DAIDS HIV/AIDS Network Clinical Research Site (CRS) Survey: SARS-CoV-2 Testing

Results Summary | 30 April 2020

Contents

Introduction

The *DAIDS HIV/AIDS Network CRS Survey: SARS-CoV-2 Testing* was developed in consultation with the Office of Clinical Sight Oversight (OCSO) of the Division of AIDS (DAIDS) and distributed by the Office of HIV/AIDS Network Coordination (HANC) to 125 Clinical Research Site (CRS) Site Leaders, representing 131 unique domestic CRSs, on 21 April 2020. CRS Site Leaders were requested to complete the survey for each domestic CRS affiliated with the NIH HIV/AIDS Clinical Trial Networks (ACTG, HPTN, HVTN, IMPAACT, and MTN), including the NICHD-funded IMPAACT CRSs and protocol-specific sites. CRS Site Leaders were requested to submit survey responses by 23 April 2020. (*The survey is attached in Appendix 3.*)

The purposes of this survey were:

i. To identify opportunities to support expanded SARS-CoV-2 testing at DAIDS Clinical Research Sites to help meet needs for expanded community testing in the United States as well as needs for future DAIDS research studies.
ii. To understand current capacity for testing.

iii. To understand potential challenges with testing.
iv. To understand current/potential linkages to other organizations in support of testing, if any.

Upon receipt and review of the initial survey responses from CRS Site Leaders representing 80/131 unique CRSs, OSOC sent a couple of additional questions to the respondents, and a separate set of questions to the non-responding sites.

Executive Summary

Despite the rapid response time requested, responses to the initial lengthy survey were received from 74 CRS Leaders representing a total of 80 unique CRSs (61% of CRSs reporting). The secondary survey questions sent to the initial respondents were responded to by 62/80 CRS Site Leaders (Appendix 1). From the original non-responding sites, responses to a separate query from were received from 46/54 CRS Site Leaders (Appendix 2). Results are summarized below and in more detail in the rest of this report.

Just over 20% of CRSs are conducting SARS-CoV-2 RNA testing at their research site, but 80% of the CRSs have SARS-CoV-2 RNA testing available at their affiliated institutions. Most testing is performed at local hospital/institution labs, with commercial labs being the second most common testers and state health departments the third. Turnaround time for hospital labs is the quickest, most frequently reported to be 1-24 hours, with commercial labs taking a range from one to more than 4 days. For state labs, there were sites reporting 1-2 days and other reporting more than 4 days. The most commonly cited delay was due to back log at the labs. For the populations being tested, most are symptomatic patients and health care workers. Just under half of respondents also reported that SARS-CoV-2 RNA testing is available for all hospital admissions, first responders, and close contacts. Only 15% reported testing for asymptomatic patients. Some sites also reported testing for vulnerable populations (children, pregnant woman, homeless people and nursing home residents) and plasma donors.

Barriers to accessing patient populations for SARS-CoV-2 RNA testing at the CRS included, in order of frequency: institutional policies and procedures, equipment and staffing (Question 11). The CRS Site Leaders reported robust linkages, in order of frequency to: outpatient clinics, hospitals, state/county health departments or clinics, long-term care facilities, home health agencies, and jails and/or prisons (see Question 13 for details of many of these extensive linkages). Barriers to expanding SARS-CoV-2 RNA testing at the CRS were most commonly insufficient clinical consumables (i.e. swabs), insufficient personal protective equipment (PPE), and insufficient testing kits, in that order (Question 14). Also cited as barriers to expanded testing were insufficient reagents, criteria of who gets tested, and lack of safe collection facilities. Open text comments about the barriers to expanding SARS-CoV-2 RNA testing at your CRS were many and focused on testing restrictions/procedures, equipment, and staffing, in that order. The equipment needs for PPE included N-95 masks, face shields, protective clothing and surgical masks, ranging from 85% of respondents for N-95 masks to 43% for surgical masks. The comments of these barriers are grouped into insufficient PPE, insufficient clinical consumables, insufficient test kits, insufficient reagents, personnel limitations, staff concerns about personal safety, inadequate funding, lack of safe collection facilities, and changing or limited testing criteria. Fewer comments were received about inadequate linkages to potential pool of patients, system/software incompatibility between clinic and testing lab, not being an approved testing lab, lack of ability to bill for services and reimbursement provided does not cover expenses (Question 16).

If these barriers were overcome, 54% of sites projected they could test an additional <1,000 people per week; 22% projected 1,000-2,000; less than 10% of sites projected 2,000-3,000 and 3,000-4,000; and 9.5% projected

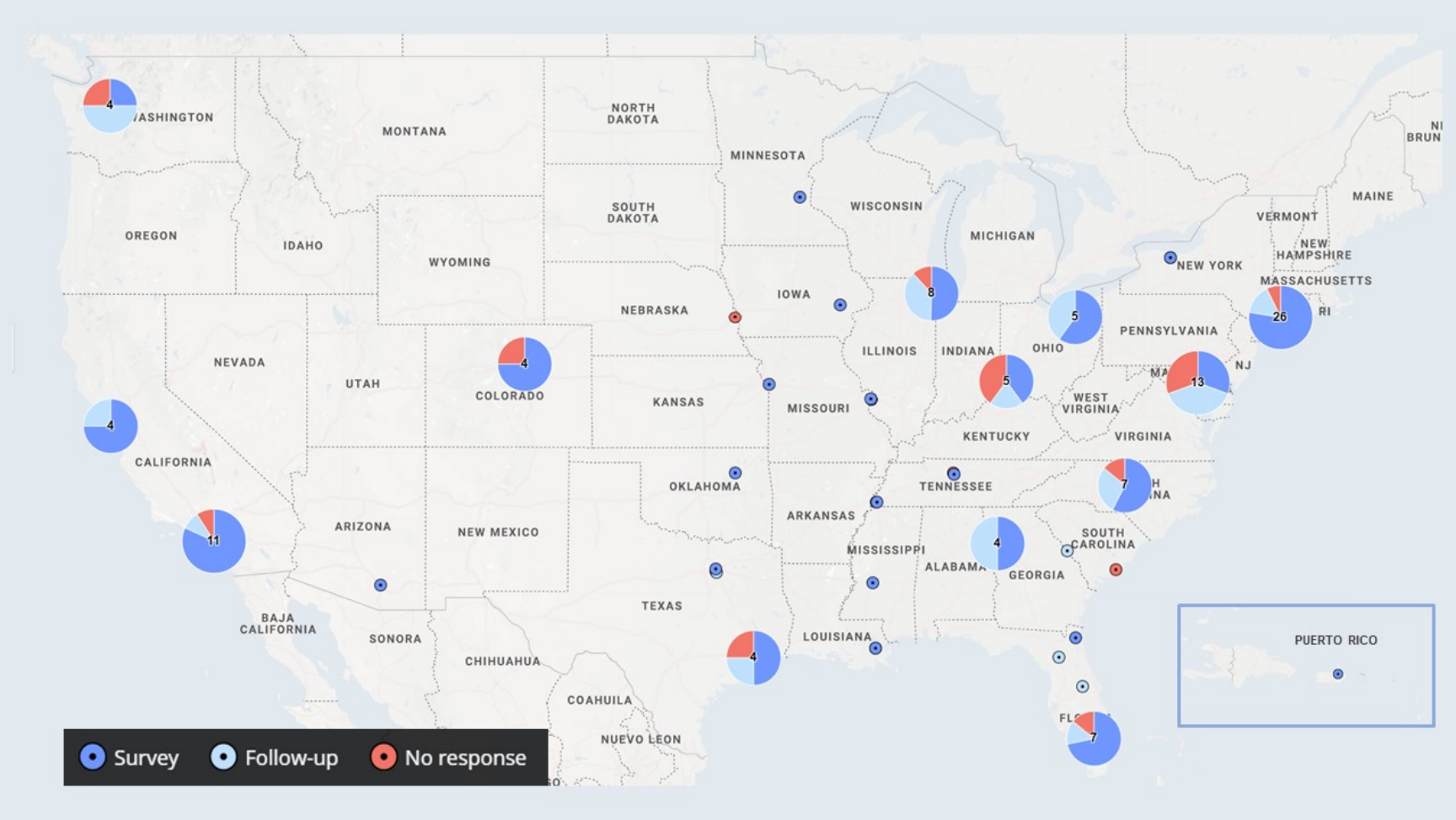
being able to test >4,000 people per week (Question 17). Most sites are able to perform SARS-CoV-2 testing as part of a gradual entry back to normal operations immediately (63%). However, a range of needs for additional support and limitations related to testing were identified. These issues clustered in the areas of personnel/policies, equipment, and funding (Question 18A and 18B). Most respondents (69%) identified items that NIAID/DAIDS could do quickly to help support increased SARS-CoV-2 testing at their CRS. These items grouped into themes of procedure equipment/supplies and staffing/training support. The supply needs covered the range of swabs, reagents, test kits, and PPE. The staffing/training needs focused on funding support and staff training (Question 21).

The last item in the initial survey addressed serology testing for anti SARS-CoV-2 antibodies. At the time of this survey, only 39% of 80 respondent CRSs or affiliated labs offered serologic testing. 67% of 42 respondents reported that their institutions had not yet determined the available serology tests to be reliable enough for clinical use. Where the serology tests are in use, the purpose ranges from testing health care workers, documenting past infection, serosurveillance, and screening for plasma donors. The few barriers noted around the offering of serologic testing concern reimbursement and the validation of the tests. Testing for SARS-CoV-2 on demand was thought to be an asset to CRS reengagement of participants with face-face visits by 70% of the respondents.

The supplemental questions asked of the responding sites showed that 94% of the sites could address their needs to conduct testing if NIAID provided the additional funding to support this effort. The comments of the affirmative respondents focused on the same general themes noted above: need for funding for supplies (swabs, reagents, PPE, staffing, testing machines; and a few sites noted some facility needs such as negative pressure tents, rooms or biosafety hoods). Some sites also noted though that their institutional testing capacity is strained with the current burden of tests being performed, but that additional funding to support testing at the CRS would help. Other sites noted though that even with adequate funding, supplies to purchase ae difficult to find, including reagents, PPE and supplies for rapid testing. Sites indicated that they would be able to begin testing quickly if funding was provided: 12 (1-14 days); 5 (15-28 days); and 2 (>28 days). Several sites did note external factors which would impact their ability to start testing including: stakeholder buy-in; local stay at home orders; and institutional policies on testing criteria. (Appendix 1).

Responses from 46/54 of the sites who were not able to respond to the first survey are summarized below. Support needs to expand testing at the CRS again primarily focused on supplies (PPE, swabs, reagents, test kits, instruments and test cartridges). Also, funding for expanded staffing needs were often cited. One site identified the need for support to perform validation studies necessary to perform these tests under CLIA. Most of these sites indicated they could expand testing if additional funding was provided by NIAID (24/26). However, a couple of sites noted that even though they have adequate funding at their institutions for testing, supplies are on back order. Several sites commented that assurance of an adequate supply chain would be as important as provision of funding. Rapid implementation of testing was thought feasible if funding was provided: 11 (1-14 days); 4 (15-28 days); and 4 (>28 days). Likewise, most sites indicated they could rapidly implement serologic testing with funding (21/22). Almost all sites indicated their institution has implemented or validated serologic tests. The primary need cited for funding by most sites for staffing was for research nurses, phlebotomists and test kits. A couple of sites noted the need again for a biosafety hood. (Appendix 2).

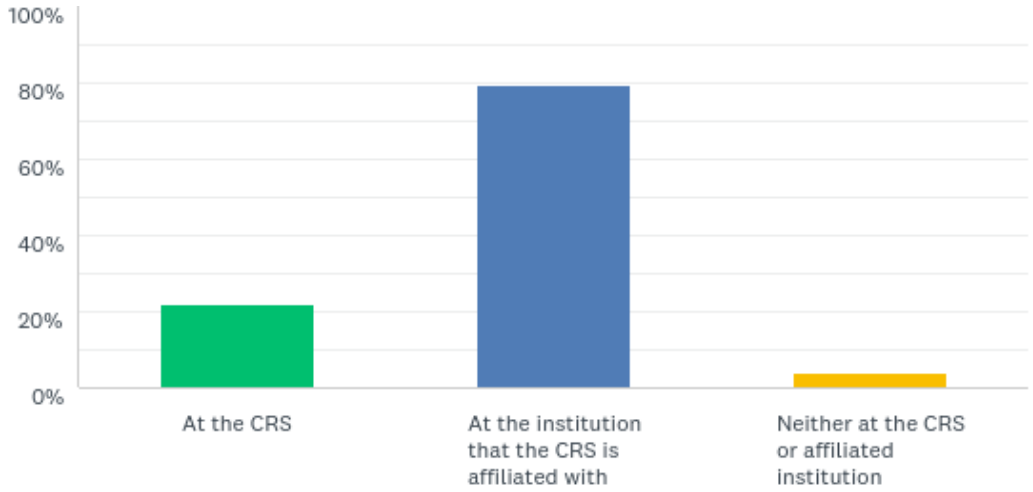
Clinical Research Site Respondent Distribution (N=80)



Current Capacity Performing SARS-CoV-2 RNA Testing at Clinical Research Sites

Q5: Is SARS-CoV-2 RNA testing currently being conducted at your CRS and/or at your CRS Institution?

