests, we observed the RGB as we increased glucose at a constant pH of 7. Although the average pH level of a healthy patient is 6, we expected that the glucose graphs that were to be obtained by both the Siemens Multistix and the Cynmar Precision Strips to be close in trend to the original graphs we obtained in isolation tests.

The RGB graph obtained for the glucose isolation test for Siemens Multistix, seen in Figure 5.1-1, displays trends that are similar to the ones observed in Figure 5.1-11 for combination tests of varying glucose and constant pH using Siemens Multistix. However, the red intensity for the combination RGB graph is far more linear than the one seen in combination testing. Further testing is required to acquire a more accurate graph and determine how much variance occurs when multiple biomarkers are present.

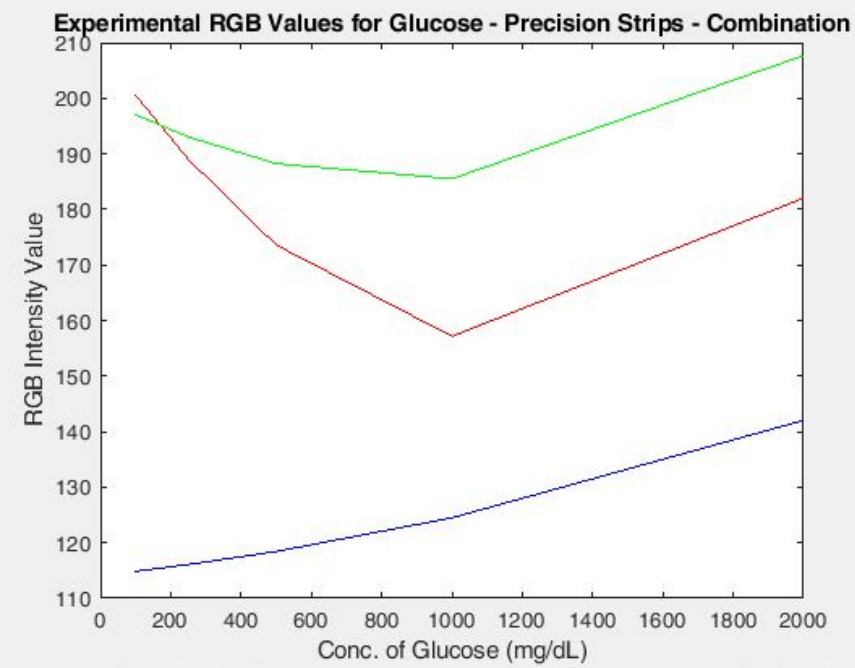

Figure 5.1-12: RGB Graph for Glucose for Precision Strips with Constant pH of 7

The results for the Cynmar Precision Strips for combination testing of varying glucose and constant pH 7 can be observe in Figure 5.1-12 above. Like the Siemens Multistix, the graph has differences compared to the one found in isolation testing, which can be seen in Figure 5.1-2. However, the variance between the combination graph and the isolation graph for Cynmar Precision Strips have greater differences in the changing RGB intensities, which means the Precision Strips are much more sensitive when multiple parameters are present. While the blue intensity was previously observed to be nearly flat in the isolation graph even as the concentration of glucose increased, the combination graph above shows a drastic increase of blue as glucose increases. Further testing is required to determine how much variance occurs when multiple parameters are present and how to take these different factors into account when creating the algorithm.

