CoviDetect

Automatic COVID-19 Testing Solution

ENGR 180 Project

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Background

After mass lockdowns and closures of public places such as schools, offices and shops due to the COVID-19 pandemic in 2020, we begin to observe full or partial reopenings in the US and across the world. Meanwhile, testing requirements have been widely implemented to reduce the risk of transmission. For instance, schools may require their students and faculties, and companies may require their employees to accept COVID-19 tests regularly if they wish to be on site. Negative testing results are also often enforced for domestic and international travels. So, we realize that there exists a huge demand for COVID-19 testing services right now and in the foreseeable future. However, conducting a convenient test directly on site requires a complicated system with expensive fixed assets and experienced labors, an unworthy investment for small or medium sized organizations. While they may ask their people to accept tests on their own, it leads to higher variable cost, more inconvenience and reliability concerns. Thus, they may benefit from a general testing solution that enables low fixed and variable cost, on-site convenience and reliability at the same time.

Description

We plan to construct an unmanned COVID-19 testing solution. Our main customers are organizations such as governments, schools, companies who want to provide affordable, easy and reliable testing services to associated people such as local citizens, students and employees. Upon agreement, we install our machines on customers' sites. Our machine is capable of three testing methods: PCR Swab, PCR Saliva and Antigen Swab. Sample collection is completely automatic, and no people are required on site. Antigen samples can be analyzed directly inside the machine with results available in a short period of time. PCR samples will be collected by our employees and transported to our labs for further experiments. Test results will be reported to the customer organization, and we consider our process done. We also provide software interfaces, so that we can exchange data with the customer organization, such as user authentication info and test results.

Stakeholders

We identify the major stakeholders who will be affected by our system. However, there can be some other stakeholders, mostly during the operation phase, that we may fail to cover thoroughly.

- Customers (mainly organizations such as governments, schools, companies, etc.)
- Users (those people considered part of that organization, such as students inside a school, who will be getting a test)
- Health regulators (who permit the operation)
- Suppliers (who provide mechanical parts, testing kits, etc.)
- Manufacturers (who manufacture our testing machines)
- Employees (maintenance, delivery, lab, R&D, etc.)

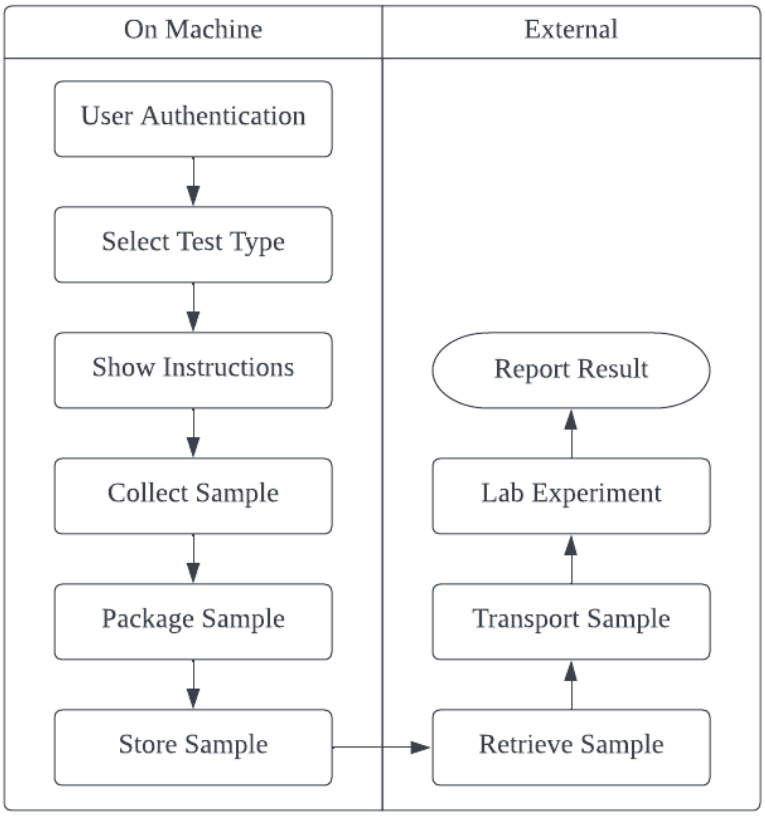
Methodology

We plan to adopt the "Vee" model in our project. In the earlier design phases, we will first break our system down into a few subsystems which perform certain functions required in operation. Each group member will be assigned one or two subsystems which will be further broken down into smaller components, with level of details allowed by time constraints. While not included in this project, we expect integration of lower level components first in the construction and testing phase, and then integration of higher level components until all subsystems are combined into the final working system.

Operating Scenario

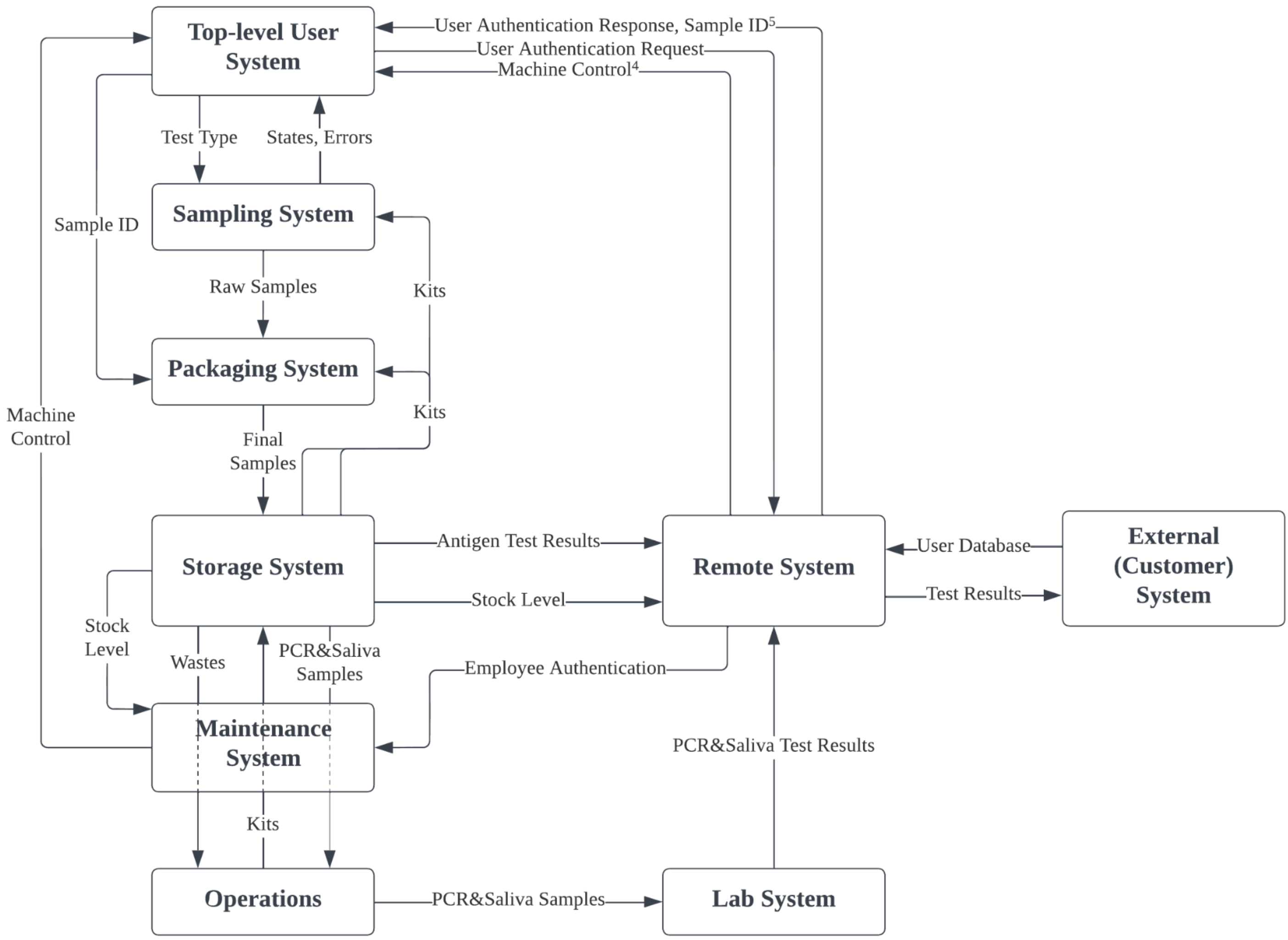
Assume that a university has mandatory weekly COVID-19 testing requirements for all students, and for accuracy the testing method must be PCR. It purchases the solution from CovidDetect and many testing machines are installed across the campus. A student walks to the machine. He taps his university ID card, and the machine recognizes his identity. The machine asks him which type of test he wants. He selects PCR Swab. The machine displays instructions and warnings. He clicks on a button to acknowledge and continue. A robotic arm gets out of the machine, grabbing a swab, inserts into his nose and moves around. The arm retracts back to the machine with the swab, and the student leaves. The sample is then safely processed, packaged and stored inside the machine. An employee of CoviDetect retrieves the sample from the machine and transports it to our lab. The lab technicians perform experiments on the sample. When the result is ready, they enter the result into our system, and the system sends the result to the university.