Answered: 73 Skipped: 1



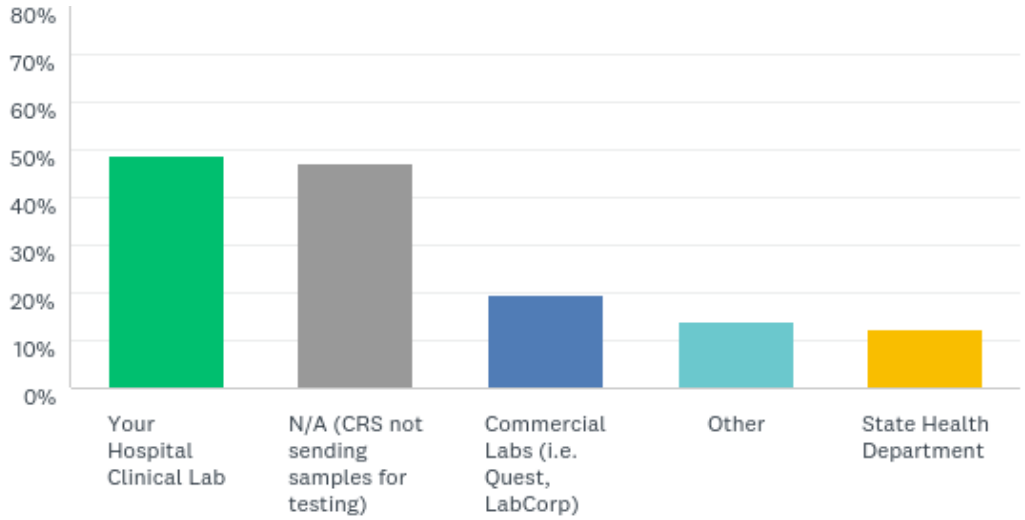
Names of CRS-affiliated institutions:

Baystate health
BIDMC. Our site will begin testing in May.
BronxCare Health System (formerly Bronx-Lebanon Hospital)
Broward Health Medical Center
Children's Hospital Colorado
Cone Health
Denver Health
Eisenhower Health
Emory University/Children's Healthcare of Atlanta
FL Department of Health, Tampa General Hospital, USF Health
George Washington University Hospital and the GW MFA
Harbor-UCLA
Hospital of the University of Pennsylvania
Jackson Memorial Hospital
Johns Hopkins University
LAC+USC Medical Center
Lifespan Health System
Mass General Hospital
Mount Sinai Health System
NewYork Presbyterian Hospital
Ohio State University Medical Center
OSU
Rush University Medical Center
San Francisco Department of Public Health – Public Health Laboratory.
San Juan Hospital
Stony Brook University
Texas Children's Hospital
Tufts Medical Center
Tulane Medical Center (HCA/Tulane)
Tulane University School of Medicine
UCLA Health: Ronald Reagan UCLA Medical Center, UCLA Santa Monica, and multiple community based clinics in the health system, including a drive-in testing facility
UCLA Medical Center
UF Health Jacksonville
UNC Health
University of Cincinnati Medical Center
University of Illinois at Chicago
University of Miami Miller School of Medicine

University of Mississippi Medical Center
University of Pittsburgh medical Center
University of Rochester Medical Center
University of Washington
University Pediatric Hospital
Vanderbilt University Medical Center
Whitman-Walker Health
Whole Family Health Center

Q6: Please indicate the labs your CRS is sending samples to for SARS-CoV-2 PCR RNA testing. Select all that apply.

Answered: 72 Skipped: 2

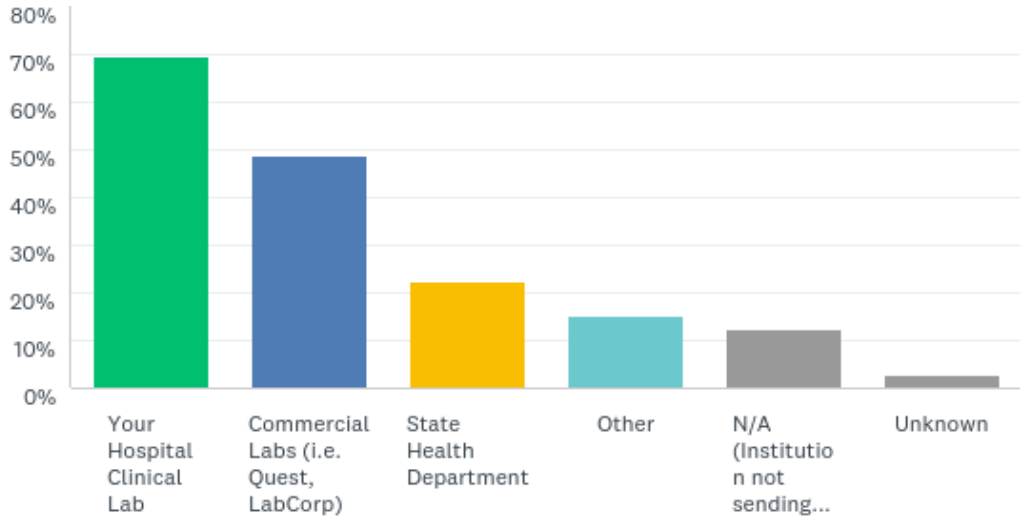


Other:

- Referring clients to various testing sites in Boston
- Research CLIA CAP lab also doing Abbott m2000 testing
- Through USF Health research labs
- Doing mostly Telehealth, once reopened, will be able to send to Quest and Labcorp
- We have the ability to do SARS-CoV-2 PCR RNA testing at the SFDPH PHL.
- Tests can be sent to our hospital clinical lab
- Regeneron
- Dr. Alland has a lab that has been doing some Cepheid testing for the co-located clinic, the CRS can do the same if needed and supplies are given
- In addition to the CLIA-certified clinical lab localized at the CRS, there are several research labs conducting PCR testing

Q7: Please indicate the labs your Institution is sending samples to for SARS-CoV-2 PCR RNA testing, if known. Select all that apply.

Answered: 72 Skipped: 2

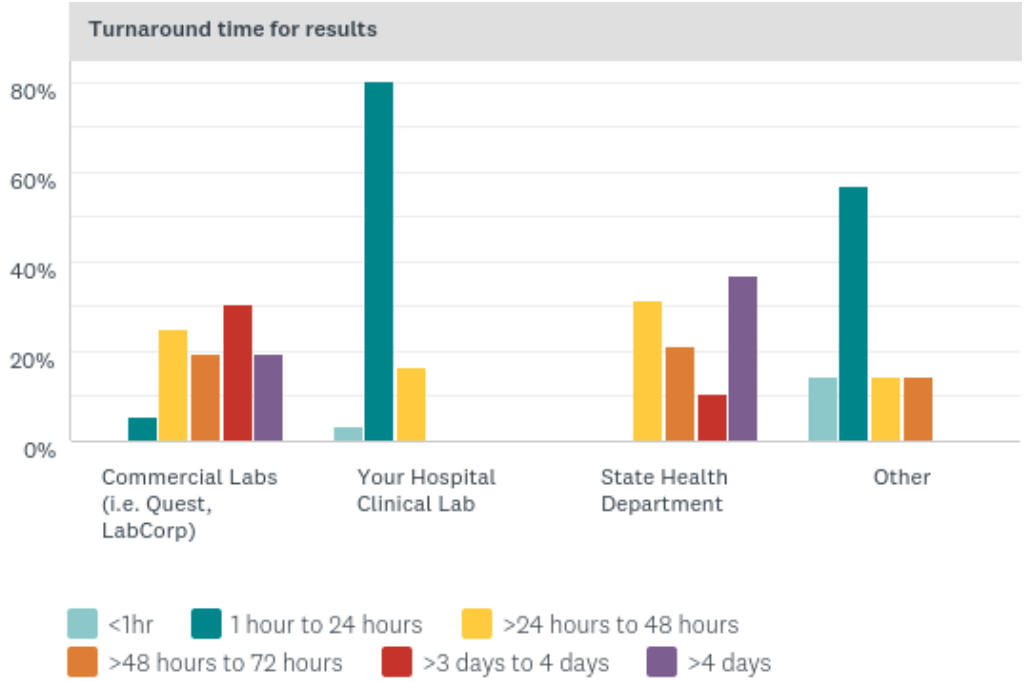


Other:

- Expanded qRNA testing capacity within University
- Robert Garry has developed a QPCR test that results in less than 24 hours currently capable of about 100 tests a day that have been used for symptomatic Outpatients, Health Workers, First responders, etc. and may be available for research samples if funding could be applied.
- University lab
- Houston Methodist, MD Anderson Cancer Center
- Local Health Department
- If specimen results are equivocal, they were being sent to the State Health Department lab.
- UVA
- USF Health research labs (if applicable, turnaround time varies)
- The hospital is testing every admission with a rapid test. The hospital also has a drive thru testing site. Those specimens are sent to a commercial lab.
- San Francisco Department of Public Health Laboratory
- Tests can be sent to our hospital clinical lab

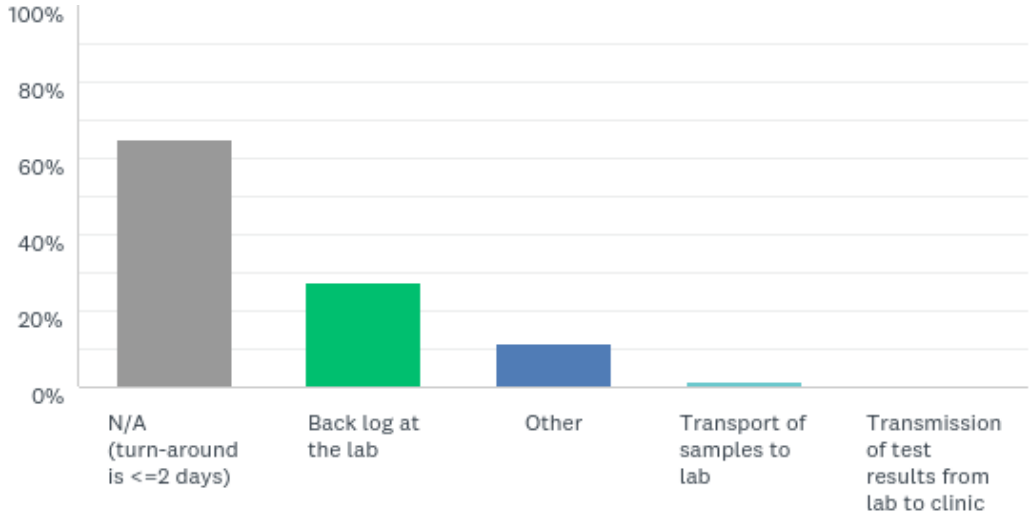
Q8: What is the turnaround time for results for the labs selected in Q6 and Q7?

Answered: 70 Skipped: 4



Q9: If the turn-around time for results is >2 days, what is the main cause of delay?

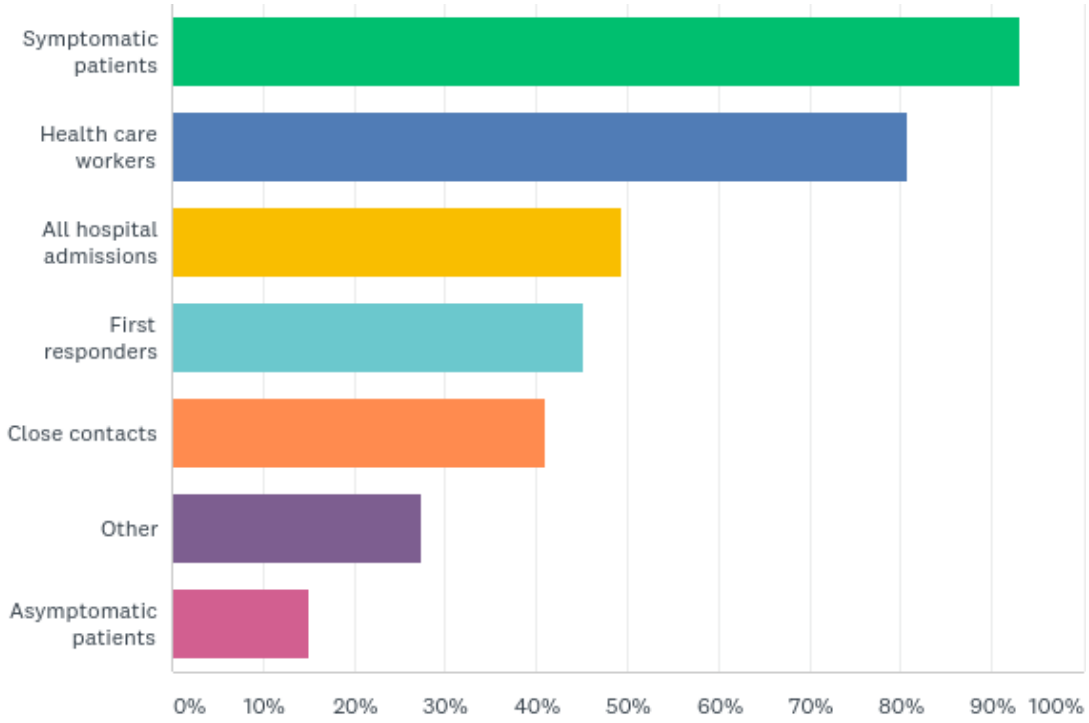
Answered: 69 Skipped: 5



Patient Access at Clinical Research Sites

Q10: Please describe the patient populations that are able to get tested for SARS-CoV-2 RNA testing at your CRS or Institution. Select all that apply.

