

## Amp It Up

### St. Luke's University Health Network Laboratory

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## Executive Summary

At the advent of the SARS-CoV-2 pandemic, testing, treatment, and vaccine administration were essentially non-existent across the country. St. Luke's University Health Network utilized Diasorin Simplexa and Cepheid Genexpert platforms, as well as the existing partnership with Laboratory Corporation of America Holdings (Labcorp) to implement a testing protocol for the hospital network. While the partnership with Labcorp was essential for providing Covid-19 testing, as in-house testing platforms were unable to manage the rapidly increasing sample volume, there were extensive challenges with sending out testing to a reference laboratory. Millions of dollars were being spent per month for COVID-19 testing, the turn-around time (TAT) ranged from 48 hours to 5 days, and appropriate patient care was subsequently delayed. In addition to delaying patient care, fluctuating TAT resulted in epidemiological effects such as the implementation of isolation protocols and contact tracing. For the Network's patient-facing staff, ensuring that patient care was being administered in isolation conditions and with proper personal protective equipment (PPE) for COVID-positive patients was not only best-practice, but was critical in protecting the vulnerable Network staff tasked with treating patients. These delays had an immeasurable effect on the region's ability to prevent the spread of this infectious disease.

St. Luke's University Health Network did not have an instrument already available to produce high-throughput COVID-19 testing, making the installation of a third-party vendor product essential. The vendor technology available at the time that would provide high-throughput testing was the ThermoFisher Quantstudio 7, which could accommodate a 384-well plate for patient testing. The Applied Biosystems Software was accompanied by the purchase of the Quantstudio 7 instruments and was not a choice that needed to be made by the Network team. Even though the IT team had a heavy lift with correlating the Quantstudio Applied Biosystems Software with EPIC, the possible of completing 2,000 or more samples in an 8-hour period was reason enough to choose this instrument. While this platform and the materials were not FDA-approved at the time, it was approved under the Emergency Use Authorization (EUA), a tool used by the FDA to expedite the availability of medical products during a public health emergency.

These substantial hurdles to high-quality patient care would have been reason enough to warrant the implementation of an in-house platform, but the financial expenditure added fuel to the fire. Each COVID-19 test sent to Labcorp was costing \$100.00 for the majority of the pandemic. There was a slight fluctuation in the Quarter 1, where the average spend per test was \$51.31. When a multiplex test (COVID-19/FLU A/B/RSV) became available through Labcorp, that pricing was \$150.00 per test. A negotiation was reached in the summer of 2021 to reduce the COVID-19 cost to \$75.00, primarily for saline samples that required the use of the Labcorp platform. The

beginning of the pandemic took place within the first Quarter of 2020 (January-March), resulting in a total of 1,335 tests at \$51.31 per test (\$68,499) being sent to Labcorp. During the second Quarter (April-June), St. Luke's University Health Network sent out 14,940 tests, costing a total of \$1,494,000.00. In the third Quarter of 2020 (July-September), St. Luke's University Health Network sent out 33,163 tests at \$100.00 per test, costing a total of \$3,316,300.00. In the fourth Quarter of 2020 (October-December), that number increased to 79,850, costing \$7,985,000.00. In comparison, by 2021 when the in-house testing platforms were up and running, St. Luke's University Health Network sent out 16,314 tests (\$1,223,400.00) in the first Quarter, 452 tests (\$64,904) in the second Quarter, 9 tests (\$675) in the third Quarter. By 2022, only 11 tests (\$825) were sent to Labcorp in the first Quarter. This dramatic decrease in tests sent out to Labcorp corresponded to a dramatic increase in tests being completed in-house for a lower cost, despite the initial start-up costs and labor costs.

Overall, for fiscal year (FY) 21 and FY 22, the total number of tests completed was 262,986 at \$100.00 per test, totaling an overall expenditure of \$26,298,600 if the tests were being sent to Labcorp. With the advent of the Thermofisher platform, the test cost dropped from \$100.00 per test to \$27.94 per test. The total St. Luke's University Health Network expenditure amounted to \$7,347,828.00, saving the Network \$18,950,772.00 – an approximate 72.10% savings.

At the time that this task was brought to the laboratory by senior administration, there were already two functioning platforms for COVID-19 testing: Diasorin Simplexa and Cepheid. The difficulty with these platforms was they were not high-throughput and could not accommodate the rapid increase in sample volume. Prior to the decision to install a high-throughput platform, the Centers for Medicare & Medicaid Services (CMS) disseminated a Ruling (CMS-Ruling-2020-01-R) on April 14, 2020 concerning the designation and payment of certain clinical diagnostic laboratory tests related to COVID-19 under the Medicare Part B Clinical Laboratory Fee Schedule. This Ruling defined high-throughput technology as a platform that employees automated processing of more than two hundred specimens per day. These platforms were noted by CMS as requiring more intensive technician training and more time intensive processes, representing an increase in resources. As a result, CMS concluded that clinical diagnostic laboratory tests that make use of high-throughput technologies as defined by CMS-Ruling-2020-01-R administered during the ongoing emergency period defined in paragraph (1)(B) of section 1135(g) of the Act beginning on or after March 18, 2020 for the detection of SARS-CoV-2 were to be paid for at the rate of \$100. The following codes were utilized in identifying these tests:

U0003: Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique, making use of high throughput technologies as described by CMS-2020-01-R. Identifies tests that would otherwise be identified by CPT code 87635 but for being performed with high-throughput technologies.

U0004: 2019-nCoV Coronavirus SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC, making use of high throughput technologies as described by CMS-2020-01-R. Identifies tests that would otherwise be identified as U0002 but for being performed with high-throughput technologies.

CMS disseminated a second Ruling on January 1, 2021, amending CMS-Ruling-2020-01-R by modifying the payment amount established based on a re-evaluation of the resources necessary for the timely administration of these tests. For tests not completed within 2 calendar days of specimen collection, the payment amount would be \$75 per test. However, a third code was established to produce an add-on payment of \$25 for tests completed using high-throughput technologies within 2 calendar days of specimen collection. This code was designated as U0005.

The charges related to high throughput testing using the ThermoFisher Scientific equipment was established by the St. Luke's University Health Network financial department for fiscal year (FY) 2022 and 2023 as follows in Table 1.

Table 1: SLUHN Response to CMS Rulings

Procedure Code	Procedure Name	CPT	Cost Center	Cost
<b>FY2022</b>				
275001356	HB 2019-NCOV CORONAVIRUS ANY TECHNIQUE	U0004	LAB MICROBIOLOGY	\$221.00
275001357	HB NOVEL CORONAVIRUS 2019 (COVID-19), NAA	U0003	LAB MICROBIOLOGY	\$219.00
275001400	HB INFECTION AGENT DETECT AMPLI PROBE	U0005	LAB GENERAL TESTING	\$27.00
<b>FY2023</b>				
275001356	HB 2019-NCOV CORONAVIRUS ANY TECHNIQUE	U0004	LAB MICROBIOLOGY	\$221.00
275001357	HB NOVEL CORONAVIRUS 2019 (COVID-19), NAA	U0003	LAB GENERAL TESTING	\$219.00
275001400	HB INFECTION AGENT DETECT AMPLI PROBE	U0005	LAB GENERAL TESTING	\$26.00

In response to the lack of high-throughput, in-house COVID-19 testing, senior administration tasked the laboratory leadership, information technology (IT) support, and material management support with developing an operational molecular laboratory to perform all COVID-19 testing in-house with a deadline of two months. Administration was confident that this novel laboratory would be able to decrease outpatient testing TAT by 50%, reduce testing expenses by 75%, effectively eliminate delays in patient treatment, and decrease the time it would take to implement isolation protocols.

This project was an organizational priority with an extremely rapid implementation deadline. The team was faced with planning the project, acquiring all necessary materials during supply chain shortages, and completing instrument validations with a very manual, labor-intensive protocol utilizing the ThermoFisher Scientific Quantstudio 7 and Kingfisher Flex instruments. The key considerations for design of the clinical workflow were safety for laboratory staff completing testing, minimizing contamination risk, and the efficiency of sample receipt and preparation. The Information Technology (IT) considerations included ease of ordering for providers, the ability to interface results, and maintenance of network security. St. Luke's University Health Network required the collective experience and expertise of all team members to rise to this seemingly insurmountable challenge.

The teamwork involved in planning the lab layout, procedure writing, supply acquisition, testing and data collection, process validation and goal achievement made this project a success. The team, involving partners in laboratory leadership, laboratory project management, laboratory managers/supervisors, laboratory technical staff, materials management staff, and information technology staff, was able to complete this project in the span of a few months. This team experienced severe supply barriers due to the pandemic and world-wide consumable shortages, leading to various modifications of the testing processes to accomplish maximum efficiency despite the lack of proper supplies. With repetitive practice and adaptations to the workflow, the team was able to consistently increase COVID-19 specimen throughput to ultimately perform all COVID-19 testing in the new laboratory with an average turn-around-time of 4.7 hours from specimen receipt to completion. This decrease in turn-around-time universally correlates to more efficient and effective patient care for patients located in the hospitals and in the community. This new laboratory was designated as the St. Luke's University Health Network Molecular Laboratory.