The following simplified FFBD shows the entire operating process (more detailed FFBDs for each function provided in the System Requirements section):



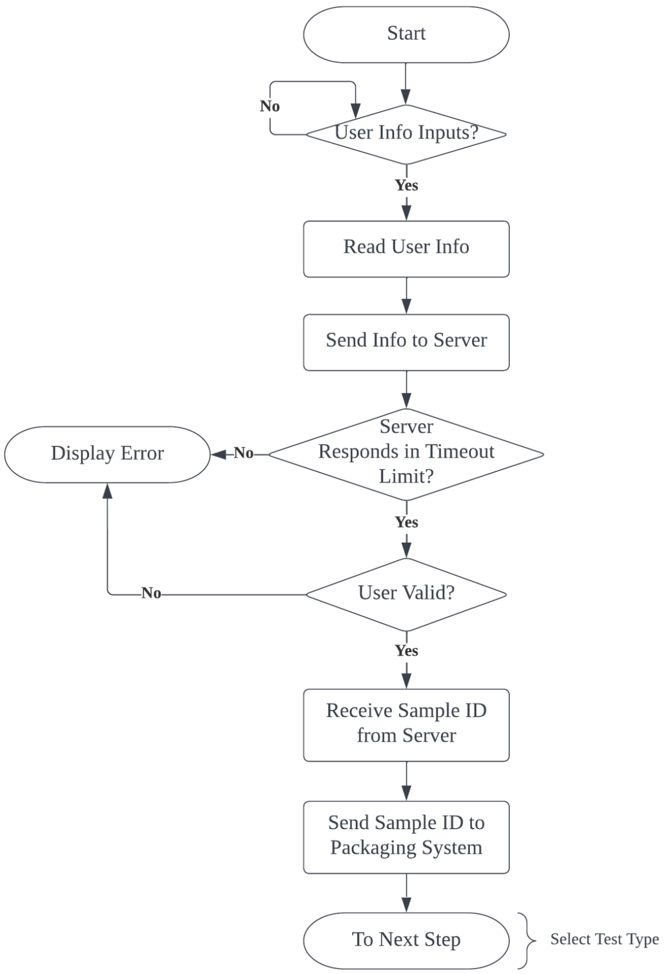
System Requirements

This section covers the major requirements of each subsystem mainly on the conceptual level and partially on the preliminary level. FFBDs for the whole subsystem or one individual component may be provided to assist the requirements. In addition, the following interface document defines the relationship between the subsystems, which helps the reader to easily track the flow of physical objects or data in operation:



Top Level User System

- **The machine must be operable in most inhabited environments around the world.** We want to maximize the range of customers with different operating conditions.
  - The machine must be able to withstand common temperatures and humidities because it may be installed or transported in various environments.
  - The machine must be able to withstand common weather conditions because it may be installed outdoors. For example, for sunny days, both casing and internal components must be able to resist UV light. And, for rainy days, the casing must be water-proof to prevent damages to components inside.
  - The machine must support various power standards. Since it may be installed in various countries or regions, it must be able to operate at different voltages, currents and frequencies without causing damage to the electrical components.
  - The machine must have reasonable physical dimensions, so that it can be easily transported and fit into limited space.
- **The machine can be used by most people without external human guidance.** We want the design to be as accessible as possible. However, requiring human guidance introduces unnecessary labor costs and defeats our purpose of creating an automatic testing service.
  - Both the front-end software and hardware must have reasonably satisfying UI and UX design, so that people who have no prior experience are still able to navigate.
  - The machine must have sufficient computing power to allow fast responses.
  - The interactive hardware components must be physically positioned correctly to be usable by people of different heights, disability conditions and so on.
- **The machine must be able to authenticate legal users.** We only want users that belong to the user group provided by the customer organization to be allowed to request a test, since unauthorized tests from outsiders will lead to unnecessary test costs paid by the customer organization.

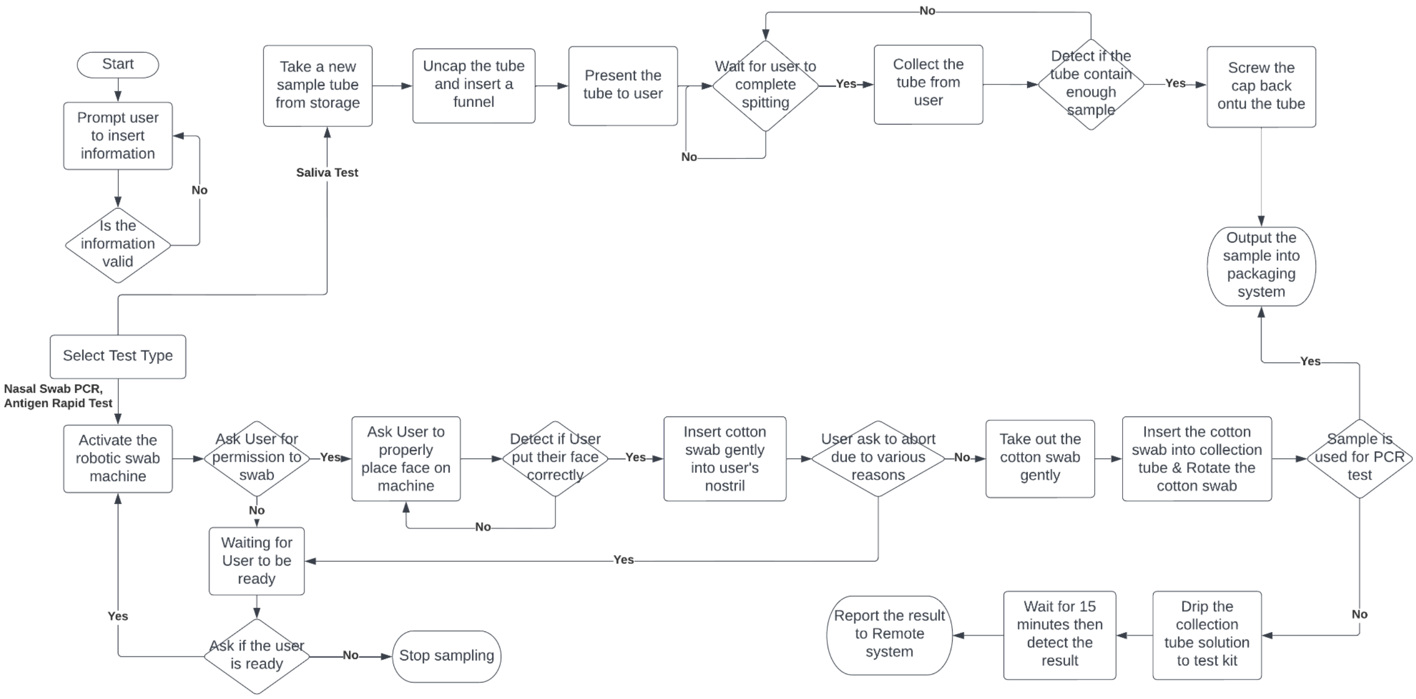


- There must be some hardware to read identifications from the user. Since the most common type of identification is a chip card, we may specifically need some hardware to read a chip card.
- After the information is read, it must be sent to the remote server through some software interface across the network, which means that our machine must be connected to the Internet. Depending on the validation response from the server, the machine must either proceed to the next step (test type selection) or reject.
- The unique sample ID received from the server must be stored for later use, which means we need memories inside our hardware.

- **The machine must allow the user to select a test type.** There are three types of tests available: PCR Swab, PCR Saliva and Antigen Swab.
  - The machine must have some hardware to accept inputs from the user.

