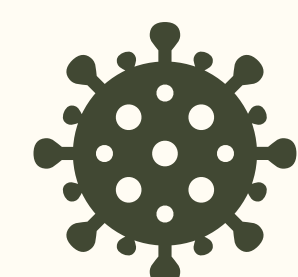


CLINICAL NEED



Sepsis is the body's response to harmful microorganisms in the blood resulting from an infection. Septic shock is the final stage of sepsis where blood pressure falls and organs do not receive enough oxygen, leading to organ shutdown.



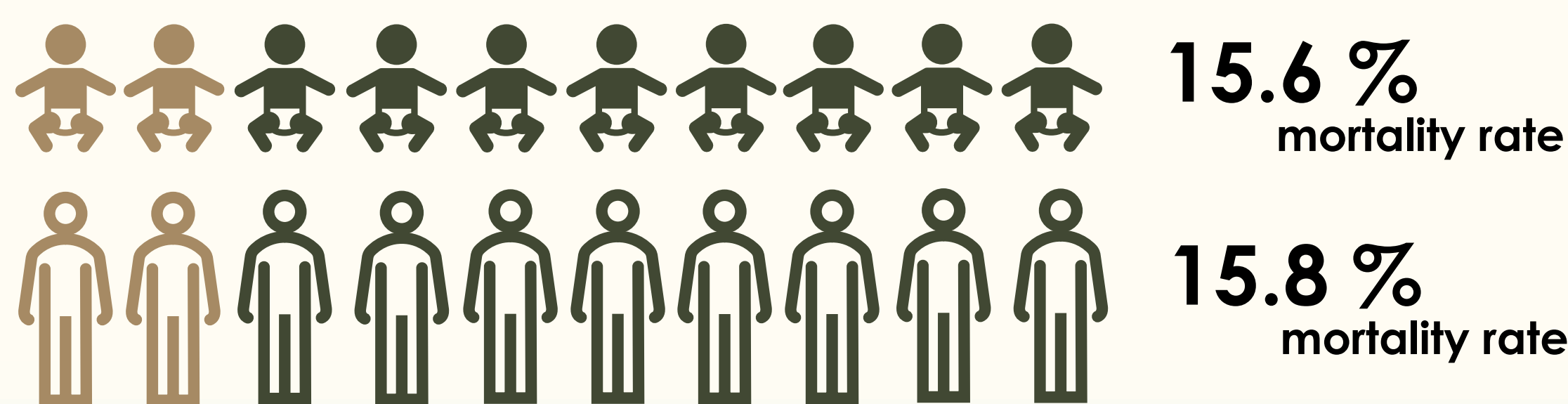
1.7 million people in the U.S. contract sepsis each year, resulting in **270,000 deaths** annually.¹ Especially vulnerable populations include neonates, immunocompromised, and elderly patients. **1-2 babies out of 1,000 live births** contract sepsis in the U.S.² Globally, there is an estimated **1.3 million** annual cases of neonatal sepsis with **203,000** neonatal deaths.³



The current gold standard of sepsis detection is blood culture. A blood culture requires a large volume of blood to run and can take 24-72 hours for results. This makes blood culture testing inaccessible for patients who cannot safely give enough blood or may experience organ failure more rapidly.



Our device will provide a fast and noninvasive way to monitor a patient's risk for sepsis while decreasing negative patient outcomes and broad-spectrum antibiotic usage.