Figure 1: Fishbone Chart for Plan Development

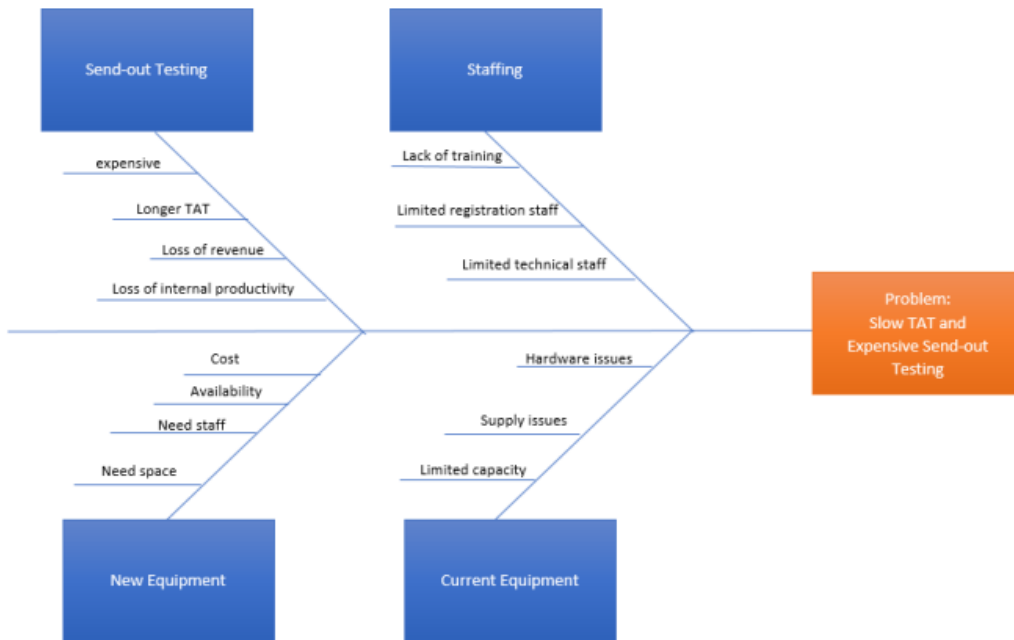
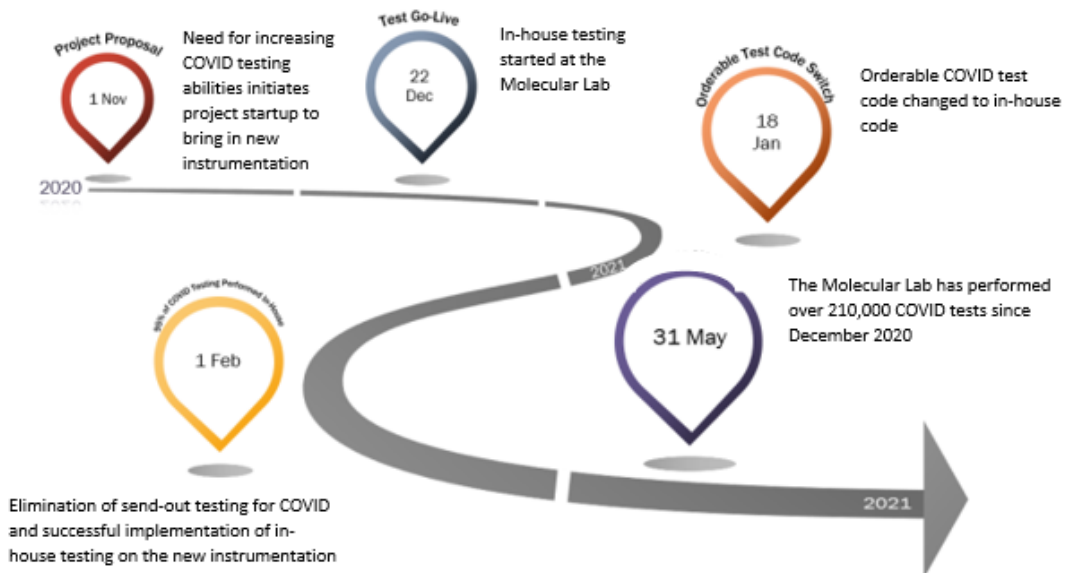


Figure 2: Project Timeline



## **Define the Clinical Problem and Pre-Implementation Performance**

The clinical problem was the lack of in-house COVID-19 testing. The goals of this project were to decrease outpatient testing TAT by 50% and reduce expenses by 75% through the implementation of high-throughput, in-house COVID-19 testing. The clinical quality measure used to assess the adherence to the standard of care was the COVID-19 testing turn-around-time (TAT). The College of American Pathologists (CAP) outlines test TAT as an indicator of laboratory as part of the laboratory quality management program. The laboratory analyzed the number of patients tested in-house in the established Molecular Laboratory, the total number of COVID-19 tests ordered at St. Luke's University Health Network, and the overall test TAT.

In general, there were a few exemption criteria that may have excluded a particular patient from the above analysis. Requirements from insurance payors may have dictated a specific reference laboratory for testing. In addition, certain specimen collection types such as saline and bronchoalveolar lavage were not validated on the in-house testing platforms.

The targeted goals were to have all COVID-19 tests ordered at St. Luke's University Health Network be completed in-house to decrease turn-around-time, improve patient care, and decrease overall cost to the Network.

With respect to health equity, access to COVID-19 tests and associated testing materials was a challenge faced around the world. At the beginning of the pandemic, only symptomatic patients could be tested and the locations for testing were limited to hospitals and outpatient care-now facilities. As patients flooded the hospitals and care-now facilities with COVID-19 testing needs, St. Luke's University Health Network implemented a plan to improve access for not only the COVID-19 tests, but for tests, exams, and procedures that would be completed at the once-overrun hospitals and care-now facilities.

St. Luke's University Health Network converted trailers in parking lots of the hospitals and affiliated areas into mobile testing tents. Assessments were conducted by Network partners to determine appropriate locations for the mobile testing tents to remove testing barriers for patients in densely populated areas of the region.

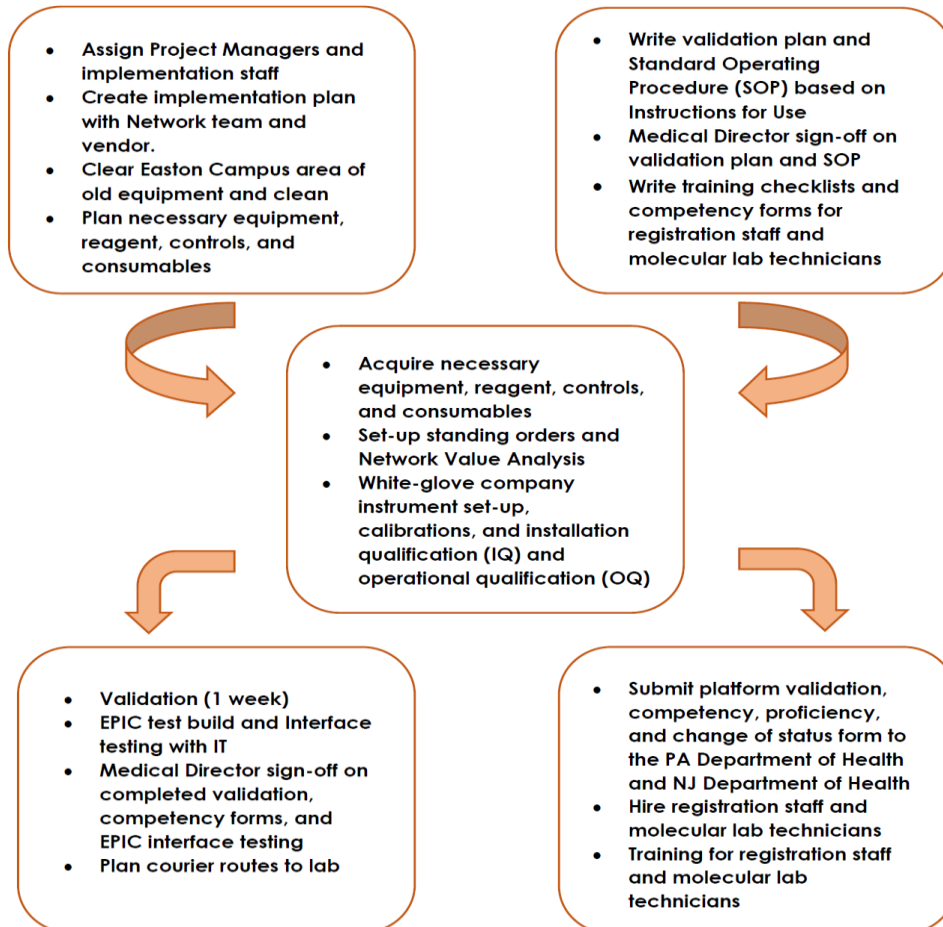
Patients were able to have a physician request a COVID-19 order and could drive through the mobile testing tents instead of taking away space, time, and resources from the hospitals and care-now facilities. The COVID-19 samples were picked up from the tents daily at regular intervals and brought to the St. Luke's University Health Network Molecular Laboratory for testing. This action not only improved patient access to COVID-19 tests in all areas the Network serves, but improved patient access to emergency and urgent care.