  - Upon selection, the corresponding procedures for the next step (display test instructions) must be invoked depending on the test type selected.
  - The user system must also be capable of communicating with the sampling system through some internal software interface to send the test type selected, so that The sampling system could also invoke the right sampling procedure afterwards.
- **The machine must convey test instructions to the user.** We expect the user, mostly inexperienced, to follow certain requirements to ensure that the test is conducted effectively and safely, so we need to convey necessary information to the user before and during the testing process.
  - The machine must have a reasonably large and clear display to show visual information.
  - The machine must have a reasonably clear and loud speaker to convey additional sound information.
  - The user system must accept real-time feedback from The sampling system through some internal software interface during the testing process. Depending on the feedback type, we must notify the user with visual and sound information, so that he or she realizes instructions are not being allowed correctly and make adjustments.
- **The system must be able to communicate with the Packaging System.**
  - There must be some internal software interface between the user System and the packaging system. The unique sample ID stored earlier must be sent to the Packaging System so that it can tag the sample correctly.

Sampling System



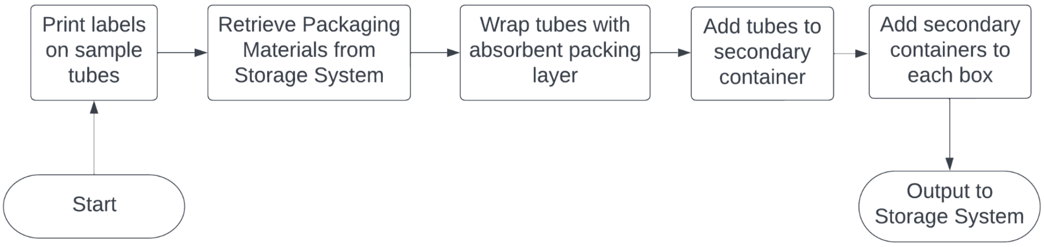
- **The sampling system must be able to communicate with the storage system and packaging system.** We want to deliver test kits from the storage system to the sampling system and provide kits to users.
  - The sampling system must be able to take test kits out from the storage system using a conveyor.
  - The sampling system must be able to output the cotton swab to the packaging system after sampling.
  - The sampling system must be able to output the saliva collection tube to the packaging system after sampling.
- **The sampling system must be able to perform tests safely and properly on users.** We want to perform three types of tests on users, in which two are nasal swabs and one is saliva collection:
  - The general requirement of a robotic arm
    - The sampling system must have a robotic arm that can move freely, including vertical directions and horizontal directions.
    - The robotic arm should be built with strong material so that the arm can't break easily.
    - The robotic arm should have agile mobility and never be stuck so that it can provide stable and consistent service all the time.

- Nasal swabs
    - The robotic arm must be able to tightly hold the cotton swab.
    - The sampling process must be gentle and slow so that the user will not feel uncomfortable.
    - The sampling system must be able to abort the nasal swab process whenever the user presses the abort button.
    - The sampling system must be able to rotate the cotton swab gently while the swab is inside the nostril.
- Saliva collection
    - The sampling system must be able to unpack and take out the saliva collection tube and give it to the user.
    - The sampling system must be able to measure if the saliva in the tube contained is enough.
    - The sampling system must request the user to spit more if the saliva in the tube is enough.
    - The robotic arm must be able to hold the test tube with a specific hole after the user has completed it.

- **The sampling system must be able to detect human faces and the position of the nose.** The system must use camera sensors to locate the user's nose position.
    - The sampling system must have a camera sensor component to detect the location of the user's face.
    - The sampling system must be able to accurately and precisely locate the position of the user's nose and its distance to the machine.
    - The sampling system must be able to direct the robotic arm's movement using the camera sensor's detection output.
    - The sampling system must be able to guide the users to move their position if the machine can't perform the test due to the users' position.
- **The sampling system must be able to communicate with the top-level user system.** The top-level user system directs which test the sampling system performs and the sampling system signals to the top-level user system any problem generated during the sampling process.

  - The sampling system must be able to respond to the top-level user system's test selection by providing one of three tests: automatic nasal swab PCR test, automatic rapid antigen test, and saliva-based PCR test.
  - The sampling system must be able to signal the top-level user system of any error or problem, including the user feeling uncomfortable or the robotic arm getting stuck.
- **The sampling system must be able to properly transfer a raw sample to a collection tube.** The sampling system should output collection tubes that contain saline solution to the packaging system.
  - The sampling system must be able to insert the cotton swab into the collection tube after the nasal swab.
  - The sampling system must be able to rotate the cotton swab while the swab is inside the collection tube solution.
  - The sampling system must be able to release and dispose the swab into the storage system garbage collection after the above processes.
- **The sampling system must be able to complete an antigen rapid test.** The sampling system should use the collection tube solution to perform an antigen test and report the result later, after raw sample transfer.
  - The sampling system must be able to hold the collection tube using the robotic arm.
  - The sampling system must be able to drip a drop of collection tube solution onto the antigen test kit.
  - The sampling system must be able to detect the read on antigen test kit after enough time.
  - The sampling system must be able to report the reading result of the antigen test to the remote system.
  - The sampling system must be able to release and dispose the collection tube and antigen test kit to the storage system garbage collection after the above processes.

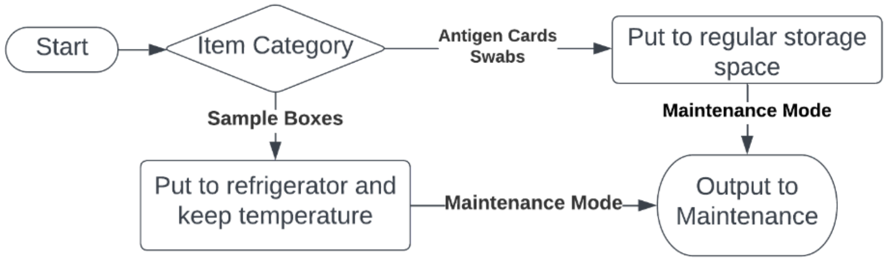
Packaging System



- **The packaging system must have enough space to store all samples.** We want to make sure the packaging system can have space to temporarily store the samples during high and low testing requests so that all the samples are delivered to the lab system.
  - The packaging system must have appropriate dimensions. The box dimension should be appropriate. It cannot be too small because there will not be enough space for the samples under high testing requests, and it cannot be too large because it will create extra waste and inconvenience for logistics.
  - The packaging system needs enough packaging materials. The materials should have enough physical strength to hold the sample tubes.
- **The packaging system must have clear labels on samples collected from the sampling system.** The packaging system needs to label the samples received from the top level user system so that the test results can be returned correctly back to the users and communicate with the lab system.
  - The packaging system must place the correct ID on the surface of sample tubes collected from the sampling system.
- **The packaging system must have clear labels on packages that collect batches of sample tubes.** The packaging system needs to label the samples received from the top level user system so that the test results can be returned correctly back to the users.
  - The packaging system should have testing type labels on the packaging materials surface, for example, the labels on the boxes, so that the labels are visible to staff responsible for logistics and lab tests.
  - The packaging system should have the correct numbering. Correct number creates convenience for tracking the missing boxes or statistical needs.

    - The packaging system should have the contact information printed on the front of the package. This helps to find the correct responsible staff for the packaging.
- **The packaging system must satisfy sanity and safety standards.** If the packaging system does not meet the sanity standard, the samples get contaminated and invalidated for the test. During transportation, if there are possible risks of the spill, the packaging system must meet safety standards to prevent the samples from spilling onto the transportation vehicle. It prevents further risks of drivers or staff being infected by the COVID positive samples.
- **The packaging system should have temperature and humidity control.** If the test samples are provided in hot summer, the biological contents of samples may change due to temperature increase. The packaging system should control the temperature and maintain the sample quality.