Answered: 73 Skipped: 1



Other responses (grouped by theme):

General testing:

- We are ramping up to make this more widely available
- Testing is in process of expanding into community. Testing criteria are fluid.

Symptomatic testing

- Symptomatic patients who are considered person under investigation (PUI) and requiring admission
- Symptomatic healthcare workers
- HCW with a lower index of suspicion than for general population

Inpatient testing

- Inpatients with new respiratory symptoms or fever
- Subset of hospitalized patients
- Close contacts - only if admitted to the hospital
- All planned procedures including outpatients
- Hospital admission as appropriate, we are not testing all

Asymptomatic testing

- Asymptomatic patients requiring surgery

- Asymptomatic patients pre-procedure and symptomatic hosp. admissions
- Asymptomatic patients having surgical or aerosolizing procedures are now being tested. Hoping to expand testing soon (in the next few weeks)

Vulnerable population testing

- All pregnant women presenting for delivery
- Vulnerable populations are also eligible, e.g. homeless, nursing home residents, employees at nursing homes. The specific people eligible has been changing rapidly over time and likely will continue to change.
- Children admitted to the hospital or outpatient setting, ED, Urgent Care, clinics
- At congregate settings (skilled nursing facilities, prisons, etc.)

For plasma donors and studies

- We are testing people to qualify for convalescent donor plasma programs
- Plasma donors
- Screens for studies
- The other groups are getting tested in context of research studies

Q11: Please describe any barriers at your CRS to accessing patient populations for SARS-CoV-2 RNA testing.

Open text responses (grouped by theme):

Institutional/policies

- Time to establish community and institutional connections that allow cooperation
- Protocols for testing require specific symptoms be present currently. Most clinics are not yet open, and clinics route patients who are ill to the hospital per protocol. Testing venues need to serve walk-in populations who currently do not have access to testing other than through the hospital (that they generally do not trust visiting at present unless they must). There were drive-up testing venues, but many have closed.
- The CRS facility is not a health-system designated location for COVID suspected or diagnosed patients/participants to be seen; the CRS is working closely with university research administration to establish a location for COVID related research that would include a "hot" zone where known or suspected COVID patients/participants could be seen for research purposes. Vetting these new sites quickly for DAIDS-sponsored studies will be critical for future study feasibility. This would require a new level of flexibility in DAIDS policies and procedures.
- COVID is a barrier
- Lack of parking, potential concern about exposure on the MBTA, not knowing who to call to schedule a test
- The patients being tested are not coming through the CRS but rather through the MFA or GW Hospital
- Only testing symptomatic patients or hospital admins with close contacts
- We are located within the heart of the Puerto Rico Medical Center consisting of 5 Hospitals within and serving a big surrounding community
- We are embedded within the SFDPH and have access to all patients from case investigation (CI) and contact tracing (CT) who have provided consent to be contacted for research through our digital CI and CT platform. We haven't previously developed relationships with skilled nursing facilities, which is

currently a barrier for our CRS; however one of our investigators is leading the clinical response team which is establishing relationships that can be leveraged for research.
- We are currently not ready to see acutely infected patients during normal business hours. We are exploring possibilities such as a temporary mobile clinic in the parking lot of our CRS to see acutely infected patients.
- The CRS has access to the population for COVID studies. The sites lab has the ability to test, see question 14 for current barriers.
- This is a moving target. As less severely ill pts are presenting, testing criteria have expanded somewhat.
- No specific barriers other than majority of testing occurs in those with symptoms; outpatient testing is done at swabbing stations. Inpatient testing is performed using various platforms according to algorithms based on clinical status/need for continued isolation. The University in partnership with the Ohio Department of Health is testing first-responders in the community.
- Will not test asymptomatic patients
- None if eligible for VA care
- Asymptomatic healthcare workers or community members with known COVID-19 exposures.
- Transportation- patients without their own transportation have difficulty coming in for testing. Drive troughs do not take "walk-ins"
- The institution is restricting testing referrals to symptomatic patients only
- Getting the health department to give us data or provide positive pts with study info
- Our CRS is an outpatient clinic that is not equipped to evaluate COVID suspects or sample NP specimens, so they must be referred to a telehealth app to be approved for testing at another clinical area.
- Our health care system (hospital) is currently only testing pts being admitted to dedicated COVID hospital or units AND health care workers. There are other clinics doing ambulatory testing and we will ramp up HCW testing. We will likely need to tap into "Health at Work" re HCW, and ER (if they test non-hospitalized pts. This has happened at times when pts have improved while in the ER and may happen more over time
- CRS staff working remotely; currently preparing for A5395; prompt identification of appropriate candidates for study a concern (but this is post-testing not identifying for testing)
- No testing on weekends or evenings
- Multiple institutions with different electronic health records. Availability of testing and infrastructure for outpatients. Not available at the CRS affiliated ED. PUI are discharged without testing.
- We don't have established linkages to populations other than individuals with HIV. (However, we don't have a need to access these patient populations since testing is fairly widely available locally through our institution.
- We have patients with COV2, testing done outside of this CRS. Will begin testing in May.

Equipment
- Shortage of PPE equipment, not appropriate infrastructure
- Personnel and PPE
- We lack capacity to do testing due to shortage of PPE and testing kits.
- Test availability and PPE supplies
- Test availability
- Testing is not fully available to anyone who does not meet criteria
- Not at the present time. The swabs are becoming scarce
- Supply chain issues for testing (swabs, etc.). Otherwise none.
- Supply issues for swabs, reagents, transport media -- like the rest of the country.
- Has been resources

- Initially we had supply chain issues for tests but this appears to have resolved for most components. Our GMP has made transport media and swabs are the biggest barrier now.
- Sometimes we have reagent supply delay, swab kit may be delay(for commercial labs)
- Testing supplies. We have been gradually gaining greater access to supplies and as we do that we have been also increasing testing
- Access to sufficient personal protective equipment, access to SARS-CoV-2 RNA testing including rapid testing, access to swabs, funding to support staffing to conduct testing
- Lack of tests
- Limited number of tests available means limited ability to test all those we would like to.
- Previous lack of test kits, getting better now
- Lack of PPE, CRS personnel not directly caring for COVID patients
- Shortage of swabs
- Not enough tests for asymptomatic community members
- PPE
- Limited PPE

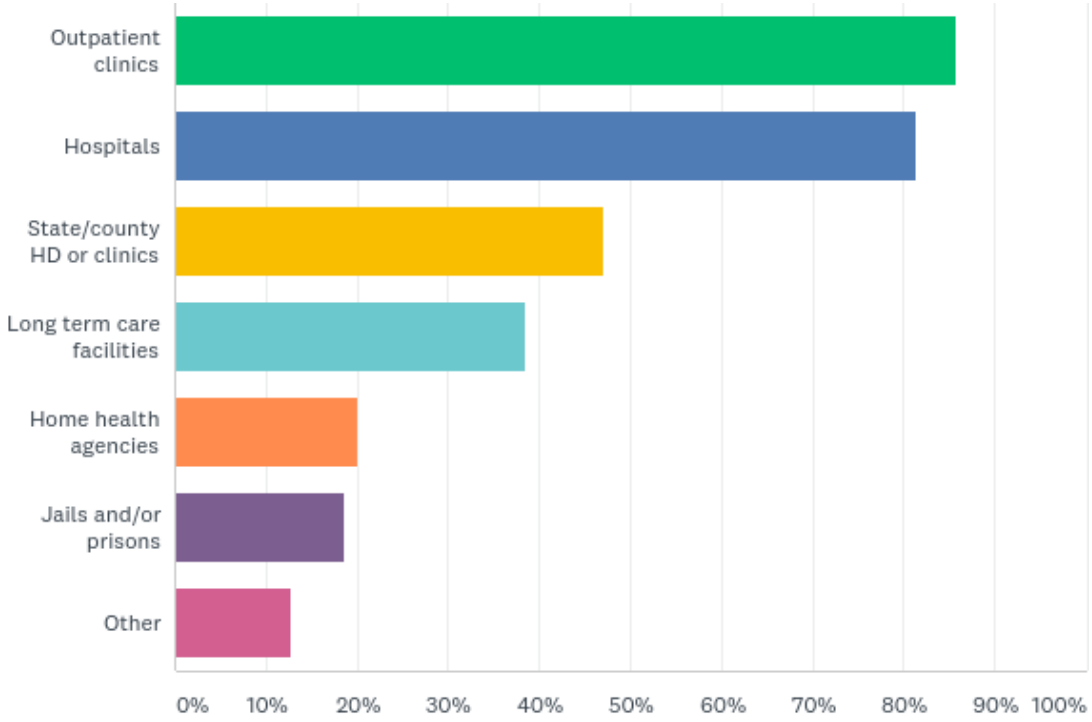
Staffing

- Currently the research center is closed due to the pandemic. However, we can reach patients in the clinics and the hospital.
- Staffing

Linkages to Organizations Within Your Community

Q12: Does the CRS have existing linkages to the following types of institutions in order to test patients for SARS-CoV-2? Select all that apply.

Answered: 70 Skipped: 4



Other:

- Drive in outpatient testing sites
- Our institution has links with all these types of organizations but not our CRS.
- Community testing tents in collaboration with Baltimore City HD
- We established COVID-19 Confirmed Clinic (COCo) which is a collaboration between FL Department of Health, Hillsborough (FDOH) and USF Health. We get referral for all confirmed cases from FDOH and our main teaching hospitals (Tampa general Hospital and Moffitt Cancer center).
- Collaborations with community-based organizations throughout New York City, affiliation with New York Blood Center and access to blood donors
- Outpatient clinics are affiliated with the University and can take advantage of the swabbing stations or OSU Emergency Departments
- All University of Rochester affiliated health centers
- SUD Rehab centers
- Employee wellness center, CRS hospital employees (8,000), surrounding university settings (UMKC, KU)

Q13: For the institutional linkages selected in Q12, please describe the nature of the relationship in the corresponding textbox below.

Long term care facilities:

- We have one researcher in the Medical School that did research at one long term care facility that was our sentinel for COVID-19. It is no longer a close relationship but could be.
- Jackson Memorial Hospital has a long term care facility
- 200 on -campus nursing home beds
- UNC/CRS staff partner with state to provide screening of residents and staff for SARS-CoV-2
- Infection Control covers some of these. JHH is providing a response team to outbreaks in LTC facilities
- Multiple facilities affiliated with UPMC
- Planned surveillance with Health Dept. Visits to LTCF underway
- Hospital owns a long term care facility
- Collaborative
- PI is a faculty member at Columbia University Irving Medical Center with access to inpatients and outpatients who are transferred to long term care facilities for care
- Providers from UCLA Health imbedded, multiple contacts in facility oversight and staffing
- Care provided by UCLA Department of Family Medicine and Department of Medicine/Infectious Diseases physicians on a visiting/outreach basis.
- Linked to pediatric and adult nursing homes
- CRS has collaborations with the Geriatric faculty who provide care at several long term care facilities
- Previous research studies
- University of Rochester affiliated
- Patients on IV antibiotics
- Pediatric Chronic Care Facilities, supervised by physicians from our institution
- Referrals
- Hospitalized patients have referral relationships in place
- Faculty colleagues who work in such facilities and an expedite linkage
- Collaborators have conducted testing, but not CRS personnel directly
- Doing studies there
- Contract with IDPH to investigate outbreaks
- There are several LTAC that are affiliated and close to our hospital
- Rush is CDC EpiCenter site with linkages to LTCF
- Affiliated
- Owned and also affiliated
- Consulting agreement from lab personnel.

State and county health departments or state and county run clinics

- The City plans to have mobile walk-up testing placed in high risk areas in the future and although we do not have current relationship with that effort, we do work closely with the City Health Department on Homeless Health Care (HCHP). HCHP has not been providing testing.
- Jacobi is a member of NY City Health and Hosp Corp--NYC municipal hosp system
- We have joint activities via CFAR with the DOH
- UNC/CRS staff partner with health depts and clinics to provide testing
- Working on this

- Providers in County Clinics
- MOU with State Health Department
- We are part of the local health department system
- Close working relationship with MA DPH.
- Long-term relationship for leadership with JHU
- Health Dept refers HIV+, coordinates w us re TB and also cases of COVID reported to HD and State
- Contractual
- Collaboration in prior studies for recruitment of study participants at the NYC DOHMH Sexual Health clinics
- Strong collaborations for research, care, policy and programs
- Our CRS is based within the San Francisco Department of Public Health.
- Ongoing relationship with the Ohio Dept of Health - as noted above; also CRS investigators have contractual relationships with Columbus Public Health (our city health department, notably in their Sexual Health Clinic and TB clinic)
- Relationship with HIV testing services
- Referrals for research studies
- STD clinics collaborative partners
- Contractual
- Collaborators on projects
- Collaborations with department of health
- Contract with IDPH to investigate outbreaks, develop policies
- We work with Chicago Department of Public Health and provide testing as needed
- Open to all who wish to be tested

Outpatient clinics

- We run a homeless youth clinic and work with the local Job Corps Center for youth that provides healthcare (but doing research in this Corporate-Federal partnership training program is nearly impossible). We have a close relationship with the adult Health Care for the Homeless clinic.
- At our institution
- Clinics from same parent organization.
- Multiple outpatient clinics associated with the hospital
- Work in a large Academic Practice with many locations
- Hospital and County-based clinics
- Jacobi and North Central Bronx Hospitals Ambulatory Care Network
- We have joint activities via CFAR with the DOH
- Municipality of San Juan Health department includes 8 outpatient clinics
- 80,000 outpatient visits per year at our facility
- CRS leadership have a close relationship to clinics for referral testing
- Inside institution
- Providers in Outpatient Clinics
- University clinics in the same health system
- OSU clinics
- CRS is located in the same location of Outpatient Clinic
- We are part of the local health department system
- Testing provided through hospital systems
- Fenway is an outpatient community health center