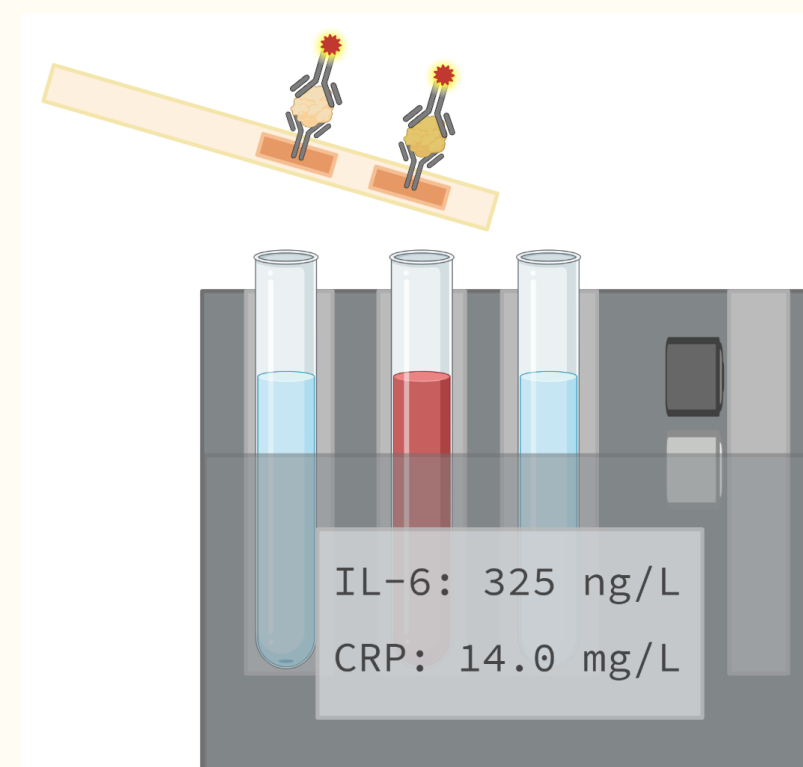
MISSION STATEMENT

inSEPSStigator

Southwest Sciences is dedicated to minimizing sepsis complications by providing an affordable and rapid point-of-care device that will successfully quantify sepsis risk within minutes using the inSEPSStigator device and saliva biomarkers.

DEVICE CONCEPT, DESIGN, AND PROTOTYPE

CONCEPT



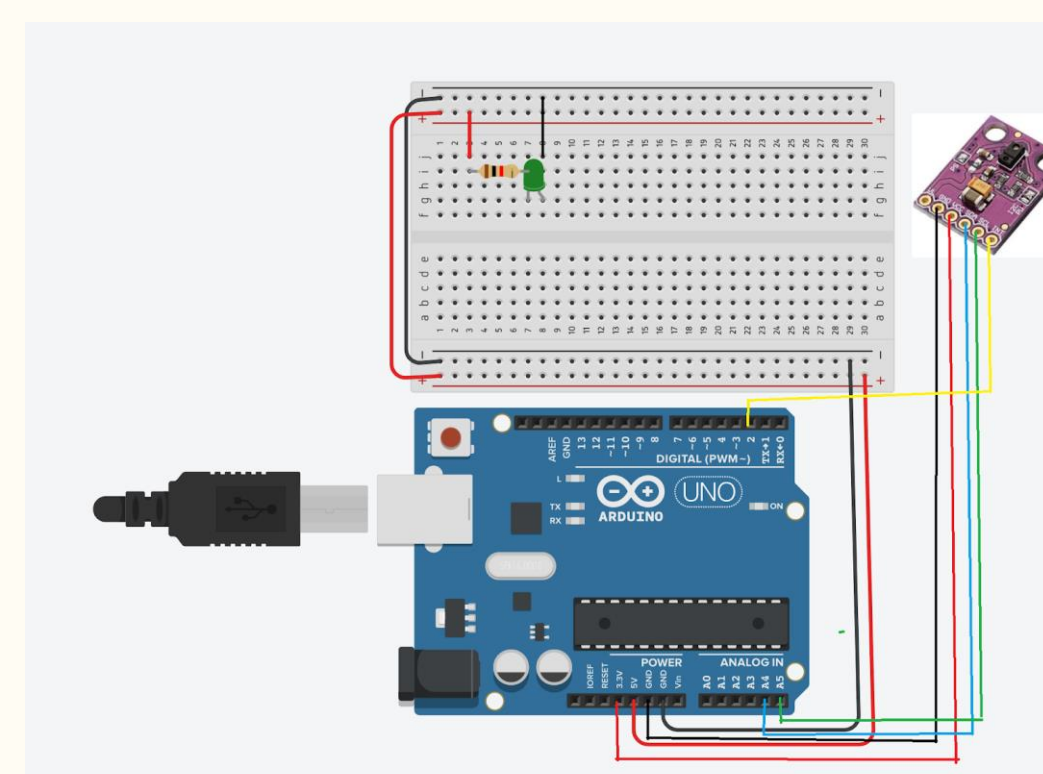
OUR DEVICE:

- Uses saliva instead of blood
- Uses a small sample volume
- Uses antibody-tagged gold nanoparticles for an immunoassay
- Detects IL-6 and CRP levels to evaluate risk of sepsis