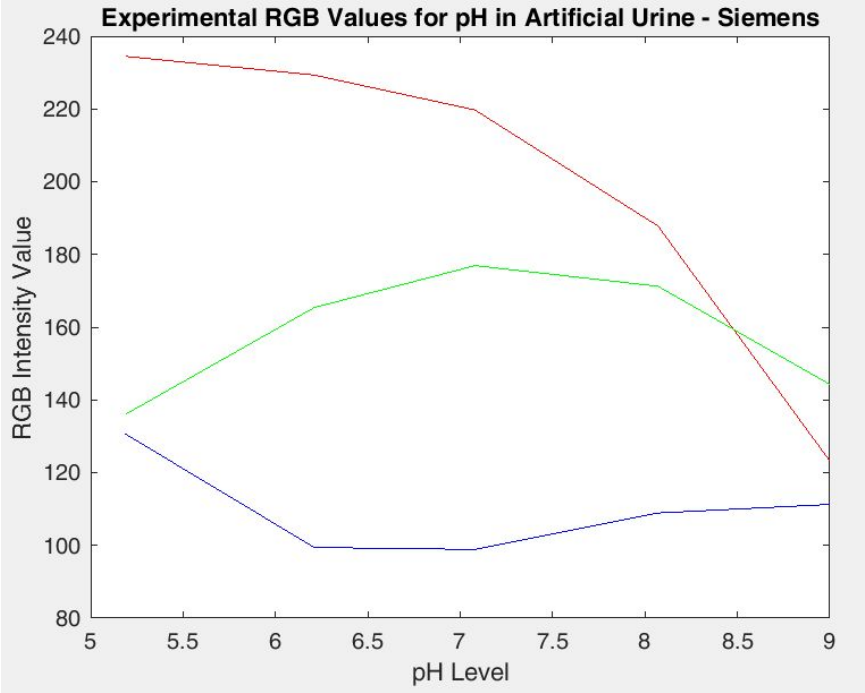

Figure 5.1-13: RGB Graph for pH for Multistix in Artificial Urine

Our final tests were conducted with solutions with the observed biomarker dissolved in artificial urine. Previously, the tests were done using samples dissolved in DI water, but artificial urine was used to obtain results that would be closer to those obtained using real urine samples.

Figure 5.1-13 above displays the RGB graph of pH for Multistix in artificial urine. The graph follows a similar trend seen in Figure 5.1-3 in the pH isolation test for Siemens Multistix. However, a drastic change from pH levels 7 to 9 is present in the artificial urine test and is not present in the isolation test using DI water. Previously, it was determined that the pH sensitive for Siemens Multistix was not good because of the lack of change, but there is a substantial difference that should allow the algorithm to determine pH change as the patient's urine becomes more alkaline. Should these tests be repeated in the future, artificial urine should be used rather than DI water because it results in changes that are closer to those found on the bottle.

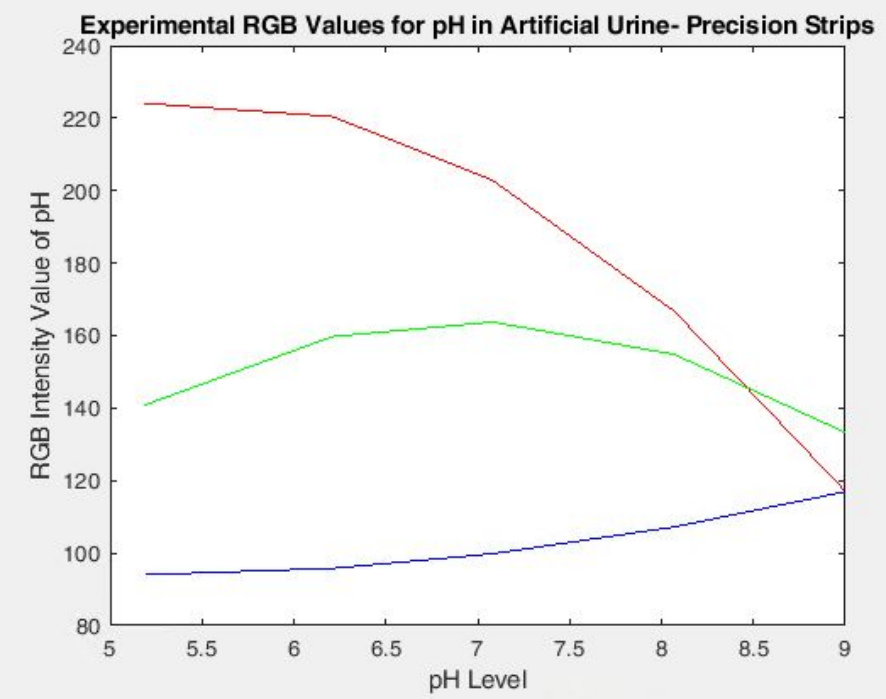

Figure 5.1-14: RGB Graph for pH for Precision Strips in Artificial Urine

The last RGB graph, seen in Figure 5.1-14 above, displays the pH graph for the Precision Strips in artificial urine. The trends seen in this graph and the isolation graph for the same test in DI water, which can be observed in Figure 5.1-4, are similar but the curve for the blue intensity is seen to be smoother. However, the drastic change in color from pH levels of 7 to 9 are similar to those found in the DI water isolation test. While the graphs follow the same trends overall, it is best to do these tests using artificial urine to obtain results that will be closer to those that will be found using patient's urine.