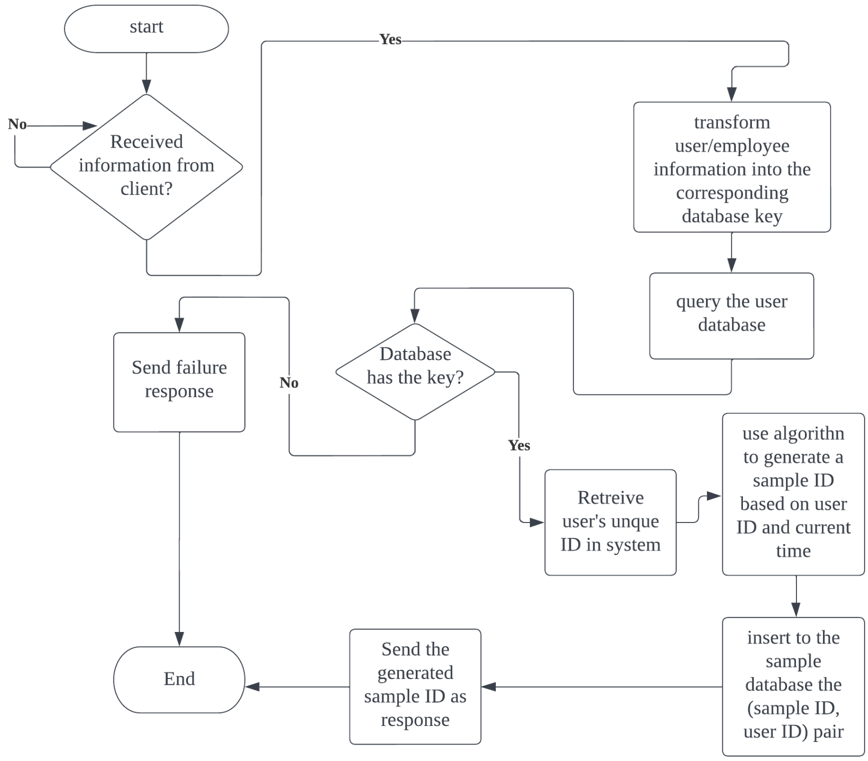
Storage System



- **The storage system must have the appropriate condition to keep the samples uncontaminated.** We want to make sure the storage system provides the appropriate environment to temporarily store the samples before they are output to the lab system.
    - The packaging system must have an appropriate temperature. If the temperature is moderate or too high, the virus may denature and the test results may turn wrong. We need to keep the storage temperature low in order to keep the quality of samples unchanged.
- **The storage system must arrange samples in the order of time arrived.** The samples in the storage system must be arranged and labeled in the storage system so that the samples that arrive first get collected with higher priority if needed.
- **The storage system must meet sanity and safety standards.** Incorrect operation may lead to the spill of test samples. The storage system must have safety measures to prevent such accidents from happening accordingly.
    - The staff working in the storage system must have personal protective equipment.
    - The storage system must have measures to deal with emergency situations.
- **The storage system must store the wastes generated from the sampling system.** It must communicate with the sampling system, where wasted swabs from the nasal PCR test and antigen test cards are generated.
    - The storage system must have enough space to store the wastes.
    - The storage system must have safety and sanity standards to store the wastes. This prevents the workers working with wastes from infecting the COVID positive samples.

Remote system

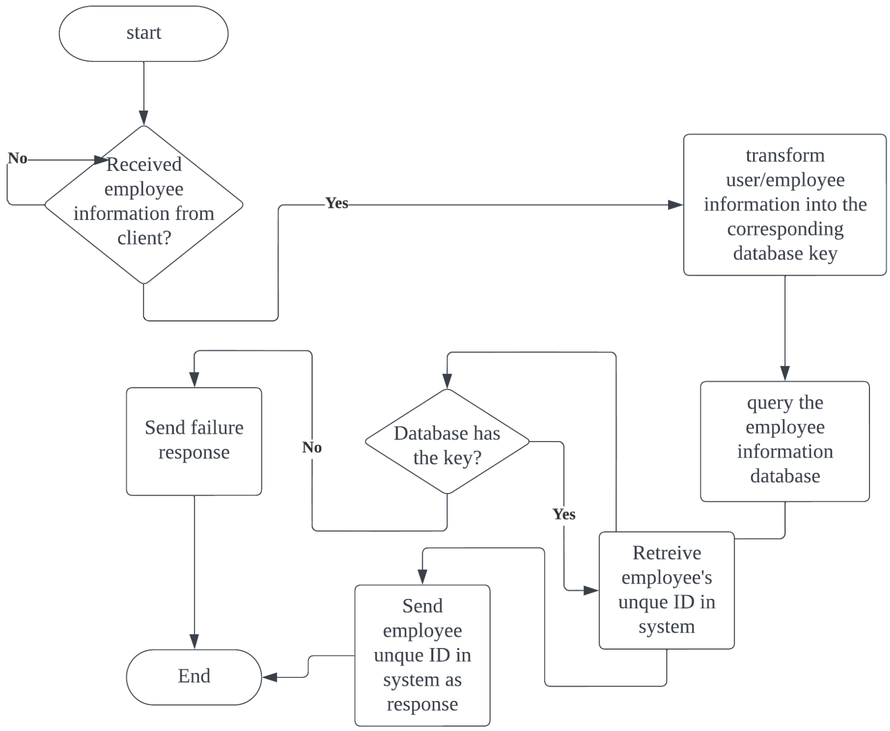
- **The remote system must be able to generate a sample id for the user when user information is received from the top-level user system.** This could provide a convenient way to easily identify the sample among all samples and establish the correspondence between sample and user.



    - The remote system must be able to convert the user information to a unique user ID in the system.
        - The existence of a user should be recorded.
        - The conversion must be the same at any time, i.e. the same user information will always generate the same user ID.
        - Send error messages when user information is invalid.
    - The remote system must be able to generate a unique sample id that cannot be the same as any other sample that existed at the same time.
    - The remote system must record the matches between sample ID and user ID.
    - Send the generated sample id back to the top-level user system.
- **The remote system must be able to retrieve employee ID given employee information received from another system.** This could provide a convenient way to

uniquely identify the employee in the system and verify whether an employee is valid or not.

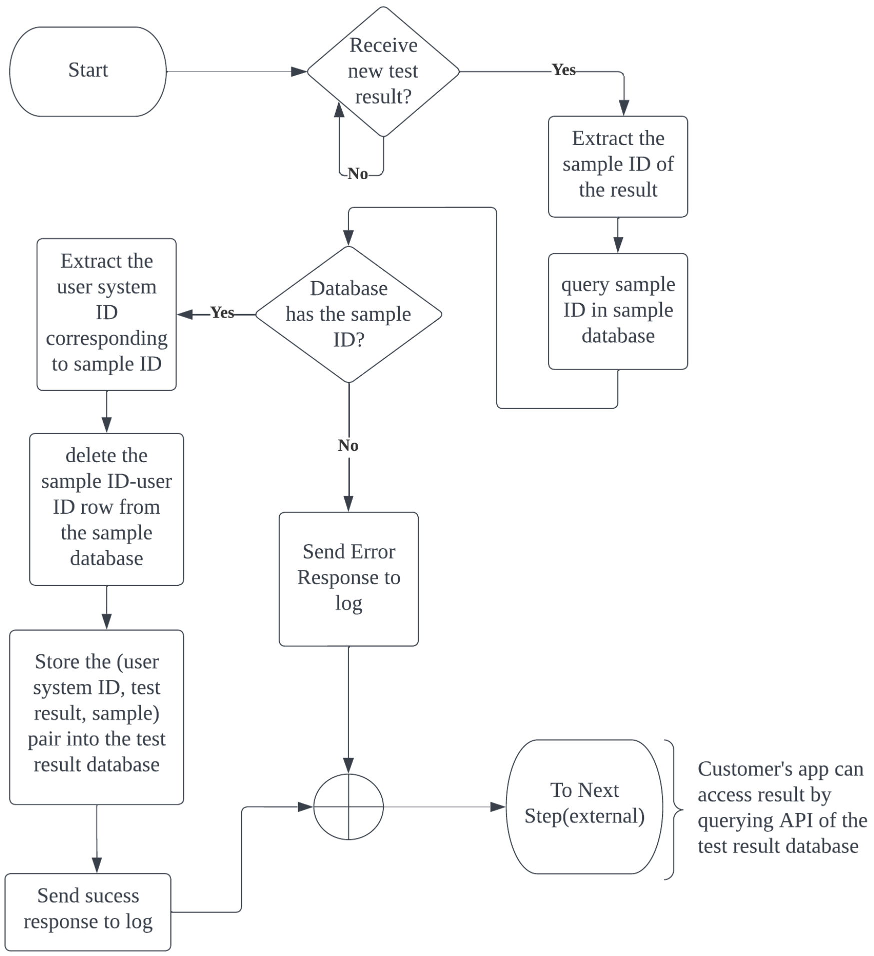
- The remote system must be able to convert the employee information to a unique employee ID in the system.
  - The existence of an employee should be recorded.
  - The conversion must be the same at any time, i.e. the same employee information will always generate the same user ID.
  - Send error messages when employee information is invalid.
- Send the employee ID back to the other system.