- Various clinics sending tests to Stanford for testing
- Within JHH. JH Community Physicians outpatient primary care
- We are part of Cone Health Medical group and also ACO Triad Health care network
- UPMC
- HFHS includes OPD clinics
- These are clinics that manage and care for people living with HIV (adult and peds ID clinics mainly)
- CRS is located at Children's Hospital with ambulatory clinics
- We own some clinics, some are collaborative
- We are an outpatient clinic and have two sites with testing
- PI is an infectious disease attending physician at an outpatient clinic at Columbia University Irving Medical Center, New York Blood Center is located in proximity to multiple outpatient clinics and hospital systems
- Enormous network of outpatient clinics throughout the LA and Southern California area
- CRS is based in an outpatient clinic
- ID/respiratory clinic
- UCLA Health operates a large network of outpatient clinics.
- Emory healthcare has a large system of outpatient clinics
- Surrounding clinics partnerships including HIV PrEP CLINICS
- Referrals
- Collaborators on projects
- Partners
- GW Medical Faculty Associates
- Multiple outpatient clinics that are associated with our health system
- Testing at homeless shelters
- There is a primary care clinic that does testing for HCW and patients as needed
- Testing done with all affiliated clinics.
- Clinics are part of the ambulatory clinic network

Home health agencies:

- Can be referral site from many of these
- Jackson provides health care to all inmates in the county jail
- JH Home Care Group
- Advanced Home Care works w us re home IV antibiotics largely
- UPMC
- Through IPD and OPD programs incl OPAT
- Collaborative
- We have begun to reach out to home health agencies including adult day care centers and meal delivery programs
- We can explore this possibility through our social work contacts
- Patients on IV antibiotics
- Referrals
- Contract
- Primarily hospice-owned
- Hospitalized patients have referral relationships in place

Hospitals:

- The CRS works intimately with University Medical Center of New Orleans, Tulane Medical Center (HCA/Tulane), Lakeside Hospital (HCA/Tulane) and Children's Hospital of New Orleans.
- Our institution
- Banner University Medical Center Tucson and South Campus
- We have 2 hospitals in our system and 2 other affiliates
- Main hospital
- Jacobi Hospital and North Central Bronx---direct care sites. Jacobi is also a member of NYC Health and Hosp. Corp (HHC) which includes 6 other major hospitals in NY. Aligned but not direct care
- Jackson Memorial Hospital is the primary teaching hospital for the UM Miller SOM
- Site located within the San Juan City Hospital
- We are located at a 250 bed acute medical surgical hospital 8000 admissions/year
- CRS leadership deeply involved in decision making for the UNC Health hospital system
- We are working with ER
- Providers in Hospital
- The university hospital is in the same organization.
- Pre-screen for surgeries or procedures (local hospitals)
- Affiliated academic hospitals.
- Affiliated Hospitals
- In the hospital where CRS is located
- CRS uses hospital site when needed for specific studies
- We are a hospital clinic associated with local health department system
- Parkland Hospital and University Hospital
- Affiliated with as a CRS and as a CHC with BIDMC.
- Other hospitals sending tests to Stanford.
- JHH, Bayview and the rest of related institutions. All 6 JH Medical Institution sites are offering COVID19 testing.
- Cone Health 5 hospital system coordinating with Wake forest, UNC Chapel Hill
- UPMC
- Affiliation
- HFHS includes Hospitals in system network
- CRS s located at Children's Hospital
- Collaborative/ Contractual
- We are affiliated with Broward Health Hospital
- I am a faculty member at Columbia University Irving Medical Center with access to inpatients and outpatients at the hospital, New York Blood Center is located in proximity to multiple hospital systems
- Two larger tertiary/quaternary care centers
- CRS is based in an outpatient clinic within Alta Bates Summit Hospital
- UCLA Health operates RR Medical Center and Santa Monica Hospital.
- Able to test all inpatients
- CRS is on the Ohio State Medical Campus; also have ongoing activities at OSU East, particularly in collaboration with the ED there)
- Emory hospitals closely works with Hope CRS
- University of Rochester affiliated
- Inpatients with and without COVID
- 5 hospitals in the surrounding area center

- Ronald Reagan UCLA Medical Center, Mattel Children's Hospital, Santa Monica-UCLA Medical Center are staffed and attended by CRS personnel
- Referrals
- We are affiliated with hospitals
- Partners
- George Washington University Hospital
- Children's Mercy Hospital, University of Kansas Medical Center
- We are based at the largest medical center in RI
- Our institution and neighboring hospitals
- Our own hospital
- We are co-located with University Hospital in Newark, NJ. one of the hot spots in the state
- Eight hospitals and several more affiliates
- 12 owned hospitals
- Do all the testing for both Dana Farber and Faulkner hospitals
- The CRS is located in a hospital setting

Jails and/or prisons:

- County run system
- HHC provides care for Rikers Island
- CRS leadership provides support as needed for SARs -CoV-2. CRS leadership has previous relationship providing care and research resources to the prison population.
- Already has testing through Parkland
- Long standing relationships through JHU AETC with jails/prisons
- OSU had the contract to care for all the State Prisons; currently testing all prisoners who are admitted to hospital (regardless of symptoms due to high prevalence in that population)
- Referrals
- We have relationships with medical directors of Philadelphia jails and prison systems
- Close collaboration between ID and the correctional facilities
- Institution is referral hospital for a jail but CRS has not previously performed research in the jail population
- Contract with Illinois DOC
- Referral lab
- Relationships are being established

Other:

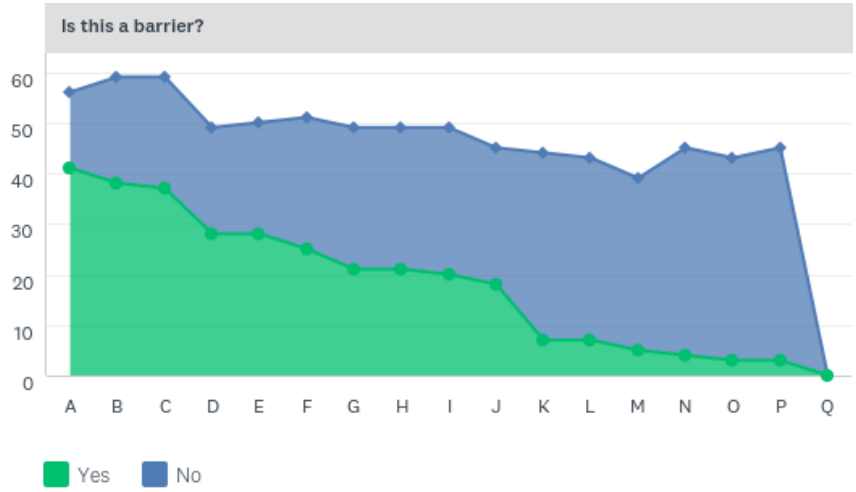
- Our onsite Pediatric Infectious Disease Clinic is affiliated with UMMSOM/HM system
- trying to set up referrals from employee health
- Dr. Farley sits on the Baltimore City HD team for community-based testing.
- Planned city-wide surveillance
- We created COCo
- Collaborations with community-based organizations throughout New York City, affiliation with New York Blood Center and access to blood donors
- Able to test clinic population
- Outpatient clinics associated with our hospital system, other linkages are possible for research studies
- Two SUD rehab centers and maintenance detox center

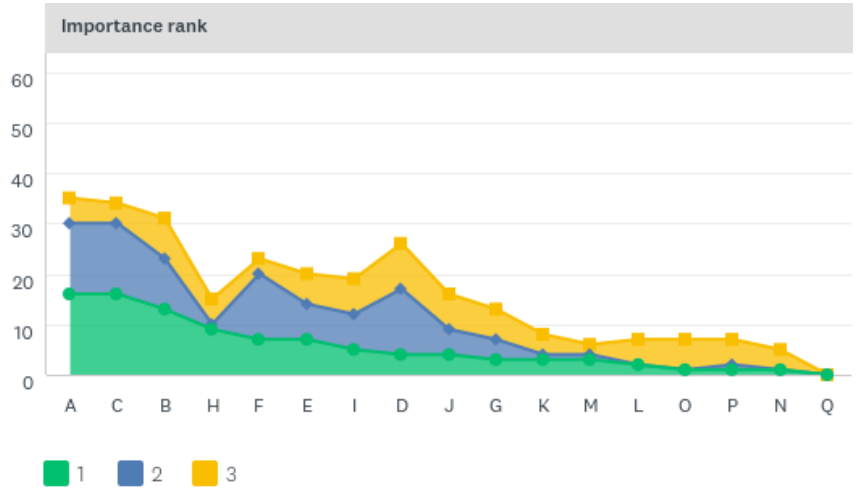
- University of Missouri, Kansas City and all affiliated schools such as nursing, dental, medical, etc. and University of Kansas and all affiliated schools
- Connection with university clinic

Challenges and Opportunities with SARS-CoV-2 RNA Testing

Q14: What are your barriers to expanding SARS-CoV-2 RNA testing at your CRS? Rank the top 3 in order of importance with #1 as most important barrier.

Answered: 69 Skipped: 5





KEY	
A	Insufficient clinical consumables (i.e. Swabs)
B	Insufficient PPE
C	Insufficient testing kits
D	Insufficient reagents
E	Criteria for who gets tested
F	Lack of safe collection facilities
G	Staff personal safety concerns
H	Lack of funding
I	Personnel limitations
J	Institutional policies
K	Lack of ability to bill for services
L	Expenses not reimbursed
M	CRS not interested/capable of performing testing
N	Not an approved testing lab (i.e. CLIA certified)
O	Inadequate linkages to potential patient pools
P	System/software incompatibility between clinic and testing lab
Q	Other

Barriers to expanding SARS-CoV-2 RNA testing at your CRS (grouped by theme):

Testing restrictions/procedures

- Protocols for testing require specific symptoms be present currently. Most clinics are not yet open, and clinics route patients who are ill to the hospital per protocol. Testing venues need to serve walk-in populations who currently do not have access to testing other than through the hospital (that they generally do not trust visiting at present unless they must). There were drive-up testing venues, but many have closed.
- None if eligible for VA care
- The institution is restricting testing referrals to symptomatic patients only
- Getting the health department to give us data or provide positive patients with study info
- Testing is not fully available to anyone who does not meet criteria
- COVID is a barrier
- Our CRS is an outpatient clinic that is not equipped to evaluate COVID suspects or sample NP specimens, so they must be referred to a telehealth app to be approved for testing at another clinical area.
- No testing on weekends or evenings
- Multiple institutions with different electronic health records. Availability of testing and infrastructure for outpatients. Not available at the CRS affiliated ED. PUI are discharged without testing.
- Only testing symptomatic patients or hospital admins with close contacts
- Asymptomatic healthcare workers or community members with known COVID-19 exposures.
- We are embedded within the SFDPH and have access to all patients from case investigation (CI) and contact tracing (CT) who have provided consent to be contacted for research through our digital CI and CT platform. We have not previously developed relationships with skilled nursing facilities, which is currently a barrier for our CRS, however one of our investigators is leading the clinical response team which is establishing relationships that can be leveraged for research.
- Transportation- patients without their own transportation have difficulty coming in for testing. Drive thrus do not take "walk-ins"
- The CRS facility is not a health-system designated location for COVID suspected or diagnosed patients/participants to be seen; the CRS is working closely with university research administration to establish a location for COVID related research that would include a "hot" zone where known or suspected COVID patients/participants could be seen for research purposes. Vetting these new sites quickly for DAIDS-sponsored studies will be critical for future study feasibility. This would require a new level of flexibility in DAIDS policies and procedures.
- We are located within the heart of the Puerto Rico Medical Center consisting of 5 Hospitals within and serving a big surrounding community
- CRS staff working remotely; currently preparing for A5395; prompt identification of appropriate candidates for study a concern (but this is post-testing not identifying for testing)
- Lack of parking, potential concern about exposure on the MBTA, not knowing who to call to schedule a test
- The patients being tested are not coming through the CRS but rather through the MFA or GW Hospital
- Will not test asymptomatic patients
- No specific barrier other than majority of testing occurs in those with symptoms; outpatient testing is done at swabbing stations. Inpatient testing is performed using various platforms according to algorithms based on clinical status/need for continued isolation. The University in partnership with the Ohio Department of Health is testing first-responders in the community.
- We are currently not ready to see acutely infected patients during normal business hours. We are exploring possibilities such as a temporary mobile clinic in the parking lot of our CRS to see acutely infected patients.

- The CRS has access to the population for COVID studies. The sites lab has the ability to test, see question 14 for current barriers.
- This is a moving target. As less severely ill pts are presenting, testing criteria have expanded somewhat.,
- We don't have established linkages to populations other than individuals with HIV. (However, we don't have a need to access these patient populations since testing is fairly widely available locally through our institution.