6 Summary

6.1 Project Goals

The goal of the project is to design a case for an imaging device in order to take images for urinalysis strips. The case should be able to provide consistent lighting so that the web application paired with the device can accurately analyze the results of the urinalysis tests. Because the device needs to be portable, the device should be designed to be compact, relatively light, and be made out of a durable material. It is also important that the lighting's

power source come from batteries and be rechargeable so it can be used without having to be plugged into another power source.

The algorithm that the web application used to analyze the images of the urinalysis tests taken by the device needed to be calibrated using known concentrations of the same biomarkers being tested. Using the images of the concentrations used for the standard, the RGB values were graphed and an equation was found for each biomarker. These equations were used to create the algorithm to analyze urinalysis results that the complementary computer engineering team will be working on.

6.2 Work Done

The bioengineering team worked on preparing different concentrations of all of the biomarkers for testing. Three images were taken for each concentration per parameter and the images were cropped to create RGB values. These graphs were given to the computer engineering team to determine the RGB equations for the algorithm needed for the web application. Additionally, they also constructed their own albumin strips in the lab as well as built an imaging device compatible with a Samsung tablet for WHP.

The computer engineering team worked on calibration by gathering the RGB equations to create the algorithm the web application plans on using in order to give an accurate reading of the urinalysis tests. The computer engineering team also worked on the design layout of the application as well as the different functionalities that would be required for the app such as cropping, image uploading, and image capturing.

6.3 Future Work

While the albumin strips made could successfully detect albumin in urine and also differentiate between microalbumin and macroalbumin, there could be improvements in in manufacturing them in order to reduce the cost. The printer used to print the reagent onto the strip could print out the small amount of reagent needed, but it was too time-consuming and also used up many liquid cartridges in the process. As a result, the final albumin strips were handmade, but the uniform distribution of the reagent cannot be confirmed. In the future, the

strips should be manufactured so that the reagent is spread out evenly on the paper and use a printer that can dispense large amounts of liquid so that the reagent pads can be cut into the desired size for the strips.

Future work on the project should also include producing strips that detect other biomarkers in addition to the ones that were used in this project. The Cynmar Precision strips used by WHP and other similar commercial strips can only detect biomarkers like glucose, pH, and ketones. The inclusion of a variety of other biomarkers would allow the detection of other diseases and greatly improve health monitoring.

Most of the tests conducted were done using DI water. However, later tests showed that artificial urine yielded results that would be closer to those that would be found if real urine were used. In the future, the parameter testing should be done using artificial urine to better recapitulate real urinalysis tests.

6.4 Discussion

The device hardware overall satisfies the customers needs. The weight and the dimensions of the device allow it to be easily transported and therefore, comply with customer constraints. The acrylic material of the device is also optimal because of its durability. The strip holder in the final device is compatible with the Cynmar Precision Strips used by WHP. The device is also compatible with the Samsung tablet that WHP uses for capturing their images. The black acrylic box successfully keeps out ambient light that could affect images used in the app, allowing for more accurate results. The device also has LEDs powered by lithium batteries, which allow clinicians to use the device without the need for an external power source. The lithium batteries also have a long battery life so that the device can be used for a long time without needing to be charged or having its battery replaced. .

Our team has successfully been able to test all desired parameters individually in a timely manner. Our isolation tests yielded results to create an algorithm that could determine the concentrations of different samples for all six of our parameters: glucose, pH, nitrite, urobilinogen, hCG, and albumin. We were also able to perform combination tests with glucose

and pH to determine how the results varied when multiple parameters were present in the sample. We determined that the parameters could affect the results and that these should be taken into account when creating the algorithm. In addition, we were able to observe the same tests using artificial urine in order to determine whether the results obtained were more accurate than the results obtained from the tests conducted with DI water. While the trends were similar, the ones observed with artificial urine yielded results that were closer to those seen on the labels of the urinalysis test strips.