*Design and Implementation Model Practices and Governance*

Figure 3: Implementation Strategy



### Implementation Strategy for In-House COVID-19 Testing



As noted in Figure 1, the development of the plan required consideration of current send-out testing, staffing, the current equipment limitations, and the new equipment that would need to be purchased. Once those considerations were outlined and presented to senior administration, negotiation surrounding plan details commenced, as outlined in Figure 3.

The first question was that of the laboratory location. Given that St. Luke's University Health Network had recently acquired Easton Hospital, the unclaimed territory in that laboratory became the topic of discussion. Once the decision was made to create the laboratory at the Easton Campus, equipment and supplies were outlined and purchased based on the TaqPath COVID-19 RT-PCR Kit Instructions for Use. The capital

equipment required planning by the project managers to ensure receipt, installation, and certification.

This equipment included but was not limited to: Two Quantstudio 7 Instruments, 3 Kingfisher Flex Instruments, 2 Sorvall Pro Centrifuges, 2 Biological Safety Cabinets, and -80°C and -20°C freezers. Reagent/controls required for completing the assay. Certain reagent needed to be shipped on dry ice and timely receipt and proper storage in -80C or -20C freezers were essential. Each of the instruments also required service contracts with Thermofisher to ensure a field service engineer would be available to come out in the event of an instrument failure. Prices are outlined below in Table 2.

<b>Equipment</b>	<b>Purchase Price</b>	<b>Annual Service Cost</b>
Quantstudio 7 Flex	\$73,470.00	\$13,200.00
Quantstudio 7 Flex	\$73,470.00	\$13,200.00
Kingfisher Flex	\$61,940.00	\$10,164.96
Kingfisher Flex	\$61,940.00	\$10,164.96
Kingfisher Flex	\$61,940.00	\$10,164.96
Sorvall Pro Centrifuge	\$6,580.31	N/A
Sorvall Pro Centrifuge	\$6,580.31	N/A
Biological Safety Cabinet	\$10,608.80	N/A
Biological Safety Cabinet	\$10,608.80	N/A
TSX Series -20 Freezer	\$5,686.29	N/A
Ultra-Low Freezer	\$13,086.34	N/A
Double Door Refrigerator	\$7,032.10	N/A
Multidrop Combi	\$22,244.16	N/A
Multidrop Combi	\$22,244.16	N/A

Table 2: Equipment Pricing

The materials management department was tasked with continually monitoring purchase orders throughout the project to ensure order and receipt of all necessary supplies. All supply orders needed to be tracked to the distribution center, logged, and sent to the Molecular Laboratory in a timely fashion. Several reagents were refrigerated or frozen, making it even more significant that material transport was not delayed. Materials management instated standing orders with the vendor for routinely used reagents, control, and consumables.

One of the major challenges for materials management was in the supply chain, particularly when it came to pipettes and plastic pipette tips. It was especially difficult to acquire ClipTips (a brand used specifically with 8- and 12-channel pipettes) which were essential for high-throughput testing. Without ClipTips, all pipetting was completed manually and increased the TAT for patients. In general, the vendors were not prepared or equipped with staff, raw materials, and time to generate the plastic products that were now being used in mass quantities around the United States. The

challenge of the supply chain has improved over the years, but still remains one of the largest challenges for the hospital system as a whole.

In addition to the laboratory equipment, computers, printers, label printers, and scanners needed to be installed on-site for sample accessioning and result reporting. There were six stations available for specimen accessioning, two additional stations for result reporting, three printers, and two stations associated with the Quantstudio 7 instruments that needed to be built.

Simultaneously, the IT department completed a special build in EPIC to add the test, methods, ordering information, packing lists, result reporting, and accessioning logic for the COVID-19 test. This required new training classes to meet the need for the EPIC workflow changes. Network Engineering fixed firewalls and uncovered a novel issue: there would need to be one monitor attached to the instrument, and one monitor for exporting the results to the SLUHN interface. This dual monitor set-up posed a challenge for Network Security but was ultimately solved. The Systems Engineering Group (SEG) mapped drives and uploaded the Excel template onto the Quantstudio 7 while Field Support was setting up EPIC label printers, workstations, MFD printers, and barcode readers. Once orders were able to be placed, the Data Innovations (DI) team completed interface testing for EPIC resulting and testing for electronic laboratory reporting, including interfaces to the PA National Electronic Disease Surveillance System and NJ Communicable Disease Reporting and Surveillance System, to interface the results from EPIC to the state departments.

Once the instruments were installed and the Installation Qualification (IQ) and Operational Qualification (OQ) were completed by ThermoFisher Field Service Engineers, a virtual education was presented to the laboratory team on the set-up and use of the testing instrumentation and additional equipment. From the IT side, SEG mapped drives and created batch files. SEG also loaded special Excel templates from ThermoFisher Scientific onto the Quantstudio 7 instruments for the users to scan specimen barcodes and create sample runs. The Excel templates were used as a map on the Quantstudio Applied Biosystems software to match the patient barcode to the sample well on the 384-well plate that was inserted into the Quantstudio 7 for testing.

The procedures were written and uploaded into MediaLab, workflow processes were established and modified to meet efficiency requirements, and the test verification was completed within regulatory guidelines. Additional staff were hired and trained to complete the in-house laboratory testing and eliminate the send-out testing requirements for COVID-19.

The training for staff was split into four distinct training sections:

1. Accessioning/Resulting
2. Deep-Well Plates
3. Sample Preparation

#### 4. Reaction Plates/Quantstudio 7

This project was unconventional in that it did not have staff dedicated to testing at the time of its inception. The laboratory leaders and laboratory team members selected for the project, some became clinical end users, but the rest of the staff were laboratory scientists hired from an agency once the project was completed. Additional staff were trained by the original team leaders and team members who implemented this project and had no collaboration with the institution of the Molecular Laboratory.

The laboratory staff training would take approximately 3-4 weeks for initial training, followed by an evaluation period to determine competency. A staff member would not be considered competent until a period of 12 weeks due to the complexity of the procedure. Training may have taken more or less time dependent on the technical experience of the staff member and familiarity with EPIC. The initial staff training on the instruments and with the workflow occurred rapidly as soon as the instruments were installed. The laboratory staff learned the instruments and workflow from the procedure provided by ThermoFisher Scientific. As deficiencies in workflow were acknowledged, changes to the workflow were implemented. By the time the contracted staff were hired, the established clinical workflow was as follows:

1. Receive specimen into EPIC and print specimen label.
2. Scan specimen label onto Excel template.
3. Print the Excel template when all specimens are scanned.
4. Prepare sample plates using proteinase K and negative control.
5. Prepare deep-well plates using wash buffer, 70% ethanol, and elution buffer.
6. Aliquot samples into deep-well plates.
7. Add bead mix and MS2 phage to the deep-well plates.
8. Place on the Kingfisher instrument for 23 minutes.
9. Prepare reaction plate using reaction mix and prepare positive control.
10. Add eluted sample from the Kingfisher to the reaction plate.
11. Add positive control.
12. Seal plate, vortex, and centrifuge.
13. Place on the Quantstudio 7.
14. Export results to St. Luke's University Health Network Computer.
15. Result in EPIC.