Equipment

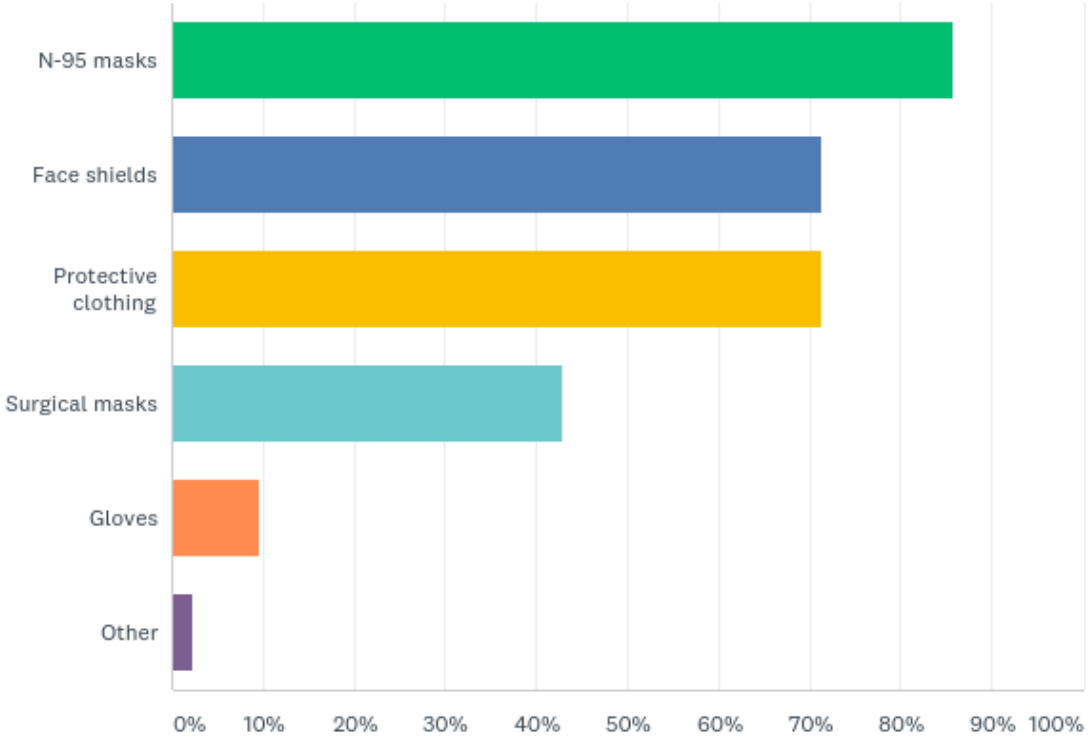
- We lack capacity to do testing due to shortage of PPE and testing kits.
- Test availability
- Not at the present time. The swabs are becoming scarce
- Shortage of PPE equipment, not appropriate infrastructure
- Personnel and PPE
- We have patients with COV2, testing done outside of this CRS. Will begin testing in May.
- Supply chain issues for testing (swabs, etc.). Otherwise none.
- Testing supplies. We have been gradually gaining greater access to supplies and as we do that we have been also increasing testing
- Access to sufficient personal protective equipment, access to SARS-CoV-2 RNA testing including rapid testing, access to swabs, funding to support staffing to conduct testing
- Our health care system (hospital) is currently only testing pts being admitted to dedicated COVID hospital or units AND health care workers. There are other clinics doing ambulatory testing and we will ramp up HCW testing. We will likely need to tap into "Health at WOrk" re HCW, and ER (if they test non-hospitalized patients. This has happened at times when pts have improved while in the ER and may happen more over time
- Test availability and PPE supplies
- Has been resources
- Initially we had supply chain issues for tests but this appears to have resolved for most component. Our GMP has made transport media and swabs are the biggest barrier now.
- Sometimes we have reagent supply delay, swab kit may be delay(for commercial labs)
- Lack of tests
- Limited number of tests available means limited ability to test all those we would like to.
- previous lack of test kits, getting better now
- Lack of PPE, CRS personnel not directly caring for COVID patients
- Shortage of swabs
- Not enough tests for asymptomatic community members
- PPE
- Limited PPE

Staffing

- Currently the research center is closed due to the pandemic. However, we can reach patients in the clinics and the hospital.
- Staffing

Q15: If you responded "Yes" to insufficient personal protective equipment (PPE) as a barrier in the previous question, please specify the types of PPE that are relevant. Select all that apply.

Answered: 42 Skipped: 32



Q16: Comments on barriers:

Insufficient personal protective equipment (PPE):

- Fluctuating amounts
- Limited PPE and no guarantee of resupply to institution, okay for now.
- Difficult to access supply
- Not enough, people reusing equipment
- See comments under Testing Kits
- SMALL N-95 masks are most important followed by protective clothing.
- Supplies for operating multiple testing sites.
- Shortage of equipment
- Challenges procuring.
- Not as tremendous a challenge for us
- All available PPE reserved for clinical operations
- We currently have enough PPE(we have to reuse N-95 and face shield) but this may be an issue if the need surges
- We are an ambulatory site. The hospital has diverted most of the PPE from ambulatory sites to the hospital

- We are using extended wear guidelines to reduce our burn rate of PPE and this is working; but if we are to scale testing we will need to be very careful and would need to receive more PPE that we are currently getting from our supplier
- Delays in delivery of PPE from vendors, limited supply
- Access to N95's and face shields is limited
- Need more N95 masks and protective clothing so the CRS is not taking from hospital supply
- Need to conserve
- It has been difficult to obtain PPE given the shortages in the US as well as the restrictions from our usual sources , including shipments from China.
- CRS (as an outpatient clinic) has lower availability, particularly of gowns and facemasks. No compelling need for N95s. All personnel are wearing masks at work and encouraged to wear eye protection with any direct patient encounter. Supplies in the hospital are being closely monitored. There is a mask re-use sterilization process for N95s
- We are gradually increasing our inventory of supplies and are expecting more
- We are unable to get steady supplies It takes >3 weeks to get orders dispatched
- Not enough
- Limited supply
- Not enough for testing personnel
- Have limited supply
- Large orders are back-ordered, we only receive partial shipments so we are rationing PPE
- No source for research
- Small supply of face shield, may have to use 3D printed face shields
- Persistent shortage of N95s
- Dedicated to clinical care, not research
- Lack of availability with supplier and delayed shipping
- Supply of gowns is low, we have consolidated most of testing to a drive thru for this reason
- Limited supplies require clinic managers to ration any PPE used for any appropriate purpose
- PPE supply is better

Insufficient clinical consumables (i.e. swabs):

- Low numbers of swabs
- Low on NP swabs and need to be able to order more
- Still an issue but not too bad
- See comments under Testing Kits
- Alternative specimen type supplies are necessary
- This is a problem lately
- Difficult in getting from state
- Backlog of swabs/VTM at commercial suppliers.
- Short supply - so far not yet limiting
- We have limit availability of swabs
- Need swabs
- Backorder from distributor
- We are quite nimble and recently evaluated alternative swab collection for middle turbinate swabs, however, supply chain of NP swabs is challenging at the moment
- The BIGGEST problem in our Health Care system + numbers of tests
- All available reserved for clinical operations

- Limited NP swabs
- Swabs are hardest to get
- Most of the swabs have been diverted to the hospital and drive thru
- Delays in order and delivery, limited supply
- Swabs are in limited supply
- Swabs have also been difficult to source as efforts to expand testing have increased demand for testing.
- Very limited
- Swabs (reagents and testing kits) continue to be monitored by the supply chain; continues to be insufficient for widespread testing of all
- We have not pursued the consumables for testing since we have not been a testing site
- There is a shortage of swabs
- Swabs are in short supply - need more ASAP
- Limited supply
- More in shortage than the kits
- We have insufficient swabs for NP testing and this will limit our ability to ramp up testing considerable.
- Limited access
- We have a supply of swabs currently but are having difficulty replenishing the supply
- Limited supply
- NA
- NP swabs have been in short supply, we have at times had to use larger swabs with bilateral nares testing
- Ration number of swabs per order
- Swabs availability with VTM needs to be monitored closely and if for more frequent testing we'd need additional swabs/testing kits
- Periodic shortages
- Supplies back-ordered

Insufficient testing kits:

- Nationwide problem
- Kits are okay for now
- This has been a delay---
- While the number being run daily has increased, so has the demand as the indication for testing has broadened
- CRS needs Cepheid's GeneXpert System test kit. This is of upmost importance for rapid efficient testing
- Difficult in getting from state
- Backlog of kits.
- as above with kits
- Reflects the situation in the US
- We do not have kits
- Unable to obtain at this time.
- We are presently offering testing to 1200 people across JH per day. This is the largest of any hospital system. The Gov. of MD recently procured 500,000 additional test kits.
- This limits us to only testing hospitalized pts and sick HCW
- All available reserved for clinical operations
- Only with commercial lab, slow in shipment

- These are rationed from LabCorp and we receive the number we used the previous week - so we have been able to gradually increase #; but can't scale dramatically or quickly
- We do not have access to rapid SARS-Co-V testing at this time; we rely on Quest local lab for testing with limits in volume and turnaround time imposed by Quest
- Limited kits
- Very limited
- Shortage of test kits (particularly Cepheid)
- We are limited by the number of kits available
- We have run low on viral transport media swabs and entertained the use of saline for PCR testing
- Not enough
- Limited supply
- Using three different types to have more available
- Quest is giving up a limited supply
- Limited access
- Limited supply
- Periodic shortages
- Supplies back-ordered

Insufficient reagents:

- Have 4 machines and plenty of reagents now also an issue
- Inconsistent reagent supply chain limits the number of tests that can be performed per day. An increase in reagents could allow all testing systems to work nearer to full capacity.
- Difficult in getting from state
- Backlog of reagents.
- Temporary shortages have existed
- Reflects the situation in the US
- Enough reagents to test 1200 people per day.
- All available reserved for clinical operations
- We do the COVID RNA PCR with Roche Cobas and our institution was able to secure the reagents so our hospital can do the test in our lab. But I think reagent availability is a limiting factor for increasing testing.
- Inadequate from supply chain
- Very limited
- Lab has had to resort to use of multiple platforms to avoid intermittent reagent shortages
- Not enough
- Often limiting factor
- Having trouble maintaining supply of extraction kits and dividing the transport media volume for use of three samples vs. one.
- Intermittent shortages
- Our hospital has developed some in house media for clinical care
- Periodic shortages
- Supplies back-ordered

Personnel limitations (i.e. not enough trained personnel to obtain, transfer, or process specimens):

- Busy
- Need more study coordinators to do work, too many studies

- This is ok
- Process is changing but for current collection, not enough trained personnel
- Need more trained lab techs at CLIA-certified labs to process and run specimen.
- Need of training to all health personnel
- We do not have personnel that are trained
- Our clinic will not have ability to do testing
- We would need to train our staff in proper collection of nasopharyngeal samples, which is a barrier that can be overcome.
- Only one nurse on CRS staff
- Logistics of transfer need to be elaborated
- No CRS personnel with training
- We have a small CRS personnel wise
- No
- Lab staff have had to work long hours, if we ran around the clock or had another Abbott machine, we could increase testing
- Not a problem
- Micro lab has been pushed hard in the COVID response

Staff concerns about personal safety:

- Staff are concerned for personal health and safety.
- With adequate amount of PPE, this is not an issue. PPE availability is
- Nurses are reluctant to assist
- The amount of personnel is becoming critical
- We will need to have interaction w pt in parking lot or possibly outside their residence
- This issue will be eliminated when we have plenty of PPE
- With evolving information. No masks, wear mask if you like, but won't be supplied by the hospital, to you must wear a mask.
- Staff concerns about personal safety are understandable but can be addressed with proper training and appropriate access to PPE.
- Staff are very concerned about personal safety and bringing COVID home to families. Need a dedicated staff to do this work - likely separate from HIV-clinical care and research facilities.
- All staff are PPE trained and have sufficient equipment
- Nursing and ancillary staff has voiced concerns over personal safety and concern over returning home after work shifts
- little experience in dealing with infected populations
- Related to PPE and facilities also
- lack of comfort doing this, need training
- Some staff have underlying conditions that puts them at risk for bad outcomes so all staff will probably not be performing the visits
- Varies depending on staff
- If enough PPE are available then NA
- Staff concerned about infecting their families

Lack of safe collection facilities (i.e. availability of negative pressure rooms, availability of drive thru to obtain specimens outside, other facility challenges):

- Not an issue

- No negative pressure room in the clinic
- This is changing but currently asked to collect in a specific clinic room with appropriate PPE but no head covering
- Limited community/clinic collection centers. Limited biosafety infrastructure at institutional CLIA-certified lab. Limited/insufficient biosafety cabinets for sample volume.
- Need to invest in proper infrastructure
- As above currently no place to test here in clinic yet
- Appropriate facilities and PPE for sample collection are limited
- No negative pressure room at our site
- We do not have access to negative pressure rooms. We will have to explore different options including setting up at other NYBC sites such as in Long Island City in Queens. We will also explore setting up testing sites at locations owned by NYC such as closed public schools or libraries that are nearby our site
- Any COVID+ patient being seen in a room renders that room unusable for non-COVID work for 3 hours after terminal cleaning; restrooms also become contaminated with use and face similar challenges. Dedicated facilities are needed, separate from current care/research enterprise.
- Areas for safe collection exist and are expanding but are currently limited.
- We are currently identifying locations that we can safely collect specimens at one of our alternative testing sites.
- Have drive through set up in parking lot
- No negative pressure rooms in our clinic, we are considering a mobile health unit in the parking lot. Drive through is an option
- We do not have at the clinic nor at the specialty research lab LPIP any negative pressure area for sampling besides the access area is separated des
- Don't have it
- We have been testing in patients cars or outside in tent, or last resort in an exam room
- As stated in the question
- One negative pressure room in the ID clinic
- No
- We do not have drive through testing yet, can look into it if needed
- CRS clinic has no negative pressure rooms & institution has limited drive through testing to the main campus 5 miles from our clinic

Changing or limited criteria for who gets tested:

- We adapt
- Without more testing capacity the UNC system cannot refer all identified populations for testing which will in turn increase testing capabilities.
- Testing approval must go through a specific telehealth encounter or hotline.
- These change as capacity changes - need to keep staff informed
- Depends on the available test kits; now testing moderately and very sick, and high risk patients
- see above
- At the moment the criteria is for COVID-like symptoms sick enough for admission, but this can change based on multiple factors (agents, hospital policy, funding)
- Most still do not have access to a test
- Criteria imposed by state health department limits testing to symptomatic individuals likely to spread disease and neglect asymptomatic contacts or symptomatic patients outside of high-risk transmission networks.