- **The remote system must have an interface for the outside system to access a user's test result given the user ID.** This provides an easy way for authorized personnels or external systems to access the test result without actually having to know how it functions.
  - The remote system must be able to match samples' test results received from the lab system to the user ID.
    - Each test result should contain the corresponding sample id.
    - The remote system must be able to look up the user ID by sample id.
    - The remote system must record the new match between user ID, test result, and sample id.

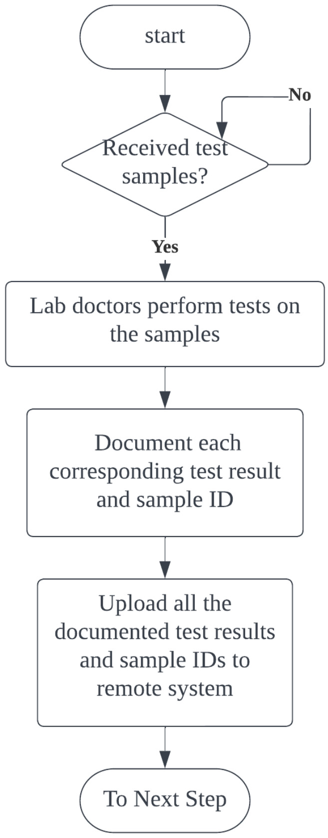
- ○ The remote system must be able to locate all test results of a user by user ID.
- ○ The remote system must be able to return the test result found to the external system requesting it.

- **The remote system must have an API for the outside system to access the stock level of test kits.** This helps the maintenance team to know when to refill the test kits based on stock level.
    - ○ The remote system must be able to record the stock level update received from the storage system.
    - ○ The remote system must be able to return the stock level to the outside system requesting it.

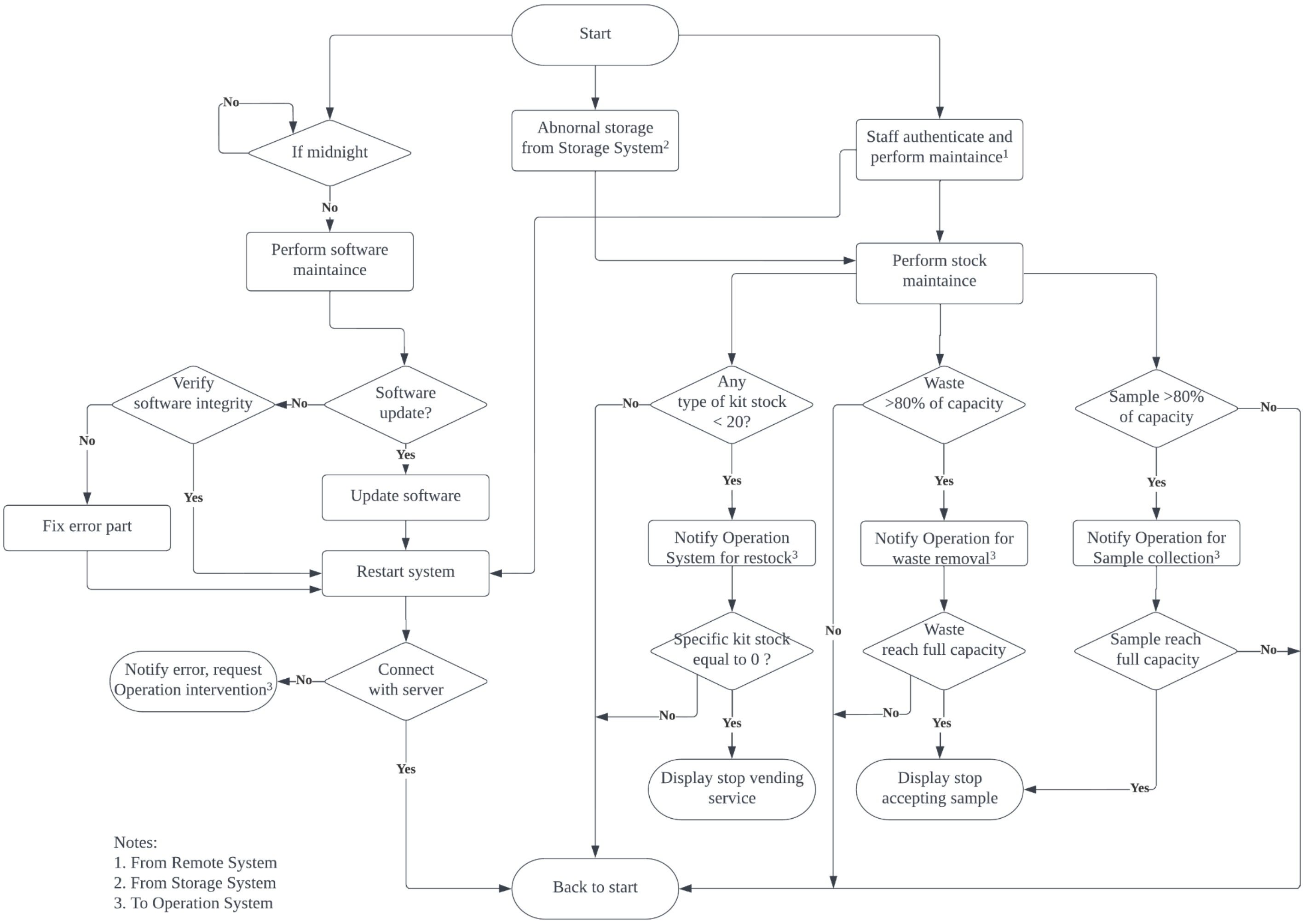


Lab System

- **We must perform experiments on the samples**. We can only know whether a person has COVID-19 or not through positive/negative results of experiments.
    - Lab technicians and equipment are required.
- **Report the corresponding test result to each sample to the remote system.** This is useful for subsequent matching between the test result and the user at the remote system.
    - The physical lab must have access to the sample id of each sample.



Maintenance System



- **The system's software must be able to be updated quickly and conveniently.** We want to let developers conveniently apply new features to the software and minimize the downtime caused by updates.
  - The machine must be able to communicate with the remote system per day to find if an update is available.
  - The machine must be able to download and apply an update if the remote provides an available update.
  - The machine must not apply an update if a user is using the system.
  - The machine must restore to the previous version of the software if the update is not successful.
  - The remote system must communicate with the updated machine to check the machine is back online after the update.

- **The Maintenance System must notify the remote system if the storage capacity is over 80% of the designed capacity.** We want to make sure the garbage and sample storage system can be emptied and proceed with service before they get fully filled.
    - The machine must have an easily accessible maintenance door for sample and garbage collection.
    - The machine must have a capacity update from the storage system and notify the remote system when needed.
    - The capacity monitor must be reset after maintenance.
- **The Maintenance System must notify the remote system if any testing kit capacity is below 20% of the stock.** We want to make sure any testing kits can be restocked before none of the kits are available for vending.
    - The machine must have an easily accessible maintenance door for restocking.
    - The machine must have a stock update from the storage system and notify the remote system when needed.
    - The capacity monitor must be reset after maintenance.
- **The Maintenance System must get authentication from the remote system to verify the identity of maintaining employees.** We want to make sure only authorized people can maintain the system.
    - The machine must only open the maintenance door for maintaining employees when the authentication is successful from the remote system.
    - The machine must only display the software maintenance window for maintaining employees when the authentication is successful from the remote system.

Operation System

This so-called “system” in the end is intended to cover some additional operating scenarios of our overall system, especially during the official operation phase after debut, that are not covered by other major subsystems. Thus, it may be more on the business and creative side, which focuses on scope instead of depth. However, due to time constraints it is still impossible to cover every aspect of our business.

- **There must be a repair system for our machines.** The repair system is responsible for analyzing and fixing machine problems as soon as possible.
  - There must be a training program for repair workers.
  - Work licenses or certificates are required for certain skills.
  - An after sales customer service team is required to record customer requests.
- **There must be a sales system responsible for selling our solutions to potential customers.**
  - A prototype machine must be manufactured before obtaining permission from regulators or getting funds from customers, since it will make our product more convincing and impressive than just a simple idea.
- **There must be a system responsible for performing daily maintenance tasks on our machines.**
  - Kit refill: setting up a delivery system to deliver test kits from our warehouse to each testing machine.
  - Disinfection: setting up a system system to disinfect our machines regularly to prevent risk of spreading viruses.
  - Health check: setting a system to detect workers who are potentially infected to prevent contaminating the machines. For instance, workers may be required to fill in a survey about their health status.
- **There must be a system responsible for maintaining our relationship with suppliers.**
  - A team of experts is required to select the best suppliers and manufacturers and negotiate with them.
  - A system is required to conduct quality control on our test kits and testing machines.
- **There must be a transportation system between testing machines and the lab.**

    - The transportation must keep the samples in safe conditions on the way.
    - The transportation must deliver the samples on time to prevent the samples from expiring.
- **A law team may be required** to analyze the legal risks associated with our business, and handle potential lawsuits with customers, users, suppliers and so on.