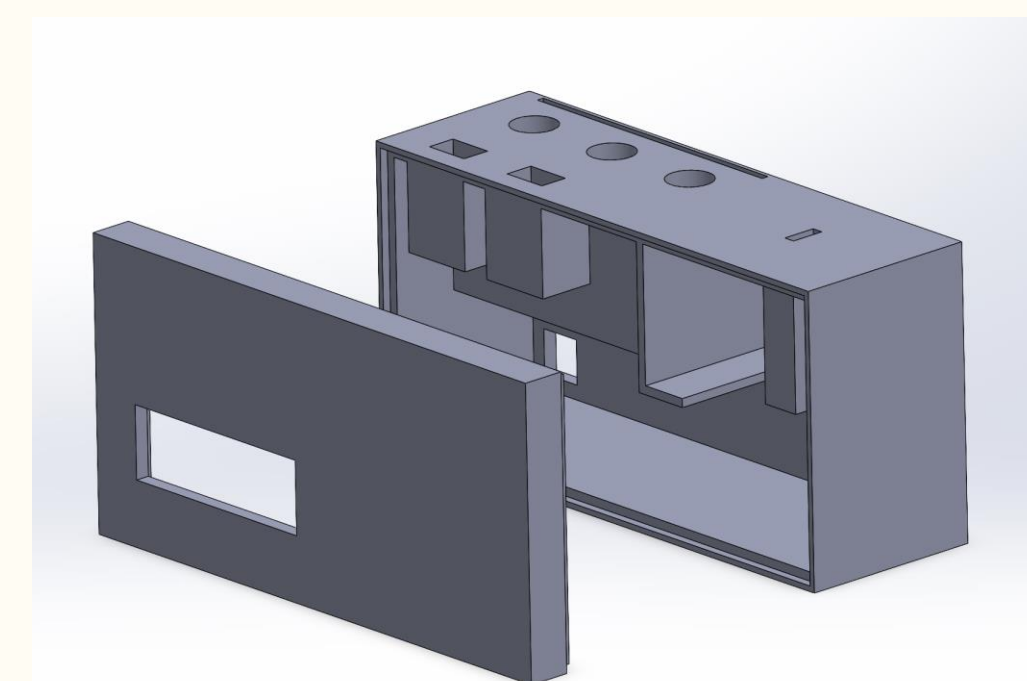
DESIGN

Key Components:

- LED light for uniform testing
- RGB sensor for colorimetric detection
- Microcontroller for easy and fast data collection
- LED screen for clear data communication



PROTOTYPE



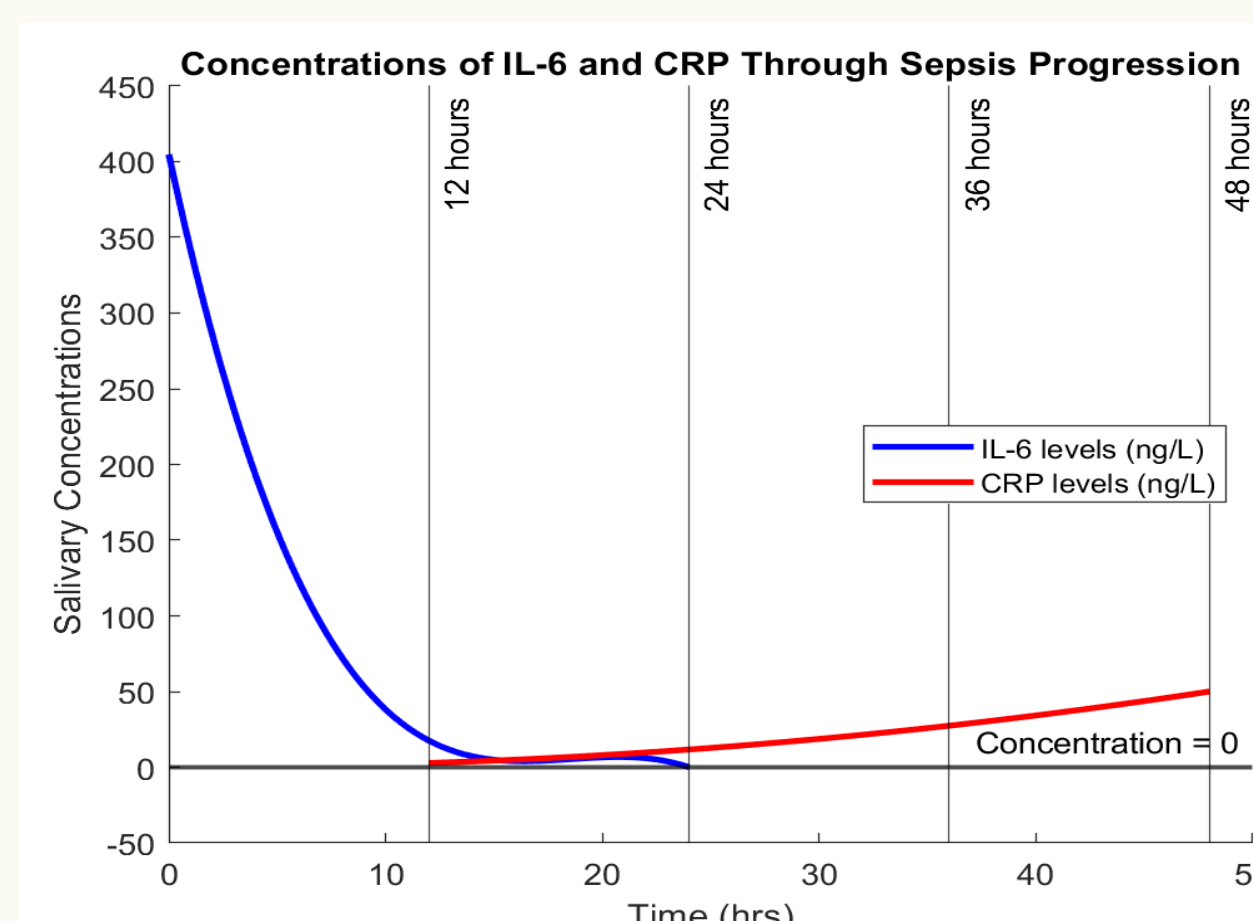
Validation Tests Performed:

- Testing different color concentrations to ensure sensor can distinguish biomarker levels
- Comparing three replicates of each strip to ensure reliability of sensor
- Testing number of steps and test turnaround time

PRODUCT SPECIFICATIONS

Customer Needs	Target Metrics
Faster test turnaround time for early detection	15-20 minutes
Small sample volume from a non-invasive source	1.0 mL of saliva
Cost effective for frequent testing	\$15 per test (\$300 device)
Accurate reading to minimize sepsis-related deaths	C statistic of .9+

TECHNICAL MODEL



The figure on the left portrays IL-6 (early marker) and CRP (late-stage marker) concentrations through the sepsis disease progression. Modeled from literature values in sepsis studies.

This model is used to provide an accurate reading of the patient's current progression of sepsis.

COMPETITIVE ANALYSIS

Target Specifications	Blood Culture	Protein microarray chip	Multiplex PCR	inSEPSStigator
Test results within minutes	✗	✗	✗	✓
Minimal training required to run test	✓	✗	✗	✓
Minimal invasiveness	✗	✓	✓	✓
Low sample volume required	✗	✓	✓	✓

MARKET ANALYSIS

Global Sepsis Diagnostics Market	\$615.4 million in 2021 ⁴ CAGR: 9.6% ⁴
US Sepsis Diagnostics Market	\$212.4 million in 2021 ⁴ CAGR: 7.6% ⁴
Our Market	\$51 million