- Policy seems to change weekly and presents a barrier to testing
- Triaging based on need
- Criteria change about weekly
- Increasing accessibility as test supply increases
- Too strict criteria at our institution
- Changes increase volume and not enough supplies
- Testing recommendations are evolving, not a huge barrier

Inadequate linkages to potential pool of patients:

- We have linkages but those Health At Work, ER will have to want to work with us and have time to accommodate our recruiting of pts
- Thousands of people have been infected in the Atlanta metropolitan area
- CRS-affiliated clinic not a COVID Rx facility
- No
- Patients are eager to be tested

System/software incompatibility between clinic and testing lab:

- no issue
- Manual entry. No interface.
- Multiple electronic health records at partnered institutions.
- No
- NA, our results come in our EMR

Not an approved testing lab (i.e. CLIA certified):

- CRS is not CLIA-certified. It is currently working with partners CLIA-certified labs at the institution.
- We are an approved CLIA certified lab (CLIA number 33D1018711).
- hospital is CLIA covered, but not research lab
- Not a problem

Inadequate funding:

- At present, NYS and NYC are paying
- No funding for PPE, test kits, reagents, personnel for testing outside of current clinical testing
- This is our number one priority to get widespread testing
- As an FQHC we have been informed by HRSA that we need to see all patients regardless of their insurance; but for those patients who have insurances that we don't take (are out of network) there is no way to electronically submit to their insurance for payment and this is a manual process and it is unclear if and what payment we will receive for these services; we also see uninsured and although we bill patients if they are 200% below poverty we eat this cost
- We would require additional funding to support staffing (salary and fringe), as well as funding to purchase PPE, swabs, and test kits and cartridges
- Funding needed for personnel, facilities, and significant investment in infrastructure to build platform to conduct and maintain this work.
- always an issue, but nothing specific
- Need funds to support expansion of testing capacity
- No funding for these resources and equipment for research
- Micro lab has been pushed hard in the COVID response. also limited space

- Additional funding would be helpful and needed if there was desire to conduct more frequent testing. The site would be highly interested in participating

Lack ability to bill for services:

- Probably a challenge but not a hindrance,
- We would need to explore ability to bill services as we are not a clinical care site
- Difficult for everyone

Reimbursement provided does not cover expenses:

- Public hospital, care without regard to pay
- We would need to assess what the reimbursement schema for testing would be and whether it would fully cover expenses including staffing

Institutional rules/policies constraining testing:

- none
- The hospital's policy is dynamic and based on community need, and can change
- Testing limited to established patients (we are a research hospital vs community) so no community testing supported
- No testing allowed at ambulatory sites at this time
- Criteria imposed by state health department limits testing to symptomatic individuals likely to spread disease and neglect asymptomatic contacts or symptomatic patients outside of high-risk transmission networks.
- institutional policies continue to evolve frequently based on supply chain and local epidemiology
- As above, no separate access to testing materials for research
- Limited to main campus and hotline has strict testing criteria

Our CRS is not interested in/capable of performing testing:

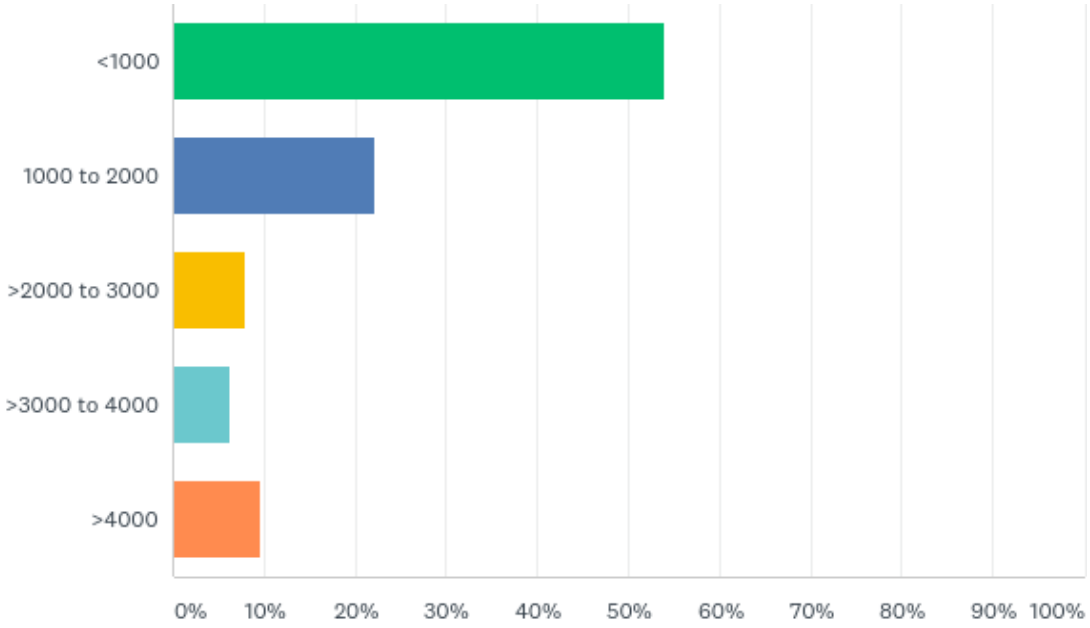
- Currently, the CRS is not CLIA-certified, which limits the capacity to perform clinical tests.
- Our CRS capacity is limited and I don't envision having the possibility of performing testing at this point.
- We are interested in performing testing
- in house testing has rapidly expanded with relatively quick turn-around-time for results
- We are interested
- we are interested
- We use the clinical lab
- Our institution is limiting testing to their main campus

Other:

- Testing is Hospital Testing at Texas Children's
- Serological testing/capacity assessment is just developing, so needs are still being assessed.

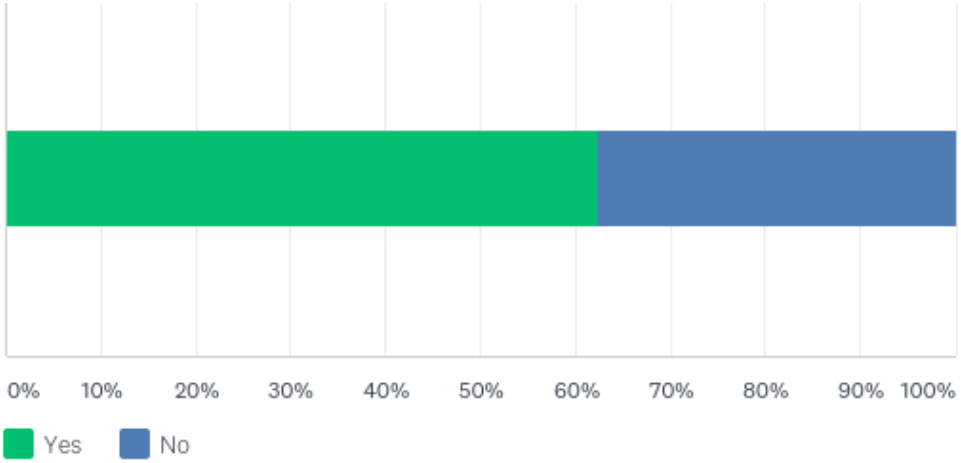
Q17: If these barriers could be overcome, how many more tests could be performed at your CRS per week?

Answered: 63 Skipped: 11



Q18: If your CRS was going to start performing SARS-CoV-2 testing as part of gradual entry back to normal operations, can you do so immediately?

Answered: 72 Skipped: 2



Q18A: If yes, please describe what additional support would help.

Open text responses (*grouped by theme*)

Personnel/policies

- Need more laboratory technologist staffing and clerical staffing for accessioning and intakes
- County is only testing ill people who are at greatest risk; surveillance testing in Harris County would help. Texas Children's only tests registered patients and has charity care for younger than 18 years. Expansion of testing for young adults would help.
- Already doing

- Send to affiliated institutions
- We would have to completely realign staff to test up to a 1000 a week and would need payment to support this staffing model and as well as supplies and PPE. This would be a dramatic shift in scale ~ 10x what we are currently doing.
- Education, plans
- Allow antibody testing for well population so that they can get out of home isolation
- We need to reconfigure our space for testing - either adding a mobile clinic or drive through. Emory Healthcare has testing sites on and off campus - we can collaborate with them
- Training
- Currently we are running ~600 tests per day. If there were staff to run our Abbott machines 24 hours per day or we had another machine we could further increase testing.
- We are dependent on the hospital for testing. It is that entity that needs support.

Equipment

- Additional PPEs
- EasyMAG for BSL2+ and easyMAG kits to be able to use the CDC kits that we already. FTE to support lab personnel time; Swabs. Realistically, if we were doing this beyond the symptomatic patient list (close contacts, asymptomatic people), we would require assistance throughout the supply chain.
- If large scale-up probably need NP swabs; likely more kits; more masks incl N-95.
- We could use additional support for PPE
- Send money and swabs
- Additional machines and kits
- Ensure adequate supply of testing swabs with viral transport media and reagents for PCR testing platforms
- More supplies for testing--swabs, reagents, kits, PPE
- PPE, extraction kits and transport media and additional funding for expansion.
- Greatly expand test kits, particularly Abbott rapid test
- Funding for additional staff and test supplies (kits and reagents)
- Space: All clinical tests need to be run in a CLIA-certified space and there is not a lot of room for new machines. Micro is completely packed and moving existing instruments / renovating would take months. We could offload to other spaces (chemistry / hematology / molecular), but we are limited by the scarcity of BSL2+ hoods. I don't know if we can add more capacity.
- We could offer more testing especially under the auspices of a research protocol. Capacity is being built up and there are research labs that can provide additional capacity

Funding

- Funding: infrastructure, update/re-certification of safety cabinets, purchase of additional machines to aid in sample preparation, automation throughput, acquire additional rapid testing platforms. Personnel: hire additional trained medical techs to support existing CLIA-certified lab staff. Reagents: acquired swabs, in house synthesis of VTM, financial assistance in purchasing additional testing, PPE for lab personnel and those collecting specimens.
- Funding
- Funding.
- Funding to support this activity
- We could use a validated serology lab or accurate point of care kit
- Dedicated funding, direct supply of PPE and testing kits
- Additional funding- we have a lot of interested investigators who would like to collect specimens for their studies, so could be coordinated.

Q18B: If no, what would your CRS need to get testing going?

Open text responses (*grouped by theme*)

Personnel/policies

- Personnel are swamped with COVID trials
- Need to know more about what is planned. Depending on the number personnel will be critical
- We are a small part of a large organization. Our organization, Denver Health, can currently do up to 500 tests per day. We would have to work with our Hospital Lab in order to expand testing and right now I do not believe there is capacity for more testing. As a CRS with two staff members, it would be very challenging for us to implement large scale COVID-19 testing.
- More personnel
- NJ still has a stay at home order; we can start testing once that is lifted. else we can test symptomatic patients for clinical research if kits, PPE available
- We need approval from our Health Care system, designated site to collect (probably parking lot where Cone WAS doing ambulatory testing) and sufficient tests and lab to run (most ideally the Cepheid one that is in house
- The designated facility (as currently approved by DAIDS) as noted above - this is NOT a match with currently designed HIV research/care facility space and personnel.
- Will need to coordinate with all other testing priorities within the health care system
- Staff would need to be identified that are willing and able to perform testing. Would need to establish a flow of how patients would come in and out of the clinic with limited staff exposure.
- At this time our testing is done at the institution affiliated with our CRS both for staff and clinic patients.
- Increase in staff capacity.
- Additional funding for personnel.

Equipment

- We need funding to buy the PCR machines, test kits, and PPE and then we can increase our capacity.
- Swabs collection kits
- More kits and swabs
- Test kits. Approval to do testing on site. more PPE
- Stable supply chain for reagents, testing kits, PPE, NP swabs; funding for supplies and personnel; expanded collection facilities
- Swabs and PPE
- The NYBC has access to both Ortho and Abbott serological testing which will be up and running soon. We do not know about kit availability yet though.
- To do so immediately (.e, tomorrow or even this week), we would need more swabs (with a watchful eye on reagents). Plans are in the works to do more widespread testing of employees/personnel in a return to work strategy.
- We need basic on site rapid test equipment
- Supplies - swabs, etc.