Risk Analysis

This section analyzes the major technical risks associated with each subsystem. For each risk item, a rating on its possibility between 1 (very unlikely) to 5 (very likely) is given with some reasoning. Similarly, a rating on its severeness between 1 (unimportant) to 5 (catastrophic) is given with some reasoning. In addition, a possible solution on the implementation level is suggested, which may help mitigate or avoid the issue, if applicable.

Top Level User System

Risk	Possibility	Severeness	Solution
Vandalism	3; machine may be installed in both safe and unsafe places with various crime rates	2; may cause minor or medium damage to hardware, which makes machine inoperable and requires part replacements	Enforced exterior design and manufacturing; add alarm mechanism
Unusual weather conditions (e.g. heavy rain)	3; occasionally happens in all places	2; may cause minor or medium damage to hardware, which makes machine inoperable and requires part replacements	Add water-proof, thermal insulation and other common capabilities
Natural disasters (e.g. earthquake)	1; unlikely to happen in most places	3; may cause serious damage to hardware, which makes machine inoperable and requires replacement of entire machine	Not worthy for additional concerns given low possibility and infeasible cost
Display failure	2; LCD screen has long lifespan and little burn risks	2; machine will become inoperable, requires screen replacement	Use LCD display from reliable suppliers instead of OLED
Board failure	1; unlikely to happen for modern hardware	2; machine will become inoperable, requires board replacement	Use boards from reliable suppliers; apply some external protection
Software flaws	5; completely unavoidable especially for a new product	1; machine may still be operable despite poorer user experience	Automatic reboot in case of crash or freezing; remote status reports; code quality inspections

Unauthorized user access (e.g. fake student IDs)	2; possible due to design vulnerability	1; waste of test costs to customer organization, but still relatively inexpensive	Enforced user authentication; code quality inspections
Power outage	2; occasionally happens in places with less robust infrastructure	2; machine will become temporarily inoperable before recovery	Add UPS (Uninterrupted Power Supply) capability as power source backup
(Wired) Internet outage	2; occasionally happens in places with less robust infrastructure	2; machine will become temporarily inoperable before recovery	Add cellular (4G/5G) capability as network backup; consider offline authentication and operation design

Sampling System

Risk	**Possibility**	**Severness**	**Solution**
Robotic arm pushing too aggressively	1; the "holder" on the arm is designed only to move very slowly and has a limited range of motion, therefore very low possibility	5; could threaten user's comfort and even safety, causing nosebleeds or even worse medical consequences	Add damping to the holder's moving track and maintain a very small current going into the holder's motor; use an abort button to cut the current to the holder's motor immediately
Robotic Arm aims for the incorrect location	2; the detection software should have a higher than human average accuracy when fully tested and trained, therefore low possibility	5; failure to collect samples; but if mistakenly aims for other places like the eye of the user instead of the nose, could threaten user's safety	Train the software to achieve better than human accuracy. Guide users to move closer to the camera or other locations to make the software perform better.
Robotic arm stuck/broken	2; the arm segment should be made with strong materials and the motor should have tens of thousands of lifetime, therefore low possibility	3; machine will stop providing any service until repair; requires replacement of expensive parts	Test the motors and the strength of the robotic arm once every two weeks to ensure they are working properly.

Packaging System

Risk	**Possibility**	**Severeness**	**Solution**

Spill of Samples	1; very unlikely for samples to spill because it is packed by the machine and collected in a capped tube.	5; there may be severe results if the samples spill because we need to clean the spilled samples inside the machine; If the sample contains viruses, the staff may be infected.	Use appropriate and multiple layers of protective packaging material to prevent the spill from spreading to other people.
Missing labels due to printer errors	3; usually unlikely for printers to miss printing on individual sample tubes unless the printing paper is stuck or it runs out of printing paper.	3; if the sample labels are missing, users will not receive the results back and resampling is needed.	Use a sufficient amount of printing paper and regularly check the status of the printer during routine maintenance.
Missing samples (dropped or stuck and never transfer to the storage due to mechanical errors)	2; since samples are packed automatically, it is unlikely to happen if the design is well tested.	3; the customer may not receive the result if there are missing samples during the process. However, no party gets hurt so the level of severeness is an average value.	Count and record the number of samples. If the number of the samples received and the number of samples left do not match, then we could realize the error.

Storage System

Risk	Possibility	Severeness	Solution
Spill of Samples	2; usually unlikely for samples to spill because it is done by the machine and collected in a capped tube.	5; there may be severe results if the samples spill because we need to recollect the sample; if the sample contains viruses, the staff may be infected	Require staff to wear personal protective equipment when handling the test samples.
Sample Denature	3; samples may have some risks of denaturing if the storage time is too long	3; if the samples denature we need to recollect the sample	Require low storage temperature at -10 C to -30 C in the refrigerator. The samples are stored in different sections according to the time delivered so that older samples get tested faster.
Missing samples (stuck	2; may happen due to machine design	3; the customer may not receive the result	Count and record the number of samples. If the

and cannot be collected due to mechanical errors)	limitations but unlikely if design is well tested.	if there are missing samples during the process; however, no party gets hurt so the level of severity is an average value.	number of the samples arrived and the number of samples retrieved do not match, then we could realize the error.
COVID-Postive Waste	4; likely to happen because the storage system will have direct contact with COVID-positive swabs.	5; there may be severe results if the COVID-postive swabs are treated improperly; the staff dealing with the waste may be infected.	Use BSL-3 level biohazard standard to build the waste storage system. The staff dealing with the waste should have a BSL-3 training.

Remote System

Risk	**Possibility**	**Severeness**	**Solution**
Invalid/malicious requests received	3; occasionally happens; customers may not be familiar with the format of requests; hacker attacks sometimes happen	2; depends how malicious it is; 3 if a serious hacker attack, the whole remote system may crash; 1 if regular invalid request, which is harmless	Reject and send an error response to the original sender. Enforce security defense with measures like DDOS protection
Algorithm Flaws	5; relatively easy to make programming mistakes	2; may cause wrong information stored in the system or user unable to update or retrieve information	Add a rigorous testing process before an algorithm is deployed. Increase coverage of test cases.
Database Failure	2; unlikely but has the possibility; the database is usually hosted by mature and reliable solutions e.g. MySQL, Oracle, etc.	4; may cause some data loss and need time for recovery; whole system may shut down	Add a backup database to backup new information from time to time.
Server Failure	2; unlikely but has the possibility. There may be occasional programming errors to cause the server to crash but these errors could be discovered through testing.	4; the whole system will shut down as services rely on servers; may cause some data loss	Develop a data backup plan and use logs for the recovery process.

Power Outage	1; rarely happen for data centers	4; server will become inoperable before recovery; the whole system will shut down	Add UPS (Uninterrupted Power Supply) capability as backup, which is commonly equipped on servers

Lab System

Risk	**Possibility**	**Severeness**	**Solution**
Infection Risks	2; unlikely but possible. Lab professionals usually have appropriate protection measures when working	5; lab professionals may catch COVID-19 when contacting positive samples if not careful enough	Enhance the protection by wearing protection suits, medical N95 masks, etc.
Sample contamination	2; unlikely but possible. It is not easy for samples to directly contact each other given the precautions taken in transportation	3; positive samples contaminate others; people may get wrong results	Enhance protection for each sample. Sanitize and change gloves when contacting a new sample
Human mistakes of wrong recording and failure to upload	2; unlikely but possible. Lab professionals are focused when working and usually check their work more than once	3; people may get wrong results and getting results may have a delay	Add mandatory verification process after recording results
Upload System Failure	2; unlikely but possible; programming errors or server failures could lead to it	3; unable to send results to the remote system; getting results may have a delay	Additional technicians may standby in lab and fix if any problem occurs
Power outage	1; very unlikely but possible. Usually the electricity system is taken care of by the government	4; the lab may not be able to perform any experiment as equipment cannot operate; getting results may have a delay; samples may expire	Add UPS (Uninterrupted Power Supply) capability as backup

Maintenance System

Risk	**Possibility**	**Severeness**	**Solution**

Internet Outage	2; unlikely but possible: Although the network connection is wired, occasionally it can happen in places with less robust infrastructure	3; fine if the update cannot be applied in the short term due to Internet outage, but the low-stock message is more concerning if it cannot be sent to the remote system in time	Add cellular data compatibility for the machine for redundancy purpose
Human Mistake	5; completely unavoidable. Human errors are often unavoidable	2; maintenance people may perform wrong operations on the system. If the error is fatal, they will often catch the error on site (e.g. system does not boot up after maintenance), so the error may not be that severe	Mandate a detailed double-check procedure after maintenance is performed
Physical damage to the maintenance door	2; unlikely but possible. Human damage (on purpose/not on purpose) and weather conditions may all give physical damage to the maintenance door	3; the related maintenance work cannot be performed (samples and garbage cannot be collected on time); requires some part replacements	Make the maintenance door less obvious to the public and list maintenance door physical structure integrity as one of checklist items for routine maintenance

Operation System

Some risks during daily operations will be mentioned in the Recommendations part.