DESIGN VERIFICATION AND VALIDATION RESULTS

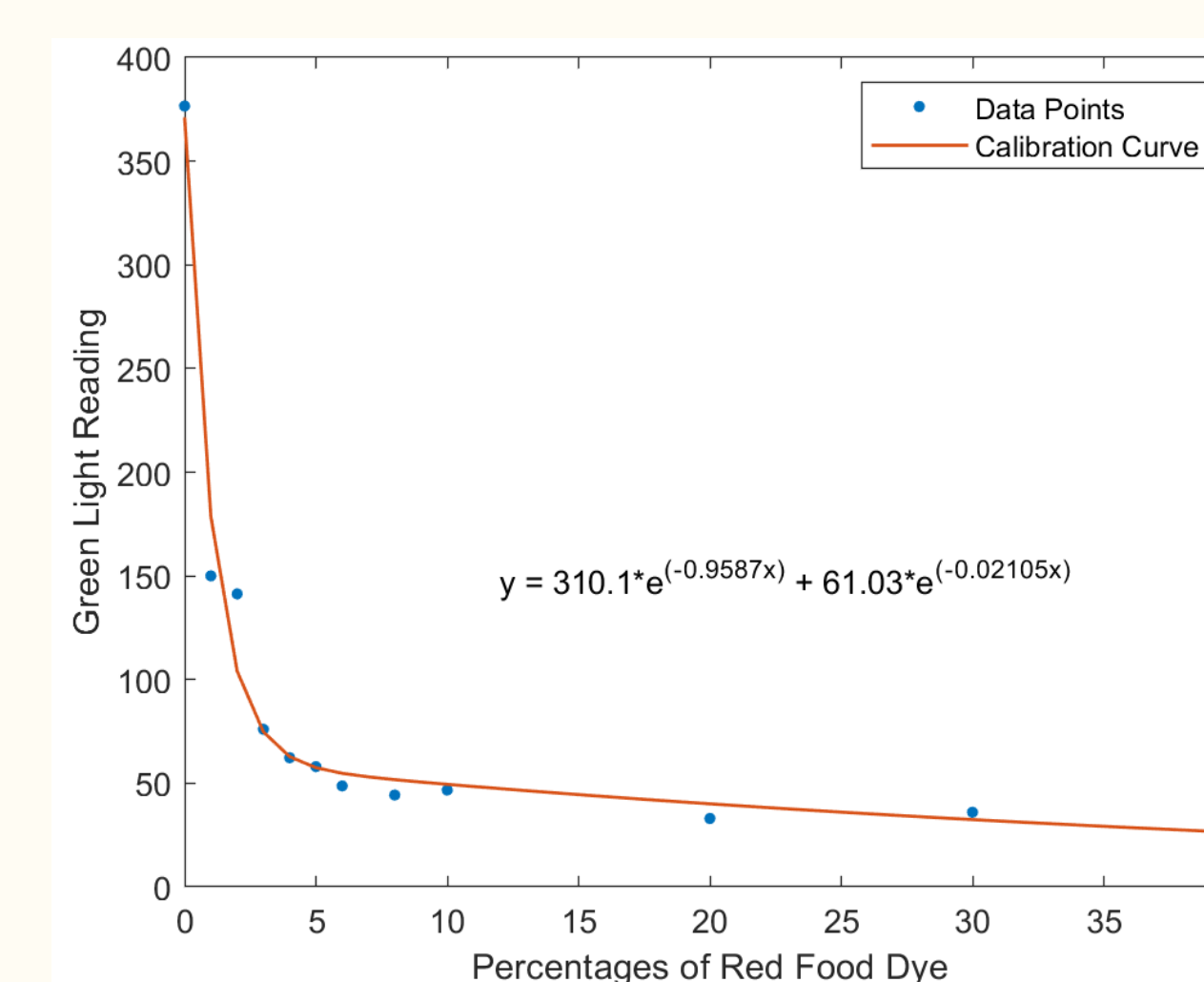


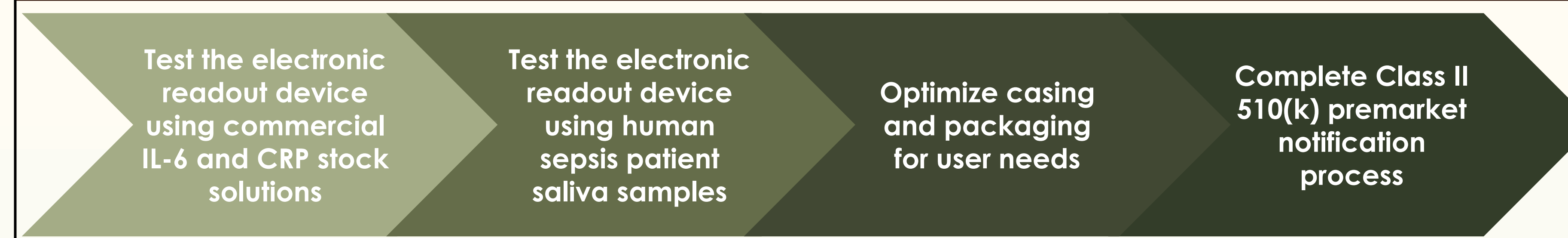
Figure 1: Calibration curve showing the obtained absorbance values of a green LED light shined through a test strip saturated in red food dye with concentrations ranging from 0-40%.

Analysis of Replicate Tests

Trial	Reject null	p-value
1 and 2	No	1
1 and 3	No	0.9878
2 and 3	No	0.9879

Figure 2: Validation testing to determine reliability of the device to give the same result given the same input. Each strip with varying dye concentration was measured three times and the difference between the replicates was analyzed. No significant difference was found.

FUTURE DIRECTIONS



ACKNOWLEDGEMENTS

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- [2] "About Neonatal Sepsis - Minnesota Dept. of Health," <https://www.health.state.mn.us/diseases/neosep/basics.html> (accessed Nov. 11, 2022).
- [3] C. Fleischmann et al., "Global incidence and mortality of neonatal sepsis: a systematic review and meta-analysis," *Arch Dis Child*, vol. 106, no. 8, pp. 745-752, Aug. 2021, doi: 10.1136/archdischild-2020-320217.
- [4] "Sepsis Diagnostics Market Size, Share & Trends Analysis Report By Product (Assay Kits & Reagents, Blood Culture Media), By Technology (Microbiology, Immunoassays), By Pathogen, By Method, By End-user And Segment Forecasts, 2022 - 2030," *Grand View Research* (accessed Nov. 16, 2022).