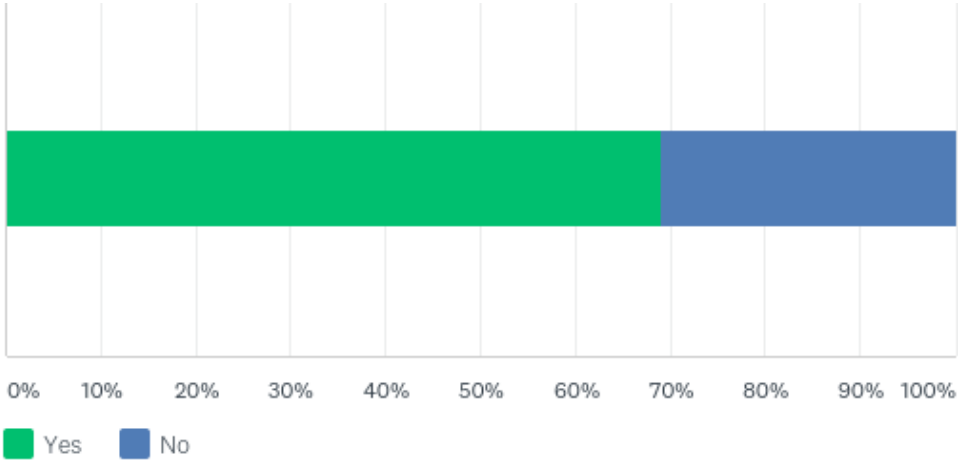
Other comments

- I am not sure how SARS-CoV-2 PCR testing can help gradual reentry since for acute cases and isolation not for reentry to society.

- We are in the unusual situation of being at an institution with widely available testing so there isn't a need for us to do testing. There are already drive-by testing locations and sufficient capacity within our institutional lab.
- N/A as out hospital lab does testing effectively
- An outdoor testing set up in our parking lot which is located in a multipurpose strip mall
- There is no intention to perform testing

Q21: Is there something that NIAID/DAIDS can do quickly, including any of the items addressed previously, to help support increased SARS-CoV-2 testing at your CRS?

Answered: 71 Skipped: 3



Open text responses (*grouped by theme*)

Procure equipment/supplies

- Help us order more NP swabs
- Support for PPE when challenged in identifying and resources for tests.
- Choose antibody tests to be used in clinical and research studies
- Provision of the necessary number of test kits and PPE.
- Help site meet testing kit availability when institution can not
- Send us swabs and testing kits validate saliva testing
- Access to rapid SARS-Co-V testing, access to serologic antibody testing including cartridges/test kits
- Increase in testing supplies and PPE
- Need more swabs and testing kits
- We could certainly benefit from assistance with supply chain and/or machines to do rapid POC testing.
- Assist in supplying testing kits
- Provide access to more swabs
- PPE, extraction kits and transport media
- As above, provide direct access to PPE, testing kits, and standalone funding for this purpose
- Direct more test kits to our site
- Provide PPE

- Distribute centrally PPE
- NP swabs, it would require coordination with our hospital lab to determine if more staff or another Abbott machine makes sense to pursue.
- Provide PPE
- If we had a centralized supply of test swabs and PPE, that would facilitate the collection of SARS-CoV-2 testing. Our laboratory has the capacity to do testing, but we will likely be limited by supplies.
- Push new kits (good sensitivity and specificity) for rapid testing into clinical care
- Provide necessary supplies (swabs/reagents)
- Access to testing supplies and PPE
- If we could get the Abbott ID NOW COVID-19
- Send money and swabs
- We either need full equipment on site or testing materials (swabs, test kits, reagents) to our existent equipment at the LPIP research lab.
- Tests and PPE
- Ship swabs and PPE.
- Linking us to more tests
- Purchase upgrades for automated SARS-CoV-2 RNA testing, specifically Hologic Panther Fusion upgrade
- Provide funds, swabs/VTM, PPE.
- Approve funding for PPE, and personnel training
- Increase testing availability
- Availability of test kits, reagents, and PPEs
- You can't solve our space or staffing problems. Perhaps with supplies?
- Funding and additional supply of swabs

Staffing/training support

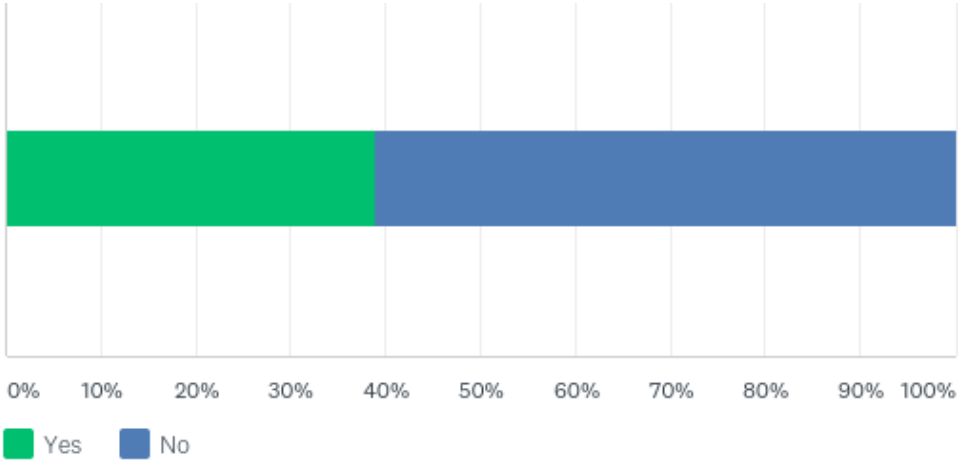
- Financial support for personnel to perform necessary testing and for test kits for research use.
- Pay for additional research staff to help with this depends on how the testing will be utilized for research or for clinical or epi information?
- Money for surveillance testing of uninsured
- Support for properly trained personnel
- Funding for 1-2 FTE
- If actual planned program would need to address specifics.
- Our hospital lab may be able to accommodate increased testing if there is funding to pay for it. However, we can ship to Quest as we were doing before and it can be facilitated by funding to pay for the tests, whether RNA PCR or antibody or saliva tests. We can do point of care tests at our CRS if we get funding to get testing kits and to employ a lab person for full time testing. With substantial support we can approach our institution to set up a venue with the hospital where we can test, with their approval.
- Provide funding to support test cost, personnel and test kits.
- The process of registering new patients into care and then billing for their testing is cumbersome and limits access to testing. If we had a process to pay and register for testing for patients in an efficient way that eliminated barriers (even perceived from a patient's perspective - people won't come for testing if they think they don't have the money for it) this would be a great help. We would also need increased access to increased testing kits and PPE. However, we do have staff that could support this and would be eager to step up to do this work.
- Increased funding for facilities/staff, and nimble approval of new site/facility for DAIDS-sponsored work. If this were made available, this could be implemented immediately.

- Provide the tests, training and budget for staff
- It is partly a matter of funding but also being able to get them [supplies] even with funding
- Additional funding for personnel.
- Support for research initiatives that involve evaluating novel diagnostics, expanded testing to evaluate different compartments and understand viral persistence, correlation with infectiousness and transmission

Serology Testing for anti SARS-CoV-2 Antibodies

Q22: Does your CRS or affiliated lab(s) currently offer serologic testing for COVID-19?

Answered: 72 Skipped: 2



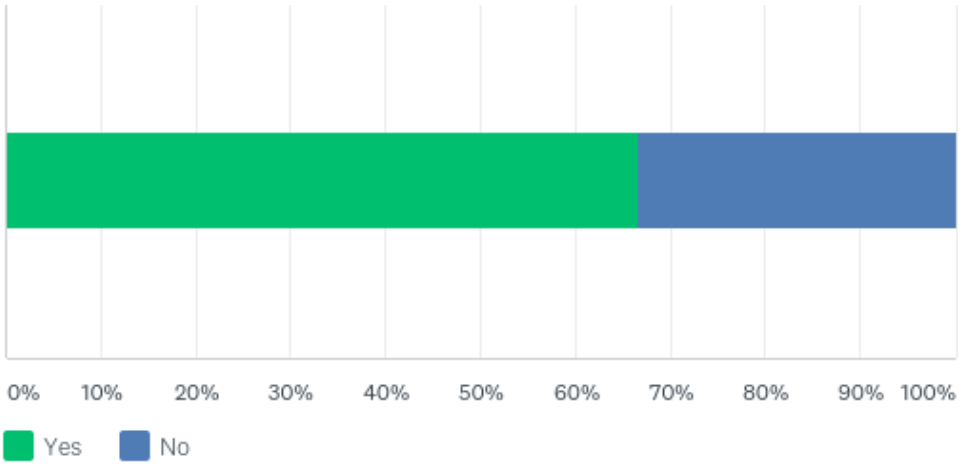
Q22A: If yes, please describe the purpose of the testing.

- Identify previously infected patients and staff --can help guide individuals to provide convalescent plasma --would like to screen health care providers and hospital workers
- To assess the possibility of herd immunity and to possibly identify potential donors of convalescent plasma. The question remains, however, what the significance of a detectable antibody response?
- Leveraging COVID-19 testing along with enhanced screening, distancing and protection through PPE to ensure a safe work environment for staff and our patients.
- Seroincidence studies
- Verify antibody in possible contacts or asymptomatic individuals
- As of yesterday (4/21/20), serologic testing is available as a routine test done by the institutional lab to document past COVID-19 infection.
- Health care workers; patients can request.
- PUIs with negative RTPCR. Convalescent serum studies on inpatients recovering from COVID19. Clinical immunology is working to increase the availability of this testing, but this is a work in progress. From a CRS perspective, we have access to FDA EUA approved POC tests, but those are being used for planned cohort studies.
- Convalescent plasma donor screening, estimation of seroprevalence (testing of limited number patient samples ongoing)
- We offer to health care workers who were confirmed with or exposed to COVID-19. We also offer serology to the confirmed cases in the community for plasma pool.
- The NYBC has started a study on convalescent plasma study to test antibodies to SARS-CoV-2.
- Surveillance, establishment of prior infection.
- We do a research lab evaluation of serology as part of a program to qualify convalescent plasma donors
- Serologic testing has just been introduced and its intended use remains unclear.

- Our affiliate laboratory, Vitalant and academic partner UCSF, currently offer serologic testing for research purposes.
- Very limited. being used for screening for plasma IgG donation program
- Emory hospital lab will do IgG Elisa - plans are to use for serosurveillance
- Healthcare workers with prior documented or suspected COVID, plasma donor screening, and diagnosis of suspected COVID with negative NP swab
- Testing healthcare workers to see if they have asymptomatic infection
- To determine prior infection in patients with suspected COVID-19, determine if staff have been infected,
- We will have the Ortho clinical serologic assay (EUA) by May 1st and will need about 1 week for validation in the Hospital CLIA lab. We have not yet defined how who we will be testing and how we will interpret the results
- Working on validation to help with different difficult clinical scenarios, also to understand positive rate in health care workers, or HIV population
- Verify exposure to sarscov2
- We are beginning to test employees. These data may be utilized to determine return to normal work practices.
- Plasma donation; recovered COVID for research and redeployment
- Right now, mostly diagnostic in those with negative PCRs.
- Serology is offered to the following cohorts: health care workers who were previously PCR+ or had a COVID-19 like illness and are >=14 days after resolution of symptoms. Discussions are ongoing about expanding testing to other groups, including patients. Research projects [initiated by CRS leader/co-Investigators] are underway to assess point prevalence and establish prospective cohorts.

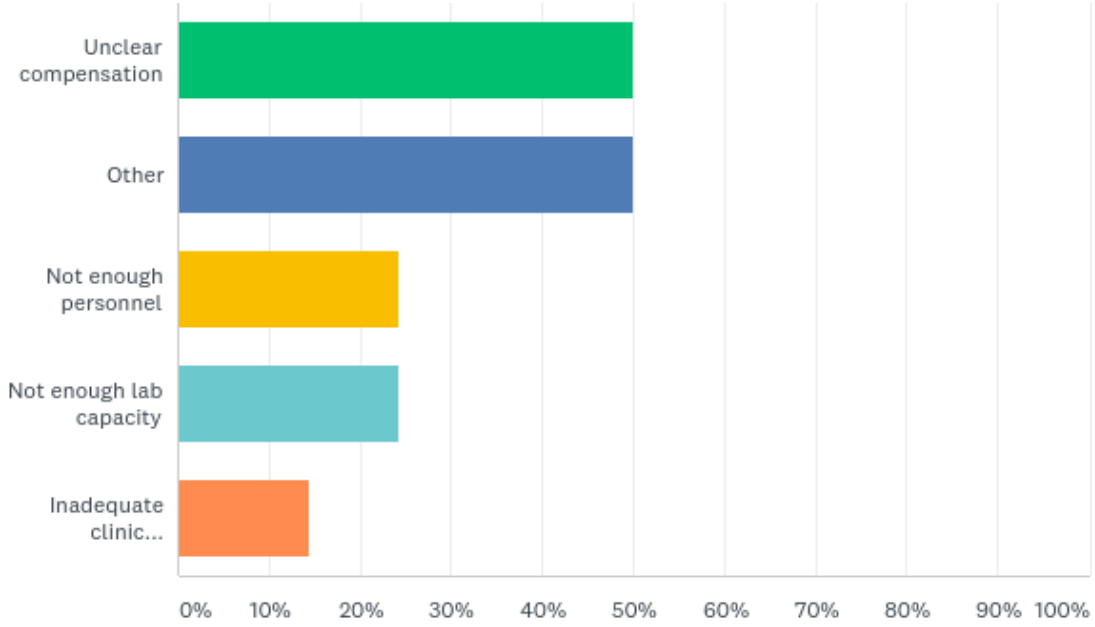
Q22B: If no, is it because the available serologic tests have not been determined reliable enough by your local institution?