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7 Appendix

Static Color Indoor
NFLS X3 LED Flexible Light Strip
Part Number: NFLS-X3

Features

- Features 5050SMD high powered LEDs delivering up to 6,600 lumens
- 12 VDC operating voltage
- Available in Black and White finish options
- LED Light Strip features adhesive backing & cuttable 3-LED segments for easy installation
- 180° optics improve visibility with wider area illumination
- Applications include back lighting, task lighting, cove lighting, retail, sign illumination, under cabinet, display case, accent decor, and automotive accents

Standards and Certifications

UL LISTED · ISA · RoHS · 5 YEAR WARRANTY



Accessories


Remote Dimmers & Switches


Strip Interconnects


Mounting Hardware & Extrusions


Power Supplies

General Product Specifications

Beam Angle	180 Degree	Type	Flexible Light Strips
LED Type	5050 SMD	Color	9 Different Color Options
Voltage	9~14.8 VDC	Life Span	≥30,000 Hrs
LEDs Per Segment	3	Strip Width	10.15mm
Lumens (Max)	6600	Strip Finish Options	White / Black
Water Resistance	Non-Weatherproof	Strip Length Options	0.5m / 1m / 5m
Polarized	Yes	Strip Connection Options	Connector / No Connector
Wire Length	9in		

Custom Length Options Available for Cool White, Natural White, and Warm White (#NFLS-x3X3-CL)

REV 3.26.2014

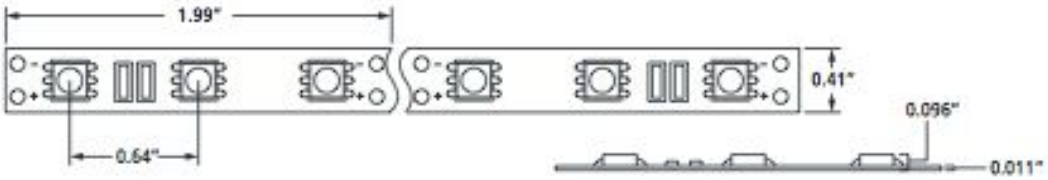
superbrightleds.com
LED Lighting For Everything

