Lyophilization of LAMP Reagents for COVID-19 Point-of-Care Saliva Test

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Abstract—**COVID-19 point-of-care (POC) testing is critical in low income, developing countries in order to mitigate the harmful health, social and economic effects on already vulnerable populations. The lyophilization of reagents will aid in the development of a disposable, single use point-of-care testing device. Reagents contain a variety of components, including enzymes and need to be refrigerated in order to keep enzymes active. Lyophilization will eliminate the need for refrigeration, which may not be available in rural areas of developing countries.**

Keywords: SARS-CoV2, COVID-19, Point-of-care testing, lyophilization

Project Description

COVID-19 poses a major threat to global public health. Many developing countries are still lacking access to vaccines and are being overwhelmed with the spread of the virus and surge in the number of confirmed COVID-19 cases. Current standard diagnostic methods are inadequate for widespread testing in developing countries as they require prolonged turn-around times and mostly rely on laboratories, expensive refrigeration and trained technicians. Point-of-care (POC) tests have the potential to vastly improve healthcare by allowing for earlier detection, easier monitoring of disease and being able to reach more remote, low-income populations.

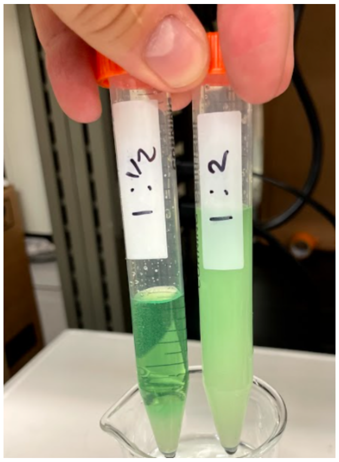

Figure 1: Multiple formulations of varying sugar concentrations were used to determine which concentration of sugars yielded the best crystal structure that would rehydrate most quickly.

LAMP Diagnostic Assay is a loop-mediated isothermal amplification (LAMP) assay intended for the qualitative detection of RNA from SARS-CoV-2 in saliva samples. Reagents include nucleotides, enzymes, primers, probes and 4 biomarkers. Because the reagents include biological components they are required to refrigerate at very low temperatures. To eliminate the need for refrigeration, reagents will be lyophilized, a kind of freeze-drying technique.

One of the key goals of the lab is to lyophilize the reagents into pellets that can be rehydrated with fresh saliva well enough to run a LAMP reaction. To better determine the appropriate formulation that will result in best structural integrity and rehydration, various experiments were done to analyze the crystal structure, as well as, time and volume of liquid needed for complete hydration based on various sugar concentrations. Anticipated outcomes include building a machine learning model that can classify images of various crystals before, during and after the process of rehydration.

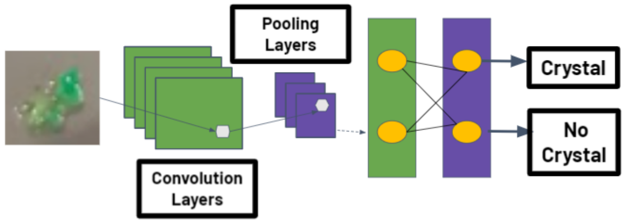

Figure 2: Block diagram of the classification model to be used to classify images of crystals compared to images of rehydrated crystals.

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