A New Device for Assessing Sepsis via Lactate Monitoring

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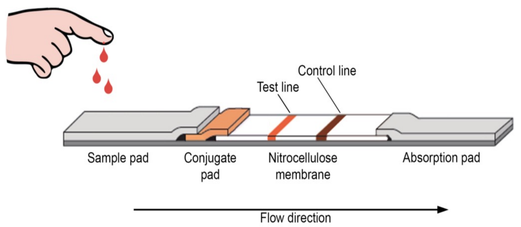
Executive Summary

- Sepsis is a potentially fatal medical illness brought on by the body's extreme reaction to infection. It can result in organ dysfunction and failure, harming the lives of patients severely. Effective sepsis treatment depends on early identification and action.
- Lactate levels in blood exhibit a marked elevation during sepsis when compared to baseline, indicating metabolic and oxidative stress. For this reason, devices are used in the ER to calculate blood lactate level.
- During my ER shadowing experience, I identified the need to improve a device for more reliable sample loading and lactate reading in emergency settings. This novel device aims to enhance sample loading and measurement reliability, using a lateral flow assay approach.



Background

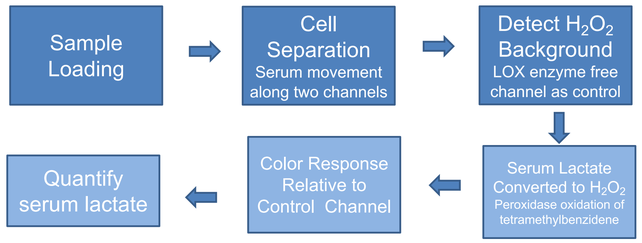
Functional requirements

- Precision in Lactate Detection: The device must detect lactate in the range of 0.5 to 20 mM (millimoles/L) with a precision of ± 0.5 mM
- Low Blood Volume: For patient convenience, the device should only require a small blood volume around 0.05ml to 0.15ml.
- User-Friendly Interface: The medical professionals should be able to use the device easily with less than 30 minutes of training.
- Filters RBC: The Pads on the Assay must filter the serum from the blood

Physical requirements

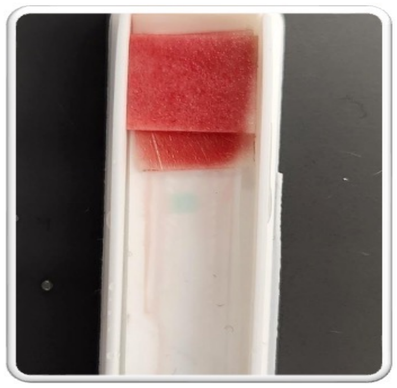
- Portability and Lightweight Design: weight < 20 grams.
- Sample Throughput: In order to meet the demands of high-volume clinical settings, the device should have a throughput capacity of at least 10-20 samples per hour
- Efficient Sample Handling: The system should minimize workflow disturbance and delays by enabling the loading of blood samples in under 2 minutes.

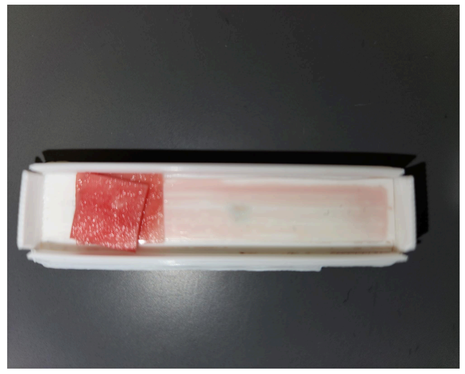
Experimental Setup



- The system is developed with three main aspects in mind: serum separation from loaded blood samples; enzymatic generation of hydrogen peroxide from serum lactate; and quantifying the serum lactate.
- In the initial stages, blood is supplied via syringe port to our device.
- Serum then travels along two parallel but distinct channels of which one has adsorbed lactate oxidase and the second blanks channel serves as a control.
- Lactic acid present in the sample is converted to hydrogen peroxide and a colorimetric signal generated by oxidation of tetramethylbenzidine via peroxidase
- The observed color is directly related to the lactate in the blood sample
- The color intensity allows quantification of the lactate concentration by comparison with a standard curve of known lactate concentrations.

Results

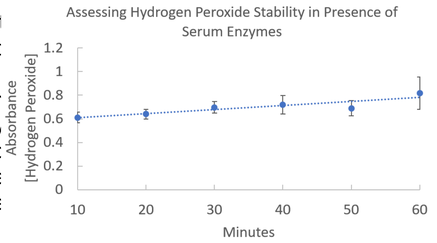


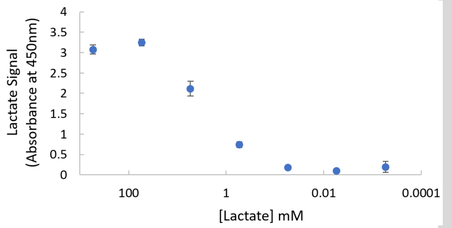


- Blood introduced into the port wicks down the test strip.
- Color change to blue occurs at the site of the immobilized enzyme.
- RBCs separate from the serum in the sample pad.

Experimental Results

- Our project has so far achieved a significant milestone as we determined the dynamic working range of visual detection in our model.
- Using the lactate oxidase mechanism in conjunction with the colorimetric readout by tetramethylbenzidine oxidation showed this to be within the clinically relevant lactate concentration needed for determining the severity of sepsis.
- We anticipate our innovative approach will facilitate accurate and efficient lactate monitoring to be useful in an emergency healthcare setting
- We also assessed the detection limit of lactate possible using the lactate oxidase enzyme for generation of H_2O_2 by oxidation of lactate.
- We also assess the theoretical working dynamic range of this detection approach by looking at the response as a function of lactate concentration.
- We can visually see a response between 20mM to 0.5mM which is suitable for detection of sepsis which is considered for [lactate] > 2mM





Conclusions

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Acknowledgements

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