4400 Earth City Expy, St. Louis, MO 63045 • 866-590-3533 • superbrightleds.com

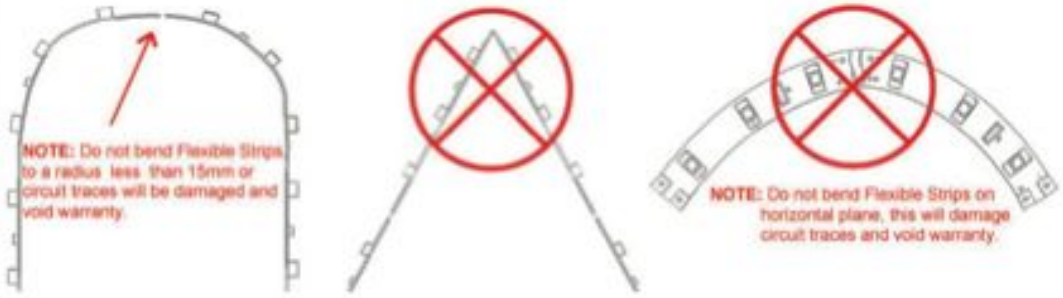
Product Specifications

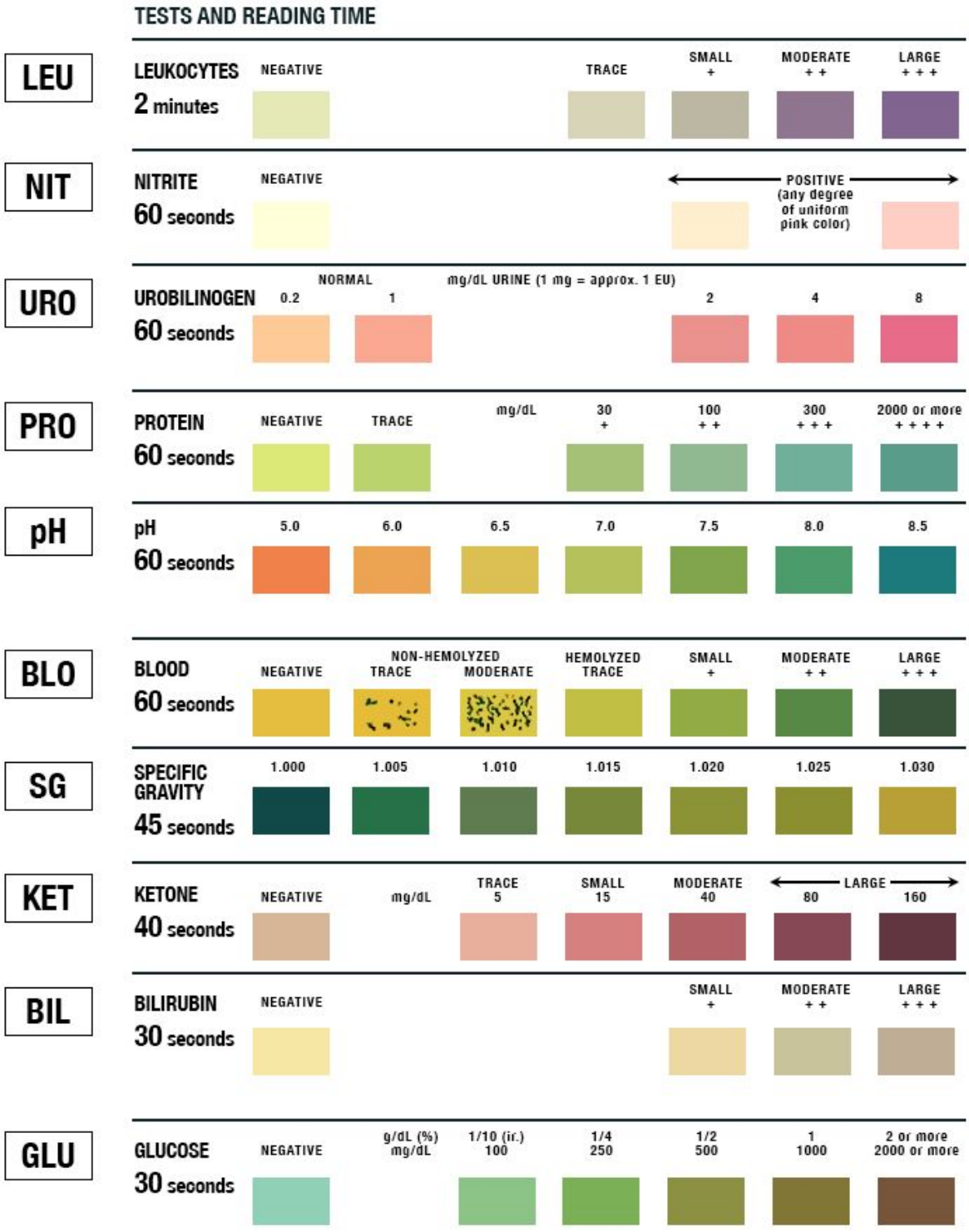
Emitting Color	Wavelength	Intensity Per Foot	Power Consumption
Cool White	7500 K	360 lm/ft	292 mA (3.5 W)
Natural White	4000 K	380 lm/ft	274 mA (3.3 W)
Warm White	3250 K	380 lm/ft	292 mA (3.5 W)
UV	400 nm	57000 mcd/ft	305 mA (3.7 W)
Blue	470 nm	32918 mcd/ft	292 mA (3.5 W)
Green	525 nm	100584 mcd/ft	292 mA (3.5 W)
Yellow	605 nm	57000 mcd/ft	335 mA (4 W)
Amber	610 nm	54864 mcd/ft	335 mA (4 W)
Red	626 nm	54864 mcd/ft	335 mA (4 W)

Dimensions



Maximum Flexibility Precaution




TESTS AND READING TIME
LEU
LEUKOCYTES
2 minutes
NEGATIVE
TRACE
SMALL +
MODERATE + +
LARGE + + +
NIT
NITRITE
60 seconds
NEGATIVE
POSITIVE (any degree of uniform pink color)
URO
UROBILINOGEN
60 seconds
NORMAL
0.2
1
mg/dL URINE (1 mg = approx. 1 EU)
2
4
8
PRO
PROTEIN
60 seconds
NEGATIVE
TRACE
mg/dL
30 +
100 + +
300 + + +
2000 or more + + + +
pH
pH
60 seconds
5.0
6.0
6.5
7.0
7.5
8.0
8.5
BLO
BLOOD
60 seconds
NEGATIVE
NON-HEMOLYZED TRACE
NON-HEMOLYZED MODERATE
HEMOLYZED TRACE
SMALL +
MODERATE + +
LARGE + + +
SG
SPECIFIC GRAVITY
45 seconds
1.000
1.005
1.010
1.015
1.020
1.025
1.030
KET
KETONE
40 seconds
NEGATIVE
mg/dL
TRACE 5
SMALL 15
MODERATE 40
LARGE 80
160
BIL
BILIRUBIN
30 seconds
NEGATIVE
SMALL +
MODERATE + +
LARGE + + +
GLU
GLUCOSE
30 seconds
NEGATIVE
g/dL (%) mg/dL
1/10 (tr.) 100
1/4 250
1/2 500
1 1000
2 or more 2000 or more