

Group Sense Solutions COVID-19 Testing Program

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Statement of Purpose

We provide a streamlined system for COVID-19 testing using the most sensitive RNA-based assay found in academic and CORE research labs, Droplet Digital PCR (ddPCR). Our system is engineered to solve the problem of testing asymptomatic populations accurately, frequently.

The world is in unique and unprecedented times. We understand that your needs as a business or community are unique and evolving. We will help craft a customized strategy that fits your needs and can adapt as circumstances require. Our main purpose is to help your organization develop a custom-tailored strategy that balances your unique needs with respect to key components of testing program design:

1. Throughput-How many tests that can be processed in a given amount of time.
2. Sensitivity/accuracy-Not all tests are created equal.
3. Predictable result delivery-If labs results are not timely the information may not be useful. Lab and health systems are stressed. Large clinical diagnostics companies are not always meeting timing demands.¹
4. Cost/Resource Utilization: Our group/pool testing strategy can help drive efficiency in this regard.
5. Time savings- After being shipped overnight or same-day, tests are immediately carried out. The same lab personnel testing your sample uses our system to notify you about results as they are read off the machine. Unnecessary steps are eliminated.

How Do We Achieve These Goals?

- Specimen tracking from collection to result delivery utilizing our customizable HIPAA compliant software system
- Ease and comfort of self-administered saliva sample collection: Minimizes need for additional collection sites and staffing.
- We have partnered with several of the most innovative medical center core molecular biology labs in the country to deliver these lab testing services.
- We have partnered with BioRad Inc. to deliver the highest sensitivity PCR system in the world for the most sensitive results available.

¹ <https://www.cnbc.com/2020/07/13/us-coronavirus-surge-leads-to-testing-delays-across-the-nation-quest-diagnostics-says.html>

COVID-19 Testing Program Outline

Our COVID-19 testing program is operationalized by our app and data system. The app has portals for patients, medical staff/coordinators and the lab personnel performing the tests. It keeps track of sample inventory, manages laboratory information and reports results.

Step 1: Saliva collection kits are labeled with randomly generated QR codes and delivered to your location.

Notes:

- Saliva collection kits are for self-administration.
- Kits are designed to deactivate preserve specimens for months without refrigeration. They will easily withstand transportation to labs.
- After kit is sealed, it can be safely handled without risking exposure.

Step 2: Identifying information and sample information including the test result are stored on two separate databases. This guards patient identity and is **HIPAA compliant**.

Step 3: Each person produces a saliva specimen and brings it to the site coordinator. Specimens are shipped to our partner research lab.

Step 4: Sample tubes are scanned by lab personnel using our app. The app will then generate instructions for your test method of choice.

1:1 tests: Each sample is assayed on its own for a test that is ~20x more sensitive than qPCR tests that are typically used by large commercial diagnostic

2-stage group testing: The samples are combined into pools for group tests. If the prevalence is low, this uses 45%-80% less test kits than 1:1 testing. Group testing algorithms are designed using current mathematical literature and sensitivity specific to ddPCR.

Person/Workforce Scale Logistics