Technical Metrics

This section lists the major technical metrics associated with each subsystem. Technical metrics are important for performance measurements of a component or system.

Top-level User System

Component	**Metric**	**Unit**	**Description**
Exterior	Dimensions	mm	Length, width and height of the machine. Must not be excessive to transport or fit in different environments.
	Weight	kg	Must not be too heavy to transport or too light to resist winds or shocks.
	Water-proof Rating	IPX	Certain water conditions that the machine can endure without water intrusion. Important in rainy weather if the machine is installed outdoors.
	Operating Temperature	°C	Range of temperatures that the machine can operate normally. Must be sufficiently wide to endure extreme weather conditions.
	Operating Humidity	%	Range of humidities that the machine can operate normally. Must be sufficiently wide to endure extreme weather conditions.
Electricity	Power Input	V, Hz	Certain or a range of voltages and frequencies supplied by the outlet that the machine can accept. Must conform to local standards to avoid damaging the circuits.
	Power Output	V	Certain or a range of voltages that the machine can supply to its internal components, typically lower than input. Being wide enough allows better compatibility with more off-the-shelf components.
	Power Consumption	W	Minimum, average or maximum power consumed by the machine under different operating modes. The lower the better to save costs for customers.
Software	Max Response Delay	ms	Maximum length of time allowed between any user input and software output response. Visibly high delay leads to poor user experience. Depends on software design.
	Network	ms	Maximum length of time that the machine will

	Timeout		wait from the server until it concludes unreachable. Depends on other subsystems.
	Minimum Network Speed	KB/s	Minimum speed of the Internet between machine and server for all functions to operate normally. Depends on software design.
Display	Maximum Brightness	nit	Maximum level of brightness that can be displayed. Impacts display visibility, especially under sunlight.
	Refresh Rate	Hz	Maximum frequency that the display can refresh its contents at. Must be fast enough for user experience if software includes videos and animations.
Board	Frequency	GHz	Base or maximum speed that the chip operates at. Affects overall machine performance and power consumption.
	RAM	GB	Amount of data that can be stored volatilely. Affects overall machine performance.
	ROM	GB	Amount of data that can be stored permanently. Depends on software design.

Sampling System

Component	**Metric**	**Unit**	**Description**
Robotic Arm Base	Diameter	mm	Size of the circular base of the robotic arm setup.
	Motor Speed	rad/s	The rotating speed of the robotic arm base.
Robotic Arm Segment	Dimension	mm	The length of the two metallic robotic arm segments.
Robotic Arm Joint	Diameter	mm	Similar to the base size of the circular joint motor of the robotic arm.
	Motor Speed	rad/s	The rotating speed of the arm joint.
Robotic Arm Holder	Dimension	mm	The size of the cotton swab holder.
	Motor Speed	cm/s	The speed at which the holder pushes the cotton swab forward.
Abort Button	Diameter	mm	The abort button should be red and

			visible. The user can notice its existence very easily and the size of it should be easy to press.
Conveyor	Dimension	mm	The width and length of the conveyor, which transports the test kit from storage to the user window.
	Move speed	cm/s	The speed at which the conveyor moves material.

Packaging System

Component	**Metric**	**Unit**	**Description**
Paper Box	Volume	mm x mm x mm	Dimension of the packaging box
Absorbent Packing Material	Absorbency	g/mm^2	Absorbency of packing material
Leakproof Secondary Container	Water-proof Rating	IPX	Certain water conditions that the container can endure without water intrusion; applies to other liquids as well
Dry Ice	Thermal Conductivity	W/(m·K)	Thermal conductivity of dry ice; crucial for temperature preservation
Insulating material	Thermal Conductivity	W/(m·K)	Thermal conductivity of insulating material; crucial for temperature preservation
Printer	Revolution	DPI	Revolution of the printer
	Black Print Speed	ppm (pages per minute)	Black print speed of the printer; affects sample processing speed
	Product Weight	g	Net weight of the printer; affects total machine weight

Storage System

Component	**Metric**	**Unit**	**Description**
Refrigerator	Temperature	°C	Temperature of the refrigerator; must be suitable to preserve samples
Biosafety Level	BSL-3	N/A	The sanity level of waste storage

			system should be BSL-3 level to prevent spread of viruses
Robotic Arm	Motor Speed	cm/s	The speed at which the robotic arm disposes the swab and antigen test cards.

Remote System

Component	Metric	Unit	Description
Server	Requests per second	# of responses	The number of requests your server handles per second (also referred to as throughput). Measure the scalability of the server, its ability to cope with high load of requests
	Average Response Time	ms	Average amount of time it takes to respond to a request for service
	HTTP Server Error Rate	%	Represents how often users see an internal HTTP error code or experience an internal server error. A high error rate undermines the trustworthiness of the service.
	Maximum thread count	# of threads	Determines the maximum number of concurrent requests that can happen in the server at a particular time.
Database	Throughput	# queries /second	Measures how quickly the database server is able to process incoming queries
	Latency	ms per query	Average response time per query. Shows how long the database server has to work before it gets a query result.
	Connection	# of open connectio ns	Number of open database connections possible before choking the database server.
	Error rate	%	Percent of unsuccessful queries among all queries measured. Need to keep the error rate low
Algorithm Testing	Failure rate	%	Percent of failed test cases among all test cases
	Test case coverage	None	Be able to include in as many different scenarios as possible

Disks for data storage	I/O speed	Bytes/s	Speed of reading and writing data
	RAM	GB	Amount of data that can be stored volatilely. Affects overall machine performance.
	ROM	GB	Amount of data that can be stored permanently. Depends on software design.

Lab System

Component	**Metric**	**Unit**	**Description**
Lab	Sample processing speed	Number of samples tested a day	Number of samples tested per day. Measures how fast a lab can process the samples and its ability to deal with a large number of samples
	Error rate	%	Percent of wrong results identified during verification/user report. Measures the accuracy of experiments of a lab

Maintenance System

Component	**Metric**	**Unit**	**Description**
Software	Software update speed	second	Time of software update needed per update
	Remote server connection interval	minute	Time interval the remote server should test the connection with local machine
	Connection timeout	second	Length of timeout when the remote server fails to respond to a connection
Storage	Testing kit out of stock	boolean	A boolean value to reflect to the remote system about testing kit out of stock
	Garbage over capacity	boolean	A boolean value to reflect to the remote system about reaching garbage collecting capacity
	Sample over capacity	boolean	A boolean value to reflect to the remote system about reaching sample collecting capacity
Maintenance	Maintenance employee authentication time	second	The time needed for a maintenance employee to wait for authentication on a local machine

	Maintenance door size	mm x mm	Size of the maintenance door

Operation System

Due to excessive scope and time constraints, technical metrics during daily operations will not be covered in this project.

Feasibility Analysis

This section selects several key functions from each subsystem and suggests the most possible implementation for that function, though restrained by time and our knowledge. Some trade-off discussion is also provided for each function, including potential drawbacks of that implementation and whether there exist other alternatives.

