

COVID-19 Monitoring Plan

Concept: As communities implement COVID-19 prevention plans, there is currently no way to monitor their effectiveness in real time. By monitoring different environmental factors, we can track how well the preventative measures are working to stop viral spread.

Purpose: Establish a monitoring program to evaluate possible SARS-CoV-2 (COVID-19) exposure and to measure the effectiveness of prevention plans.

Execution:

We will monitor 3 different areas of the community.

1. Long term monitoring of sewage.

- a. This system will test sewage samples for the presence of SARS-CoV-2.
- b. Samples can be taken at lift stations to isolate parts of a city and at the wastewater treatment plant(s) to look at the whole city.
- c. We would watch for geographic trends by comparing positive rates between multiple lift stations in a city. The initial sampling along with epidemiological metadata of the population would give us a baseline for the prevalence of SARS-CoV-2.
- d. The goal is to monitor trends over time and not look at one point in time.
- e. Sewage will potentially be positive. We do not want to react to individual positive samples but understand the trends of viral load over time and geography.
- f. Subsequent sampling would indicate whether prevention plans are maintaining a stagnant infection profile. Increases of viral load over time would indicate spread of the virus and reevaluation of prevention plans.
- g. We can also watch trends in analysis intensity to determine viral load. PCR analysis uses Ct values and a threshold to establish a positive or negative result. A higher titer of virus in the sample will be indicated by the Ct value. In sewage samples, this could indicate a higher number of cases. Further data is required to establish this correlation.
- h. Ultimately we would like to use digital droplet PCR. This analysis can quantify the number of viruses in a sample with much greater precision. If this technique is applied, routine monitoring can indicate an increase in viral load with greater confidence.

2. Monitoring of masks

- a. This system would test disposable masks used at a facility or event.
- b. Masks will collect the virus particles respired by a person.
- c. We would composite masks from an event or facility and test for SARS-CoV-2.
- d. Masks can be composited into different sections, zones, or groups of people.
- e. A positive result from an event could be used to inform attendees that they have been exposed and to self-monitor. This information will aid decision making on social distancing.
- f. Data from a facility (such as a food processor) could be used to monitor their prevention plan.
 - i. By setting up composites based on groups, the facility wide spread of the infection can be evaluated.
 - ii. e.g. - If there are 5 groups of composites and over time only 1 group is continually positive, this indicates the prevention plan is inhibiting the spread between groups. An increase in the number of groups that are positive will indicate the reevaluation of preventative measures.
- g. This system would be a way to get the public information after attending an event and provide feedback for facilities to monitor their plans.

3. Monitoring by bioaerosol analysis

- a. This system would monitor air for SARS-CoV-2 bioaerosol particles.
- b. Bioaerosol samplers would be strategically placed to sample air over a given period at a set flow rate.
- c. The samplers concentrate the bioaerosol on a filter that then can be analyzed for SARS-CoV-2.
- d. This system could be used in locations that have many people who move through and are not controlled.
 - i. schools and common areas in a university dorm
 - ii. senior care facilities, refineries, and large places of work such as warehouses and shipping centers
 - iii. public restroom monitoring could incorporate county residents that are not checked by sewage analysis.
- e. As part of a monitoring system over time we would watch for trends and not react to one positive sample.
- f. Using the same theory as the sewage analysis, we would watch PCR Ct values and could incorporate droplet PCR to quantify the virus.

What is next?

Each of these monitoring systems require data for validation. Sewage analysis and bioaerosol analysis are established techniques to monitor other viruses. However, we would want to run a few verification studies to validate the method for detecting SARS-CoV-2.

We would run a validation study for the bioaerosol analysis to establish a detection limit. An initial verification can be run on the bioaerosol sampling by placing a sampler in a room with a known positive SARS-CoV-2 patient. If the initial verification is positive, we then know that the collection method works, and the detection limit study would then give us the necessary information to establish a sampling time.

For the sewage analysis we would like to run an initial demonstration of capability study by spiking a sewage sample with a known surrogate virus. This would allow us to verify that the method we have chosen is working properly.

The testing of masks is new, and has no historical data. There has been analysis to look at the effect of masks, but we have not found a study that is using masks to monitor infection. The theory is that masks will collect the virus. The virus would be extracted from the masks, concentrated, and then analyzed. We will composite masks to efficiently monitor small groups or subsets of groups. To implement this program, we would need to run a spike recovery study on one mask to evaluate the extraction method. Then we would run a detection limit study by mixing a spiked mask with known unspiked masks. This would allow us to set a composite limit, so that we could see one virus positive mask in a set number of masks.

To analyze samples for quantitation of virus load we would need to purchase a droplet PCR unit. This unit costs around \$85,000. We could use our current PCR units to establish protocols and run feasibility studies. If there is need for quantitation, a droplet PCR unit can be discussed for purchase.

What we are currently doing.

To ensure the safety of our people, we have decided to bring in a separate extraction area. We are a biosafety level II facility and can handle SARS-CoV-2 environmental samples. The CDC advises to have a biosafety level III safety system in place. This means unidirectional airflow and a way to handle personal protective equipment. By bringing in a separate building we can build it to the specifications needed to handle the extra safety precautions. This unit, biological safety hood, and stainless cabinets will take a few weeks to get into place. We will be placing a UV light in the building to sanitize the area after usage.

We are getting a surrogate virus to begin studies to determine detection limits, extraction procedures, and method verification. We are working with Texas Tech University and NC State University on these protocols.



1355 Pacific Place
Suite 101
Ferndale, WA 98248
phone: 360.733.1205
fax: 888-818-2978
email: lab@exactscientific.com

What we are looking for.

We are looking for partners, both financial and to acquire samples. We are working on grants for financing, but the first grant opportunity may not be until October. If there are financial opportunities for support, please keep us in mind. We are willing and have spent a significant amount to get to where we are, but to move this forward we will need more. We will also need sampling partners. We will need to work with municipal governments, private companies, health officials, and healthcare providers to acquire the samples and metadata necessary to understand how our system is working and how the virus is, or is not, spreading in our communities.

The end goal is to have a system in place to monitor the spread and prevalence of SARS-CoV-2, evaluate the systems that have implemented, and monitor their effectiveness. We want everyone to have the ability to move freely through our community knowing that we are trying to prevent a widespread outbreak. There are too many people we know who are at home isolated from employment, family, social gatherings, and daily life. The current evaluation process is to watch for an outbreak based on testing people who already are infected. By putting a system in place to monitor the environment, we can get ahead of infecting more people and hopefully allow more freedom faster.