In addition to the laboratory staff training, accessioning staff, clinicians, couriers, and administration required a crash course in how this laboratory was going to function. Overall, the communication between the departments was facilitated via email and the creation of the ThermoFisher Lab Testing Team on Microsoft Teams. The ThermoFisher Lab Testing Team had different channels for General, IT, Lab, Couriers, Facilities, and Supplies to ensure all departments were on the same page. Several of

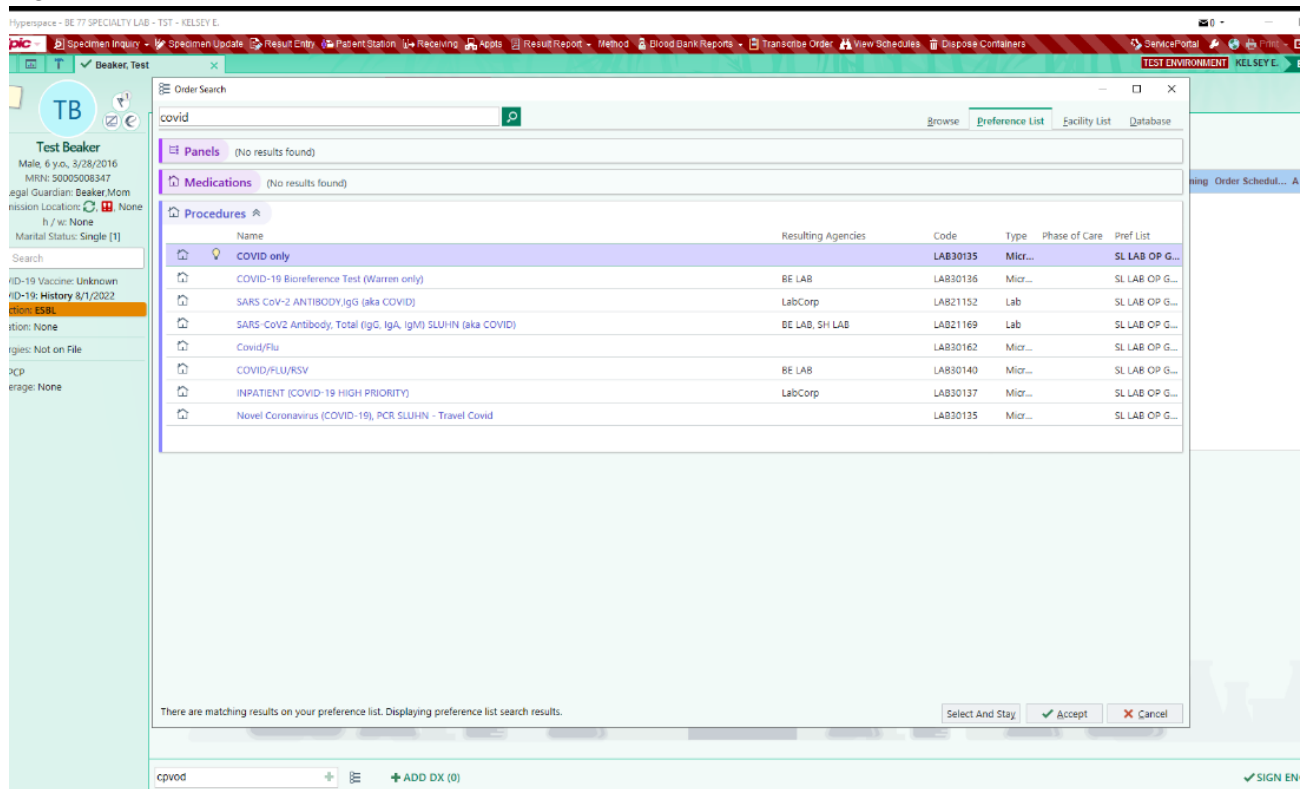
the laboratory team leaders were also clinical end users, as all testing was completed in the Molecular Laboratory.

## ***Clinical Transformation enabled through Information and Technology***

Clinical Workflow:

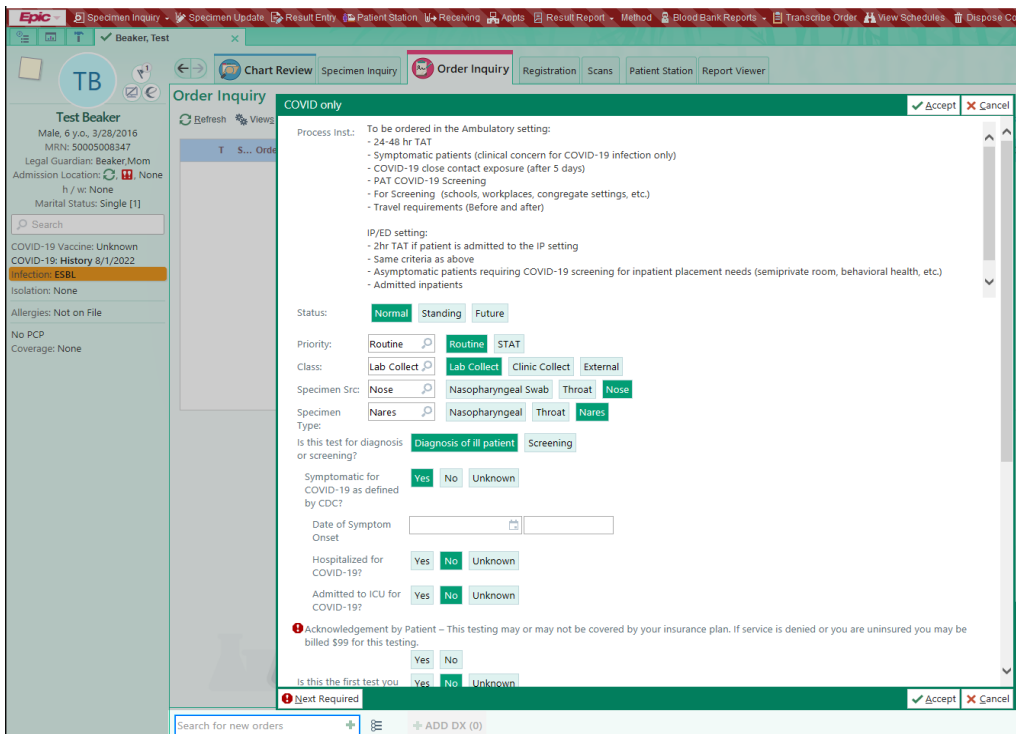
1. Patient presents for sample collection at a collection site, carenow facility, or emergency department, or contacts primary care provider to request testing.
2. Provider determines appropriate test order dependent on the algorithm (COVID-19, COVID/FLU/RSV, Routine, STAT).
3. Collector asks the patient for their name and date-of-birth and reviews the patient chart for a laboratory order for COVID-19 testing or the patient provides a paper script for testing from a provider.
4. Collector prints a specimen label or writes the name and date-of-birth of the patient by hand on the collection container.
5. Collector confirms the patient name and date-of-birth with the patient prior to sample collection.
6. Collector swabs the patient (nasal or nasopharyngeal), placing the swab into the universal transport media container.
7. Collector scans the patient barcode or types the sample information onto a packing list destined for appropriate laboratory for testing.

Figure 4: Clinician Order Set



Clinicians will need to enter the order inquiry page of the patient chart to order a COVID-19 test. From here, they will select the appropriate test order and answer a series of questions regarding the patient. If testing is not indicated due to a previous positive result within 90 days of the current order, a notification will pop-up indicating that testing is not indicated. The clinician may choose to proceed with ordering the test. Once all required questions are answered, the order will be signed. Once the order is signed, the clinician will need to collect the order in EPIC and print labels for the specimen container, which can all be completed from the order inquiry page.

Figure 5: Clinician Order Questions



The COVID-19 order was not originally considered as a standard order, particularly in the outpatient setting. Patients entering the Emergency Department (ED) were tested as part of their admission, but due to limited bed space in the hospitals, patients who could be discharged home while awaiting their results were discharged. As testing practices evolved, it became standard to test ED patients for COVID-19 and test symptomatic outpatients only. Non-symptomatic patients were not tested for a period of time until testing platforms were able to manage COVID-19 testing as routine for elective surgical procedures, travel, and scheduled screening testing requirements per corporations, colleges, and nursing homes. The testing practices for COVID-19 were evolving as the pandemic evolved, which required efficient and increased communication between all departments. Each time there was a change in ordering or collection guidance, a new memo or algorithm (examples below) was sent out to all involved parties in the network.

Figure 6: SLUHN Memo Example

**St Luke's**  
UNIVERSITY HEALTH NETWORK

**Network Laboratory Memo**

To: SLUHN Hospital Campuses and all network testing locations – hospitalists, healthcare providers, ED team leaders

Date: May 5, 2020

From: Dr. James Chiadis MD, Interim Chairman, Department of Pathology  
Dr. Michael Sherman MD, Medical Director of Specialty Lab, Microbiology


**Change of Collection Method, Change of Collection Kit; SLUHN Laboratory Services Testing for COVID - 19**

Saline collection kits with **oropharyngeal swabs** are to be used for COVID-19 testing across all SLUHN service lines now. Product code - SL 46537. Collection kits will be identified with Green labels. Acceptable swabs are synthetic fiber (flock) swabs with a plastic shaft.

OP is equivalent to NP swabs and is easier for both the patient and collector.

Collectors must pay special attention to properly collect specimen. Insert swab into the posterior pharynx and tonsillar areas. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.

UTM media and NP swabs are in short supply nationwide. UTM and NP swab collection devices will be reserved for Respiratory Panels, Influenza/RSV, and other viral testing.