Top Level User System

Function	**Implementation**	**Trade-offs**
Power Supply	Use off-the-shelf power supply products. Modularize power supply units in machine design. Use different power supply models for different markets to accommodate different power standards.	Multiple machine configurations must be produced simultaneously, which may not be ideal for economies of scale. One alternative is to use a power supply that supports a wide range of inputs across all machines produced, but they are way more expensive.
User Authentication	Use the same off-the-shelf card reader across all machines.	May not be compatible with all ID cards used by potential customer organizations. Single method of authentication may limit operating scenarios, so other methods (such as QR codes) may also be supported.
Display	Use the same off-the-shelf LCD display across all machines. They are relatively cheap and reliable, especially for large screen sizes.	LCD screens generally have lower brightness compared to OLED, which could cause visibility issues under sunlight if our machine is installed outdoors. However, OLED has a shorter lifespan and is too expensive for large screen sizes, which makes it infeasible.
User Inputs	Use touch inputs. On top of the previous component, limit display models to those that support touch inputs.	May not be intuitive to use for people (especially seniors) who have limited experience interacting with smartphones. Less responsive if the screen is wet, which could happen if the machine is installed outdoors. Best alternative is to use a non-touching display plus some physical buttons. However, it requires more effort to integrate software and hardware, and will substantially restrict flexibility of feature updates in the future.
Computation	Use the same off-the-shelf boards across all	Relatively high unit cost since they are not fully customized for our needs and we may

	machines with fixed processors, memories, I/O ports and so on. They are powerful enough, easy to develop on, and available at large quantities.	pay for unnecessary capabilities. While self-developed boards could potentially reduce unit costs, it requires time-consuming and expensive R&D at earlier stages, which is infeasible for our product.

Sampling System

Function	**Implementation**	**Trade-Off**
Robotic Arm	The robotic arm has these structures from bottom to top: a base, the first segment of the metallic arm, the “joint”, the second segment of the metallic arm, and the swab “holder”. The base of the robotic arm is a motor that moves on the horizontal plane with 360 degrees of freedom. This motor is used for the arm to rotate. The “joint” of the robotic arm contains a motor that moves on the vertical plane with 90 degrees of freedom. This motor is used for the arm to lift up and down. The “hand” of the robotic arm contains a holder that tightly clamps the cotton swab and moves the cotton swab forward to perform the nasal swab.	There are many motors on the robotic arm, which are required for a more flexible and agile movement since we need to perform tests on users with different heights and facial features. However, this will introduce the possibility of failures, including motor malfunctioning, and will consume a lot of energy.
Conveyor	This component is implemented through a gateway to the test kit storage and a conveyor belt that transports the test kit to the user. Once the user orders a Saliva collection test, the gate of test kit storage will open and drop one test kit onto the conveyor. Then, the conveyor belt will start to move and transport the kit to the user.	The motor may stop working for many reasons. No better alternatives have been identified so far.
Face Detection	This component is implemented based on a micro camera sensor. Computer Vision software takes the collected image as input and calculates the location of the face, as well as the specific location of the nose. The calculation should be as accurate and precise as possible.	Calculation error may cause the arm to aim wrongly and cause dangerous situations. A possible alternative is to require the user to stand in a specific position and place their head, but this will make the collection process less intuitive.

Packaging System

Function	**Implementation**	**Trade-offs**
Box	Use about 10 24"x18"x12" paper boxes for each test type.	Paper boxes may be easy to break and bend if in contact with liquid. However, the plastic box is environmentally unfriendly for most exterior packaging systems.
Shock absorption	Use about 15" x 20" absorbent mat. Use 5 mats per box.	The absorbent mat may be expensive but it is worth using because it prevents the spill of possible COVID-positive samples.
Leakproofing	Use about 5 1-gallon HDPE wide mouth jars per box. Put samples in batches into the leakproof jar.	The plastic wide mouth jar may be environmentally unfriendly. Its alternatives are zipped bags. However, the container can be cleaned and reused for future packaging, so it is not a big issue.
Temperature Conservation	Use 11" x 8" x 2" Gel cold packed dry ice.	Dry ice may produce CO2, a gas that may result in climate change. Can also use regular ice but ice is easy to melt and will leave water in the container. Dry ice can evaporate and will not have contamination on the box.
Insulation	Use wrapping paper rolls. Size depends on the box.	We can also use bubble wrap but bubble wrap is plastic and is not environmentally friendly.
Labeling	Use 8.5" x 11" label paper, with "time", "test-type", and "sample ID"s typed. Each box should have a labeling sticker.	We can also print the information on the box to save labeling paper but it will create extra work for printing. The box may be too thick and is inconvenient for printing. Printing the labeling stickers first and then sticking saves time and extra print cost.

Storage System

Function	**Implementation**	**Trade-offs**
Temperature Conservation	Use 2 scientific refrigerators to store the samples.	May also use ultra-low temperature freezers. There is not much difference between different freezers or refrigerators because they serve the same function.

Remote System

Function	**Implementation**	**Trade-offs**
Generate sample id	Use seed such as current time or random numbers to generate a sample id of fixed format and length. Look up the sample id in the database to confirm it's unique. Insert sample id and its creation time into the sample database.	When dealing with a large number of samples, the chance of generating repeated sample id is high, so the process may take multiple rounds in order to succeed.
Establish match between sample id and user id	Develop a one-to-one algorithm to convert user info to user ID. Store the generated sample id - user ID pair in the database	There may be a risk that the one-to-one property of the algorithm is not guaranteed. There may be a problem with users that have really similar information.
Retrieve employee ID	Develop a one-to-one algorithm to convert employee info to employee ID.	Employee id may be the same as the user id if the employee is also a user. May need to add a way for differentiation between user and employee.
Match test result of sample with user	Use sample id to get the corresponding userID by querying the sample-user database. Store test results by (user id, sample id) in the test result database.	There may be a large number of test results coming up every day. The database needs frequent update/remove/insert. Needs to regularly remove expired results (expiration time can be set to a week) from the database.
Allow access to users' test result through API	Extract user id from the request to query the test result database. Return all results/most recent results associated with each user.	The returned data may be huge and difficult to transmit if the external system requests results containing a large number of users. May need to compress the data somehow. Need to set a request limit. Outside systems may set multiple requests simultaneously, requiring strong ability to process data concurrently.
Access the stock level of test kits	Update stock level in the system when receiving an update from the storage system. Return stock level when outside systems send a request to API.	Outside systems may set multiple requests simultaneously, requiring strong ability to process data concurrently.

Lab System

Function	Implementation	Trade-offs
Perform tests on samples	Lab professionals use PCR to perform tests and wait until results come up for each sample.	Limited number of lab professionals may be slow in processing all samples. However, there is no better solution at this moment since viruses take time to reproduce. May consider performing experiments on multiple samples simultaneously to increase efficiency. Certain risks for lab professionals to get infected by positive samples, though human operation is unavoidable.
Report the corresponding test result to each sample to remote system	Record the sample id and its corresponding result every time when a test is done. Compile all the sample-result records when today's workload is done and send them to the remote system.	Possible to make mistakes when recording the result. May be possible to find an automatic result reading solution.

Maintenance System

Function	Implementation	Trade-offs
Software Updates	The remote system will signal the local machine for any software update.	If the update fails, more time is needed to go to the machine and fix the update issue physically. One alternative is requiring the employee to go to each machine physically to update the machine, but this method may require significantly greater maintenance time and costs.
Stock Communication	The system should read stock and capacity information from the storage system and warn the remote system of overcapacity or limited stock.	A threshold is set for warning. The threshold set may not be the most suitable one, which will cause lower efficiency.
Maintenance Authentication	The employee should authenticate and then be authorized for operations.	Authentication from remote systems takes time to process but is necessary for safety.

Operation System

Due to excessive scope and time constraints, feasibility analysis during daily operations will not be covered in this project.

Recommendations

We have identified the business opportunity, conducted feasibility and risk analysis, and completed the high-level requirements for the CoviDetect system. We believe that the project is generally feasible from the technical perspective. However, we still have many obstacles and uncertainties at this moment, where most of them arise from the sampling process. Though having a relatively small chance thanks to possible safety measures, we are worried that the fully automatic sampling function on noses could cause minor or serious injuries to the user. As a result, we may not be able to obtain permissions or certificates from regulators (if applicable) to operate our business, which could lead to the halt of the entire project.

In that case, if we are unable to gain a large sum of funds externally, we may not have sufficient funds to support design modifications or further R&D. Even if we are fortunate to establish our market, we may not be able to afford serious consequences such as lawsuits or investigations caused by medical accidents. Thus, unfortunately, we recommend NOT to move on to the next development phase at this moment. Instead, we recommend conducting more research on local regulations on medical equipment to further analyze the possibility that our product will be permitted. Plus, more thorough feasibility and risk analysis must be performed, especially on the sampling subsystem to identify more potential safety issues of our design. Only after those, we could have a clearer picture of the situation and decide whether this project should be rejected permanently.