Order code in Epic – Novel Coronavirus (COVID -19 PCR) SLUHN  
EAP – LAB30135

Please phone the laboratory call center 484-526-4563 for assistance as needed.

Respectfully,  
James Chiadis M.D.

Figure 7: Original Ordering Algorithm

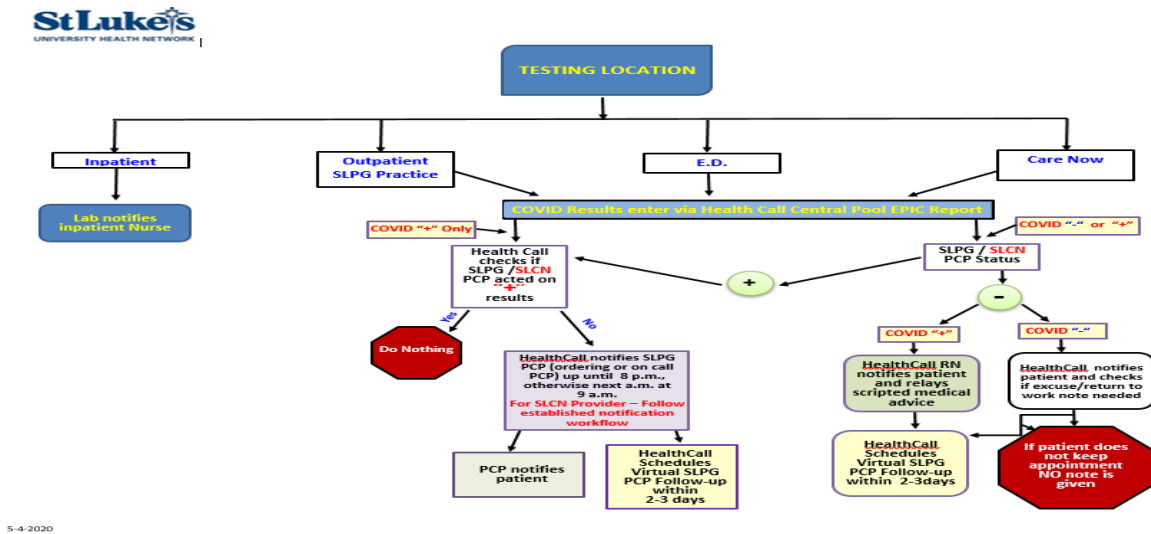
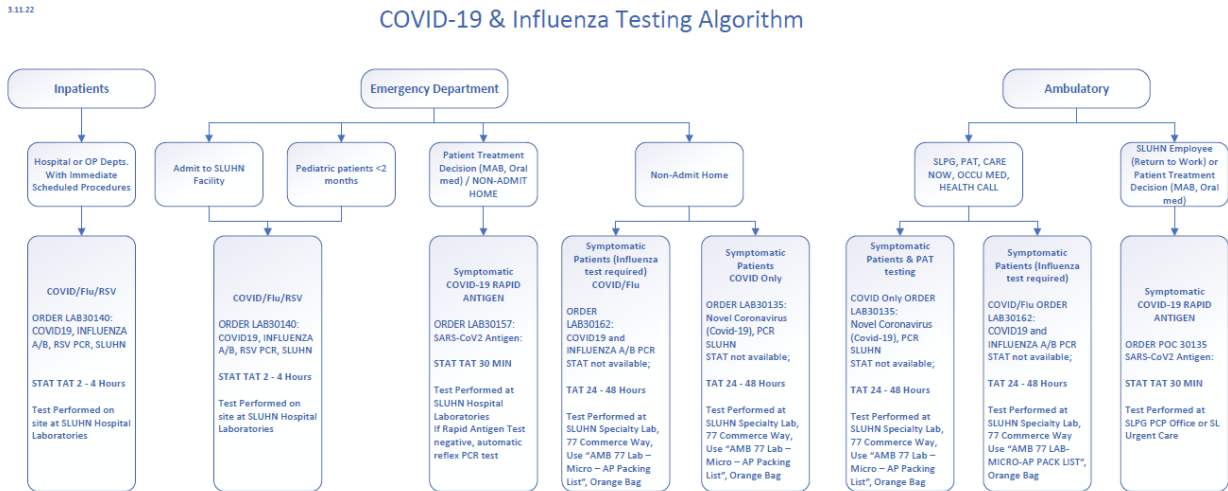


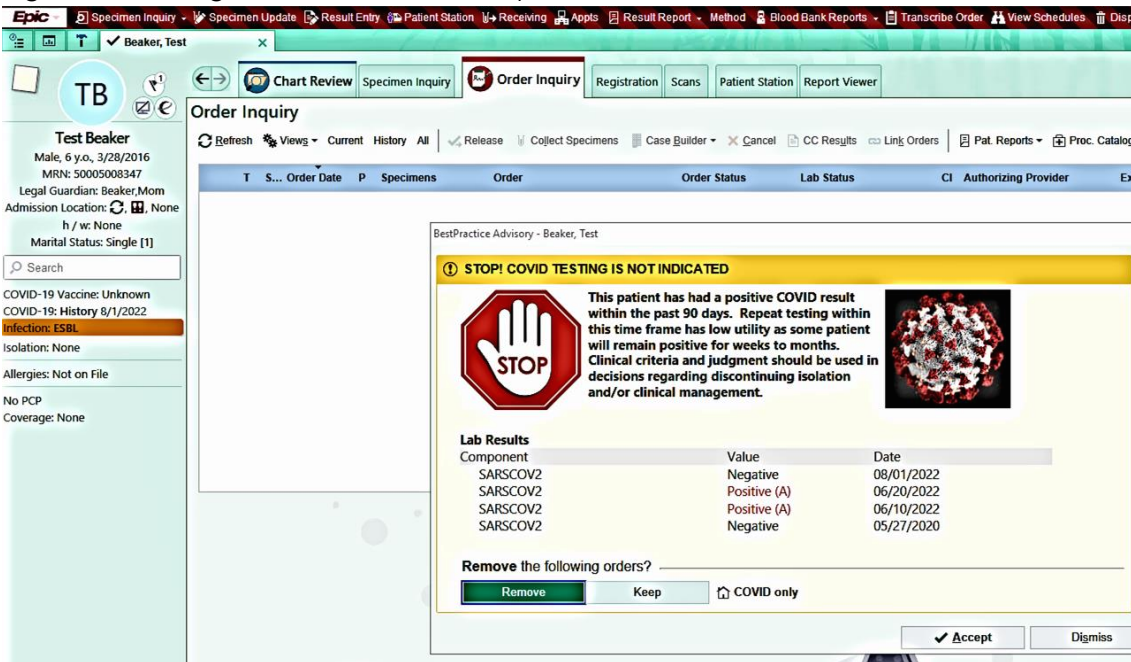


Figure 8: Updated Ordering Algorithm



If patients were recently positive, it was recommended they do not get retested. If patients were not symptomatic but had close contact with a positive person, SLUHN providers were requesting patients not get tested unless they showed symptoms. Patient refusal was also an exemption criterion.

Figure 9: Testing Not Indicated Example



While the laboratory does not facilitate any digital devices or services for remote monitoring and interventions for the clinician, there is record retention in EPIC so providers can see previous results. This may provide a timeline for patient care and correlate other test results to a given diagnosis. There is also the St. Luke's MyChart, which grants patient's access to their own test results and the COVID-19 page on the St. Luke's MyNet for COVID-19 testing and quarantine information for patients.

There is no risk adjustment for patients, but the laboratory does complete its own risk analysis and provides reassessment intervals for given criteria when it comes to testing. Examples are noted below in Table 3 and Table 4. Typical risk assessments include the following categories: Specimen, Test System, Reagent, Environment, and Testing Personnel.

Table 3: Laboratory Risk Analysis Example

Risk Identification	Measuring System Feature or Manufacturer Recommendation	Known Limitations	Internal Control	External Control	Engineering Control	Operator Training	Risk Mitigation	Residual Risk
Specimen-Patient preparation and identification	Manufacturer's recommendations for patient preparation	Specimen collection process not following in EPIC. Wrong patient label on specimen. Specimen mislabeled by lab during accessioning.	NO	NO	NO	YES	Trend occurrences through QA events. Specimen collection procedure.	Result reported to wrong patient.
Specimen Collection/Media	Nasopharyngeal or nasal swab should be collected according to standard technique and immediately placed into UTM media.	Improper specimen collection. Unvalidated collection media. Insufficient sample collection. Expired media. Contamination of patient sample during collection.	NO	NO	NO	YES – preanalytical NO – postanalytical	Trend occurrences. Refer to specimen collection procedure. Staff education for specimen collection. Training and education to include accept/reject criteria.	False positive or false negative result.
Specimen Transport and Storage	Specimen in transport media should be processed and tested as soon as possible. Storage requirements of 24 hours room temperature; 7 days refrigerated.	Specimen not shipped or stored at appropriate temperature. Sample degradation.	NO	NO	NO	YES- preanalytical NO - postanalytical	Manufacturer's Instruction for Use. Lab specimen collection procedure. EPIC Procedure catalog. Training and education of collector/lab staff. Use of appropriate transport packing list and storage. Courier education for transport of samples.	False negative result.

Test System – Using Biological Safety Cabinet with Appropriate PPE	Testing Personnel must wear clean gloves or change gloves per procedure during sample preparation.	Testing personnel does not wear clean gloves during sample preparation.	NO	NO	NO	YES	Training, education, and competency of operator.	False positive result.
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Table 4: Laboratory Risk Reassessment Intervals

Reassessment interval	Laboratory Management Action Steps
Annually	Annual Assessment of staff competency on the Standard Operating Procedure.
Annually	Annual Preventive Maintenance completed by vendor engineer on instrumentation.
Monthly	Monthly background calibration completed on Quantstudio 7 to ensure proper function of instrument.
Weekly	Weekly completion of wipe test on laboratory surfaces to ensure minimized contamination risk.
Daily	Completion of external controls every day of testing to ensure proper function of instruments.

### ***Improving Adherence to the Standard of Care***

The clinical problem was the lack of in-house COVID-19 testing. The goals of this project were to decrease outpatient testing TAT by 50% and reduce expenses by 75% through the implementation of high-throughput, in-house COVID-19 testing.

The patient numerator was the number of patients tested in-house in the established Molecular Laboratory. The patient denominator was the total number of COVID-19 tests ordered at St. Luke's University Health Network.

There was no external performance benchmark at the time the laboratory was implemented due to the ever-changing demands of the COVID-19 pandemic. Overall, the College of American Pathologists (CAP) guidelines indicated that test turn-around time is an indicator of quality included as part of the laboratory quality management program. CAP inspections occur every two years, where the quality management programs are inspected for deficiencies.

The following figures correspond to data collected using system-generated reports to determine the success percentage of the project. The following data includes total test volumes, turn-around-time reports, and financial expenditure. Overall, the St. Luke's University Health Network team responded to the pandemic by bringing testing in-house, which ultimately led to a reportable decrease in turn-around-time and an increase in cost-

savings, and a correlated increase in favorable patient outcomes, community accessibility to COVID-19 testing, and timely epidemiological data reporting.

Figure 10: In-house COVID test vs. Reference Lab Covid Test Volume 2020-2021

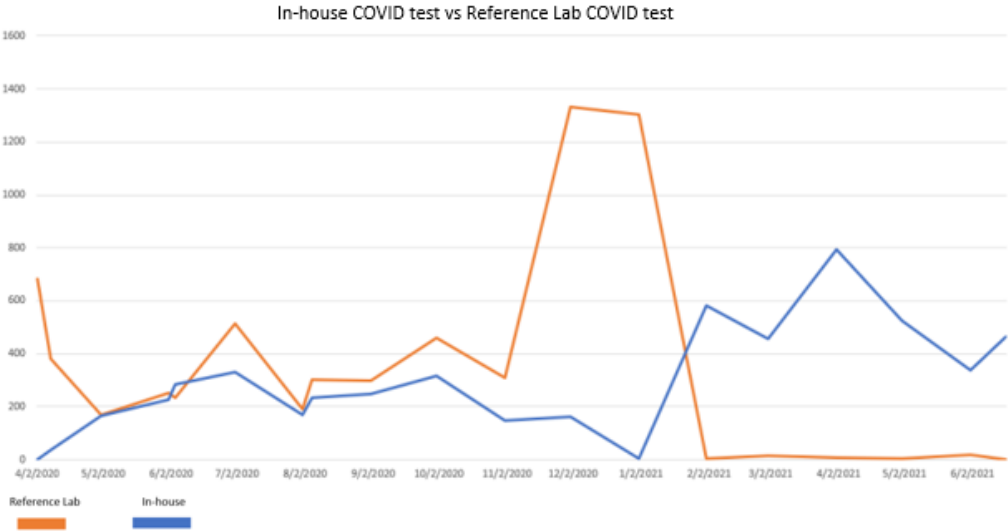
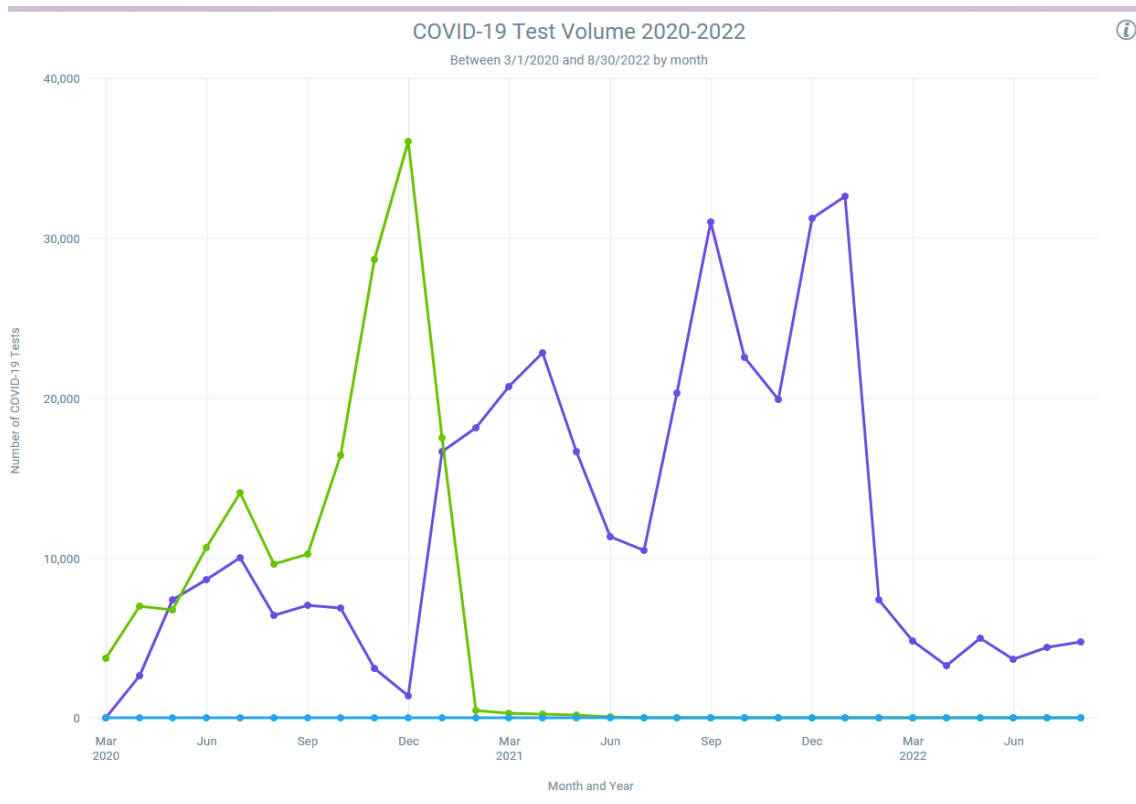


Figure 11: COVID-19 Test Volume 2020-2022



Green: Novel Coronavirus 2019 (COVID-19), NAA (Labcorp)  
 Purple: Novel Coronavirus (COVID-19), PCR SLUHN

Figure 12: COVID Testing TAT (Hours)

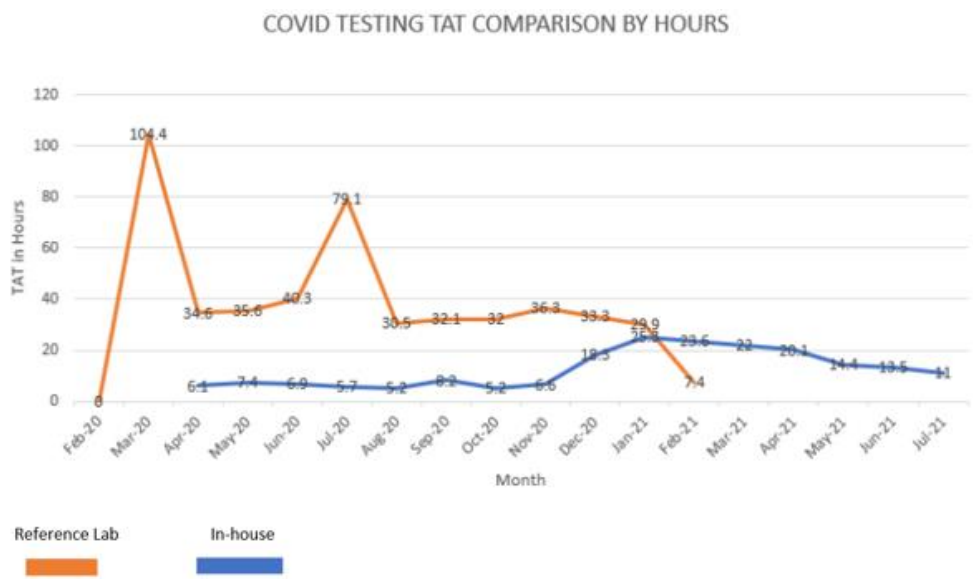
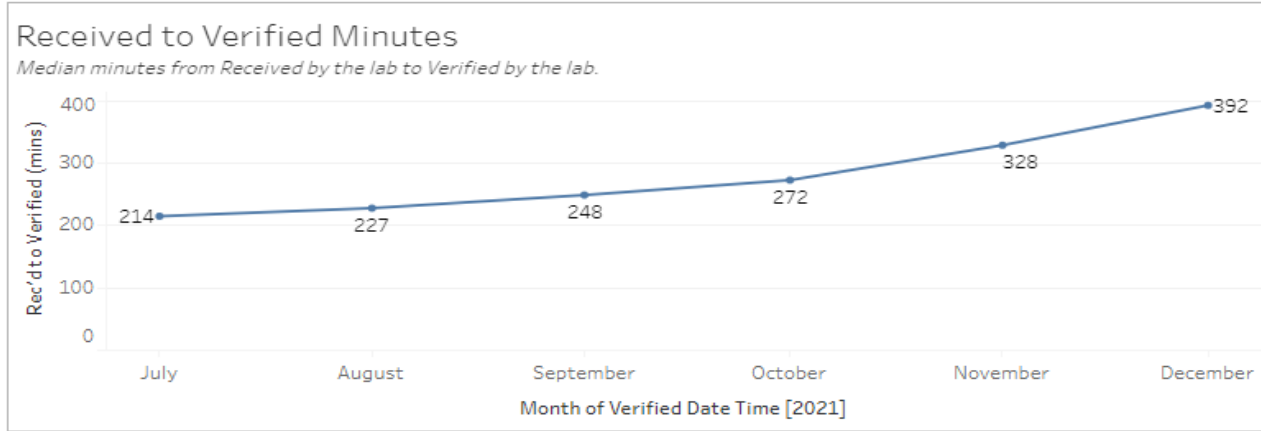


Figure 13: COVID Test Received to Verified Minutes



Once all testing was done in-house, TAT remained relatively consistent at an average of 4.7 hours from receipt to completion.

Table 5: Total Cost Savings for FY 21 and FY 22

LabCorp		In-House Thermofisher		Network
Cost per Test	Total Cost 262,986 tests	Cost per Test	Total Cost 262,986 tests	Total Savings
\$100.00	\$26,298,600.00	\$27.94	\$7,347,828.00	\$18,950,772.00 (72.10%)

Figure 14: Q3 2020 Business Review for St. Luke's University Health Network

**Top 25 Growth Tests (by Spend) Q3 2020 vs. Prior Year Q3**

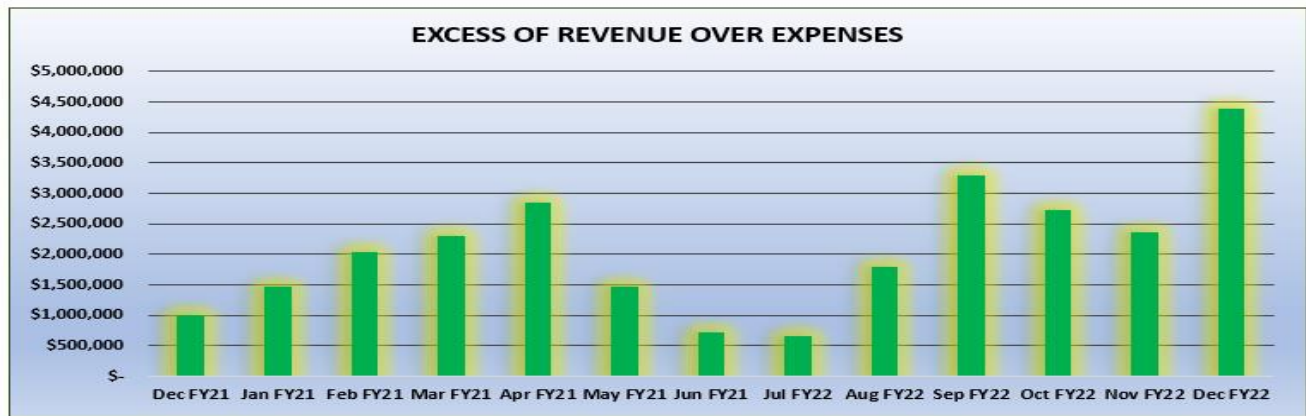
Test #	Test Name	Avg. Spend Per Test	Q3 2020		Q3 Prior Year		Q3 2020 vs. Prior Year Q3			
			Spend	Volume	Spend	Volume	Spend	Spend %	Volume	Volume %
139900	SARS-CoV-2, NAA	\$100.00	\$3,316,300	33,163	\$0	0	\$3,316,300	100%	33,163	100%

Figure 15: Q3 2021 Business Review St. Luke's University Health Network

**Top 25 Declining Tests (by Spend) Q3 2021 vs. Prior Year Q3**

Test #	Test Name	Avg. Spend Per Test	Q3 2021		Q3 Prior Year		Q3 2021 vs. Prior Year Q3			
			Spend	Volume	Spend	Volume	Spend	Spend %	Volume	Volume %
139900	SARS-CoV-2, NAA	\$75.00	\$675	9	\$3,316,300	33,163	(\$3,315,625)	-100%	(33,154)	-100%

Figure 16: Excess Revenue over Expenses FY 21 and FY 22



## Improving Patient Outcomes

This case study is unique in that the laboratory does not have a measurement to achieve causation between one test result to the overall patient outcome, length of stay, or reduction in adverse events. Laboratory testing, as a whole, correlates to a patient outcome, but is impossible to designate as an overall causative factor in their care.

An estimated 60%-80% of patient management decisions are based on laboratory data (Peter et al., 2010). Accurate and rapid diagnostic tests are required to diagnose illness, identify causative factors, monitor treatment efficacy, and perform surveillance for diseases. The relationship between laboratory and clinical patient management is interdependent; the laboratory data provide justification for clinical decision making and the clinical signs or management protocol prompt laboratory testing (Peter et al., 2010). As the significance of this relationship increases in conjunction with an increased demand for laboratory testing, laboratory investigations remain essential to patient care and focus on the quality of laboratory services being provided. Quality indicates not only accuracy and precision, but timeliness of the result. All laboratories aim to provide rapid, reliable results at a reasonable cost.

While the laboratory turn-around-time (TAT) does not have a universal numerical designation, it is often defined as the time from first registration of a sample on the laboratory information system (LIS) to the time a result is released to the ordering provider. The TAT, in part, is determined by the window of testing from venipuncture as prescribed by test manufacturers, the sample integrity, and the clinician (Coetzee, Cassim, & Glencross, 2020). Additional factors include the timing of specimen collection and transport to laboratories, sample volumes, staffing, efficiency of procedure and

instrumentation, and whether the test was ordered as routine or STAT. Several types of TAT have been described in journal articles, but the one of significance to this study is the comparison of what is called the “therapeutic TAT” versus the “laboratory TAT.” The therapeutic TAT is described as “the interval between the time a test is ordered to the time when treatment decisions are made based on the result available” (Pati and Singh, 2014). In comparison, the laboratory TAT begins from the time the sample is received to the release of results. Therefore, there is a distinct difference between an ordering provider’s TAT and the laboratory’s TAT. The differences in TAT were outlined in the 1998 College of American Pathologists (CAP) Q-probe program, according to which 41.1% of laboratories defined TAT as the interval from laboratory receipt of a sample to result. Comparatively, over 40% of physicians defined TAT as starting at the time of a physician order request (Pati and Singh, 2014). Unfortunately, these complex parameters surrounding the total TAT versus the laboratory TAT imposes a deficiency in monitoring the effect of the laboratory TAT on patient care. Additionally, patient care may not have been solely determined based on a coronavirus test result due to the possibility of co-infection or the presence of pre-existing conditions, further complicating the impact of laboratory testing.

Despite these discrepancies, TAT is an integral measure of quality and efficiency in all laboratories. The College of American Pathologists (CAP) includes in the Laboratory General checklist (GEN.20316) a Quality Management (QM) program that includes a section on the collection-to-reporting TAT, specifically for tests ordered as STAT. Evidence of compliance for this item includes indicators, frequent monitoring, and defined benchmarks for each item. The Laboratory General checklist also includes TAT in Gen.41345, requesting written policies defining test reporting TAT and process for communication of delays of TAT. Under the Reference Laboratory Selection of the checklist (Gen.41350) it is noted that “rapid TAT is required to prevent either a delay in patient treatment/diagnosis or specimen degradation.”

St. Luke’s University Health Network tracks the laboratory TAT as showcased by Figure 4. Once the majority of testing was being completed by in-house laboratories, the TAT of patient samples decreased by a minimum of 10 hours, even at peak testing. The only exception is February of 2021, by which point the in-house testing volume increased while the reference laboratory volume decreased, as shown by Figure 3. Once all testing was completed in-house, the TAT remained relatively consistent at an average of 4.7 hours from receipt to completion. The overall decrease in TAT can be correlated to more accurate patient care, decreased time to implement isolation protocol, and more efficient contact tracing.

## ***Accountability and Driving Resilient Care Redesign***



Data was collected using reports from Tableau, Stratajazz, or Hive. Reports including current data have been collected using SlicerDicer. Additional reports could be requested and generated by Matthew Zangari from Information Technology. The COVID-19 testing number reports were generated directly by laboratory management staff from EPIC production. These reports on TAT allow laboratory staff to review their performance in the goal of maintaining a 24-48 hour TAT for COVID-19 samples. The significance of these reports is that the results can trigger workflow adjustments. Particularly, the implementation of completing runs of 188 patients instead of 384 patients at one time was a significant change to the workflow and decreased the TAT for COVID-19 samples.

The turn-around-time report triggered adjustments to the workflow by implementing runs of 188 patient samples instead of 384 patient samples. Given the sample processing set-up of two biological safety cabinets, it would decrease the turn-around-time by being able to process the two sample deep-well plates (94 samples each) and run them on the Quantstudio 7 while the next sample plates were being prepared, instead of waiting for the completion of four sample plates.

### ***Process Improvement, Workflow, and Change Management***

The project completed by this team arose due to an emergent need through a public health emergency. Had this project been completed under different circumstances, the design and implementation of this project would have followed a traditional workflow. The team that completed the original project would recommend the following for any team looking to replicate this project or utilize the project management aspects of this project. Each team is outlined according to the order of the steps that would need to be taken to ensure appropriate management and compliance for instituting a new instrument or procedure.

#### Laboratory

1. Identify Network need or have need identified by the Network.
2. Determine required laboratory partners, subject matter experts, and network partners.
3. Vet options for instrument and materials.
4. Determine required instrumentation and materials.
  - a. Ensure proper storage requirements for instruments and materials.
  - b. Ensure space for room temperature, refrigerated, and frozen materials.
5. Determine location of testing (one location or multiple).
6. Write pro-forma outlining plans/estimated costs and present to leadership for approval.
7. If approved, begin contract process with legal and submit service requests for IT.

8. Complete Lab Service Now request or IDEA for IT.
  - a. Requires outline of test components, reference range, associated CPT codes, critical result flags, result comments, procedure catalog requirements, specimen volume requirements, test name and abbreviations, and label requirements.
  - b. New instrumentation requires CORL security assessment.
9. Once contract is approved, submit a capital request to materials management for required instrumentation and equipment.
10. Submit purchase orders to materials management for additional equipment, reagents, controls, and consumables.
11. Plan white-glove instrument installation with the vendor (as applicable).
12. Clear and clean space where testing will occur.
13. Plan vendor training with staff at time of instrument installation and Installation Qualification/Operational Qualification (IQ/OQ) assessment.
14. Write verification plan for review by Medical Director.
  - a. Must include accuracy, precision, and correlation with current method.
  - b. May include linearity, sensitivity, specificity, normal range comparison, interface studies, and dilution studies.
15. Write Individualized Quality Control Plan (IQCP) Risk Assessment, Quality Assurance Plan, and Quality Control Plan for review by Medical Director (if applicable).
16. Complete bench verification work and LIS interface testing with IT.
  - a. Communicate any issues directly with the vendor.
17. Complete IQCP bench work (as applicable).
18. Compile data from verification, LIS interface testing, and IQCP for review by Medical Director.
19. Write Standard Operating Procedure based on the Manufacturer's Instructions for Use/package insert.
  - a. Add to MediaLab or Procedure Manual.
20. Write Wipe Test Procedure (as applicable) and add to Medialab or Procedure Manual.
21. Establish QC log sheet, lot-to-lot sheet, and wipe test log sheet (as applicable).
22. Write result comments for negative, positive, and indeterminate results, including procedural limitations of the assay.
23. Write training checklist for staff.
24. Write competency assessment for initial, 6-month, annual, and review competency for staff.
25. Write memo on new testing to be disseminated to the Network.
26. Write ordering algorithm (as applicable).
27. Update the critical value list (as applicable).
28. Notify CAP and State Department(s) of Health of new testing (as applicable).
29. Update CAP activity menu.
30. Order Proficiency Surveys from CAP (as applicable) or determine other proficiency testing.
31. Update Safety Data Sheets (SDS) and Chemical Inventory.
32. Train staff on appropriate specimen collection, handling, contamination control, testing, and resulting.

33. Train staff on appropriate specimen ordering and registration.
34. Train staff on appropriate instrument maintenance, reagent handling, quality control/quality assurance practices.
35. Establish a go-live date with IT.

#### Information Technology/Systems Engineering Group/Data Innovations

1. Initiation of Lab Service Request or IDEA.
2. CORL Technologies security assessment.
3. Completion of Architecture Intake form.
4. Install required Network connections, computers, monitors, printers, and label printers.
5. Adjust firewalls (as applicable).
6. Build test.
  - a. Must include Epic order code, LIS validation, reference range, critical value flags.
  - b. Ensure registration is available for non-Network testing requests.
  - c. Includes build of clinical order workflow, order questions, label printing, packing lists, batching, and container storage.
  - d. May include patient chart banners or pop-ups if patient does not meet criteria for testing.
7. Update procedure manual.
8. Complete LIS interface testing.
9. Automatic state department reporting (as applicable).
10. Check sample report with laboratory.
11. Build or update existing reports to include new testing (Tableau, SlicerDicer, Strata).
12. Establish a go-live date with the laboratory.

#### Project Management

1. Work with all teams to ensure timelines and deadlines are being met.
2. Establish an on-site presence at the laboratory during installation and training.
3. Act as a liaison between the Network teams and vendors for all project aspects from the initial idea to the go-live date.

#### Network Partners

1. Determine collection sites (as applicable).
2. Establish new collection sites based on health equity (as applicable).

#### Legal

1. Revise or establish vendor contract.
2. Review reagent costs, control costs, and service costs associated with contract.

#### Materials Management

1. Determine supplier for required materials – ensure revised contract as applicable.

2. Establish value analysis for cost of materials.
3. Addition of supplies to online ordering system (as applicable).
4. Create standing orders and par levels (as applicable).
5. Determine items to be stocked at the Distribution Center versus ordered directly.
6. Determine delivery of items to facility through the courier network.
  - a. Includes laboratory supplies and collection supplies to collecting sites.
7. Determine storage requirements of items delivered.
8. Monitor supply chain limitations and inform laboratory of backorders.

#### Revenue Management Resources/Management Engineering

1. Assign CPT code for test.
2. Determine reimbursement rate.
3. Monitor CMS ruling changes.
4. Maintain revenue cycle tracking and reporting.
5. Ensure correlation of test charge code to laboratory productivity (HIVE and Strata).

#### Laboratory Outreach

1. Educate providers and collectors on proper test ordering, specimen collection, handling, and transport.
2. Handle quality assurance concerns reported by the laboratory.

Since the closure of this project, St. Luke's University Health Network has implemented novel molecular testing platforms and assays using the above project management model. As molecular testing becomes gold-standard for a variety of testing, the current team expects to continue to grow in the breadth and depth of molecular testing offered at St. Luke's University Health Network. The Amp It Up project, while arising out of a public health emergency, was the inflection point for the changes being seen in the laboratory today. Without it, the push for additional molecular testing may not have occurred for several years.

Overall, the Amp It Up project was a tremendous effort by an extraordinary team of individuals over a short time, but the contributions this project made to our healthcare system will last a lifetime.

## References

Coetzee, L.-M., Cassim, N., & Glencross, D. K. (2020, December 21). *Weekly laboratory turn-around time identifies poor performance masked by aggregated reporting*. African journal of laboratory medicine. Retrieved July 26, 2022, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7756605/>

Pati, H. P., & Singh, G. (2014, June). *Turnaround Time (TAT): Difference in concept for laboratory and clinician*. Indian journal of hematology & blood transfusion : an official journal of Indian Society of Hematology and Blood Transfusion. Retrieved July 26, 2022, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4022919/>

Peter, T. F., Rotz, P. D., Blair, D. H., Khine, A.-A., Freeman, R. R., & Murtagh, M. M. (2010, January 10). *Impact of laboratory accreditation on Patient Care and the health system*. OUP Academic. Retrieved July 26, 2022, from <https://academic.oup.com/ajcp/article/134/4/550/1760329>