Answered: 42 Skipped: 32



Q25: If serologic testing is made available, what are your barriers to providing serologic testing through the CRS/affiliated lab? Select all that apply.

Answered: 62 Skipped: 12



Other:

- **Don't know (2)**
  - I don't know what barriers will be there
  - Do not know answer; I believe capacity exists to do seroprevalence.
- **No barriers (3)**
  - No barriers.
  - None
  - None of the above
- **Scaling to demand (3)**
  - The demand for serologic testing is huge and we would be eager to try to meet the demand.
  - Our CRS lab has the capacity to do serology test but may not be able to accommodate large scale
  - Serologic testing is available through our CLIA certified lab at the CRS. Capacity to test is expanding greatly in the next 1-2 weeks. CRS leader is involved in establishing testing guidance and testing protocols. Efforts are underway to expand testing in a stepwise fashion as capacity increases and more experience is gained with the serologic assay
- **Unclear validity of lab tests (3)**
  - Unclear validity of lab tests
  - Validation and reliable tests (saliva) or serological Ab CLIA and FDA EUA or certified
  - No barrier yet, we need to decide what testing can be trusted and in whom
  - Need to be certain of the validity of the test and develop a policy on how to use the information.
  - Not enough validated tests. Cost of testing, current estimate from clinical lab is $20 per test.
- **Unclear interpretation (4)**

  - Unclear interpretative criteria, otherwise no barriers
  - Standing questions about reliability and interpretation
  - Unclear clinical implications
  - Unclear utility of serologic testing
- **New process (4)**
  - Plan to begin testing in next few weeks.
  - Serologic testing is hoped to be available soon.
  - We are just starting to do serologies.
  - Serological testing/ capacity assessment is just developing, so needs are still being assessed
- **Logistics (6)**
  - Just need to operationalize this
  - Logistics of collection
  - I will have to meet with the lab director to see if it is feasible once we have personnel in place, and testing kits or equipment, that we can go ahead with testing at higher volumes.
  - If available, should be doable
  - Supplies
  - We have a temporary hiring freeze at our institution, extra personnel would be need to ramp up serology testing
- **Funding (2)**
  - Depends on the context, if for research use, then we would need to have funding to pay the lab for billing it
  - Funding
- **Other**
  - Opportunity: Robert Garry, PhD, has developed prototype antibody assays that are showing excellent sensitivity and specificity and he is looking to get EUA approval ASAP. Planned use is for research such as serosurveys and to inform re-opening of the medical center.
  - We would only perform through the hospital lab.

Q26: For each of the items recorded as barriers in the previous question, please elaborate on the challenge in the corresponding textbox below.

Not enough personnel:

- Additional lab/testing personnel from CRS labs considered nonessential at present time
- Not enough personnel to provide wide-spread testing. We have taught very young community workers to recruit, perform structured interviews, draw blood, collect samples, run geneXpert HIV PCR, GC/CT samples, etc. This might be a model for expanded community testing, but hiring is frozen without new funding.
- Our CRS has two staff members, plus me the PI.
- Antibody assays run on separate instrument than COVID PCR. need additional laboratory staff.
- Could easily move personnel from PCR testing to rapid testing
- Lab needs additional trained techs to handle test load.
- Nasal swabbing much easier than phlebotomy and requires less skill.
- The lab personnel is overextended
- Too busy
- Very limited personnel in lab to add antibody testing to current virus testing
- We are looking to hire more staff

- We can do it if we have more people
- We have a temporary hiring freeze at our institution, extra personnel would be need to ramp up serology testing
- We have insufficient personnel to do wide scale testing
- We will need to have a full-time person processing samples through a high volume system for antibodies or POC testing of finger stick or saliva

Not enough/inadequate clinic facilities:

- Have a small area from which to do testing
- Logistics to access the lab on the medical building
- Need for an adequate isolation area
- No clinic currently allows possible COVID-19 patients to enter clinics
- No safe COVID-positive indoor clinic areas, no specific tent we can use yet
- Safe space for drawing blood from public. Perception that uninfected patients do not want to come into a hospital overrun by COVID-19.

Not enough lab capacity

- 1000/day is capacity
- Additional lab personnel and support are required.
- Current capacity is only inpatients with confirmed COVID19
- Depending on volumes, may need to increase staffing
- Ideally would have additional personnel and designated space, even for convalescent patients
- Lab capacity may plan a role, but is moving forward with validation studies
- Lab capacity would have to be determined depending on the type of serologic testing
- Need to identify best space in lab to run these assays
- New work flow would have to be supported
- Not sure if the lab we are sending to is accurate, not sure if the point of care kits we acquired are accurate
- See previous responses re: space.
- This is an item which can be discussed and negotiated with the lab
- We do not run our own labs and would have to work with our hospital lab to get this going. They are hoping to get serologic testing up and running by mid-May.

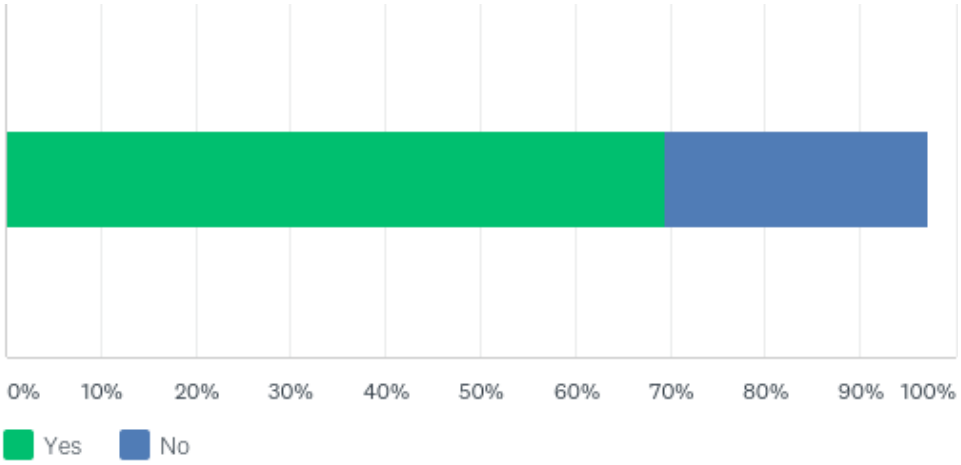
Unclear compensation:

- How this will be reimbursed. The health system is losing money, so propositions that will increase the loses are not going to be seen with happy eye.
- It is not clear how third party payers would compensate for serology testing and the frequency of testing
- It was unclear from each payer sources
- Lack of institutional funding. Unclear that capital investments required could be recouped though testing reimbursement alone.
- Need funding to support cost of test and to cover personnel salaries
- New test unclear reimbursement
- No available funding for kits; reimbursement unclear (none at present)
- No mention yet of costs
- Not an FDA approved test so unclear if it will be paid for
- Not sure if we will get compensated

- Not sure who will pay for kits, disposable materials and cost of reagents
- Testing reimbursement is not clear. Without clear support, capacity is curtailed
- This is an issue. we are a public municipal hospital though
- This needs to be established ahead of time according to market value expectations
- This serologic testing would need to be completed as part of a research protocol at this time, and would require funding to support.
- Unclear how tests would be paid for
- Unclear if insurance will pay
- Unclear of who is cover cost of lab, staff, PPE, etc.
- We need compensation to support staff involved in this effort and supplies
- We would need funding to support staff (salary and fringe), PPE, test reagents, test kits, etc.
- We would need to be able to register patients and bill their insurance for this unless there was other funding
- Will antibody testing be covered by 3rd party payers?
- Will Medicaid, insurance pay. Who will pay for uninsured?
- Would be new so not sure how would be funded.
- Would need funding to hire additional personnel

Q27: Would having testing on demand capability help with your site plans for reopening and re-engaging participants with face to face visits?

Answered: 69 Skipped: 5



Affirmative:

- Definitely we also provide care for many large populations, at risk for severe COVID--obesity, HIV (over 2400 individuals), renal disease, hypertension and minority (the Bronx). Also need to test clinicians and nurses and other employees---therefore knowing status, if it is truly immunoprotective, would put individuals at ease---and help with limited supplies of PPE
- Yes, it would help the staff if we could test patients
- It is very likely that widespread community transmission of SARS-CoV-2 will occur for some time and clinical research will reopen in the setting of continued community transmission. Therefore, identification of persons, both participants and research staff, with active COVID19 infection and

keeping them out of the research site will be extremely important to reopen clinical research while assuring the safety of both participants and research staff.
- At this time I can only speculate that the institution will benefit, but no plan has been share yet.
- Facilitate timing of reopening of services to better understand rates of prior exposure & immunity
- Leveraging COVID-19 testing along with enhanced screening, distancing and protection through PPE to ensure a safe work environment for staff and our patients.
- Hopefully will allow access to regular clinic visits
- Important for pre-operative evaluation to re-open surgical/procedure facilities.
- Will make possible to test potential trials participants and personnel
- This would not only be an incentive for participation, it would help lift university restrictions on in person visits.
- POC testing would absolutely help with our ability to see patients face to face
- It would help to screen patients who are symptomatic, high risk, or with known exposures in order to allow study visits with these patients without delay or alternative accommodations.
- Having an accurate antibody test would help identify staff that have already been exposed which in turn would make them feel more comfortable taking care of COVID patients.
- A program for testing of staff and participants would be helpful in deciding how to re-engage study subjects
- Test positive=come to clinic, both for MDs and patients. Very hard to do peds and OB visits via telemedicine
- Understanding the local prevalence of disease, and taking appropriate precautions for isolation procedures, is one of the components of re-opening operations at the medical center and university campus
- It would allow a more orderly reopening of face to face visits and help preserve PPE supply
- I think if we had immune staff it would help with patient flow, same if we knew patients were likely immune
- Rapid testing on demand would lower barriers for reopening clinics
- It would reduce fear of infection in staff despite difficulty in assessing whether an individual had past infection or is an asymptomatic carrier.
- First being able to test staff would be ideal. Thereafter, testing for participants would be helpful

Ambivalent:
- Not sure
- Still unclear how the results of serologic tests will be used and the meaning. However, it will be an additional piece needed to start thinking about the plan to re-open the clinic
- Actually not sure. This needs to be discussed locally.
- Patients want to know if they have been infected.
- To a limited extent only. Limitations re designated areas, turnaround times, remain
- We have access to this if needed. (However, until the significance of anti-SARS-CoV-2 (antibodies) is clear, not sure this will be useful.
- It was unclear how to reopen the clinic safely. We have implemented PCR testing for pre-procedure (surgery, chemo, radiation) was well as surveillance testing in the hospital. It will be challenging to scale up to clinic patients unless we increase capacity of in-house testing (turnaround time 3-8 hours).

Contingent:
- If there is a reliable fast PCR test at the site that would help; the clinical lab has the rapid Abbott test but expanded capacity would help.

- Would depend on what protocols institution decides upon
- Tentatively yes, but need data to show that antibody positive means that the patient will not transmit
- Availability of the Abbott NOW COVID-19
- If community epidemiological testing serves to establish "immune certification" of individuals this will definitely help in the scalable efforts to phase II implementation within the National planning Response
- If the test was deemed reliable and a surrogate of immunity has been well defined.
- No current policy; so maybe this would facilitate matters or override current protocols but would require in depth discussions at multiple levels - as well as some Public Health guidance.
- Testing on demand will help only if the shelter in place and lock down are eased, as I am sure the hospital will allow increased face to face visit. The problem will be precautions for transmission risk if testing for disease (and this would be substantial particularly for personnel), and not an issue if testing for antibody (establish past infection).
- If we had additional testing capacity we could determine the frequency of asymptomatic shedding in our population (and/or presence of antibody). if we then had this testing and PPE available we could reopen safely

Other:

- We are currently doing face-to-face visits; the challenge is that a large portion of the current research portfolio has been deemed non-essential. If COVID research were deemed "essential" these staff could return to work immediately.
- We are already participating in face to face visits
- Reopening is up to the state and healthy system leadership. COVID trials are ongoing and not an issue
- Face-to-face visits should resume when outpatient clinical operations at the hospital resume. We are still in peak incidence in Boston.
- I think risk will remain regardless of these tests being available.

Appendix 1- Supplement Questions to the Survey Responders

Following the close of the initial survey, OCSO sent secondary questions to the 77 responding CRS Site Leaders. Here are the responses to those questions, sent 4/25/2020, from the 51/77 respondents.

If NIAID provided additional funding to your CRS, could you address the needs you identified in the survey?

Yes- 44

No- 3

Comments of the affirmative respondents:

Additional funding would be helpful for staff support for the conduct of clinical studies and getting additional PPE. It would be preferred to get PPE since big challenges to blockage of supply chain.

Speaking with divisional members our biggest need may be staffing, followed by testing (PCR tests, swabs, reagents, a reliable serology test) We are keenly interested in serological testing a clear gap in current approach.

According to Rob Knight they could ramp up to test 5,000 samples/day within 2 weeks and could double that to 10,000 tests/day by doubling equipment and working shifts

At this time we have just received a memo from the University that they are preparing for peak number of COVID-19 patients in the hospital system w/in the next week or two and I think the new RNA testing of all patients would strain the system. Also, we're still limiting face to face visits and following University policy. It is possible after the surge of patients that is expected that we may be able to put together some testing strategies. I would say could be as early as mid-May but this is a day to day epidemic and we do not know exactly what the future will bring. Dr. Mitchell contacted several people about prospect of enlarging testing base but did not receive responses.

Because of the intensity of the local COVID-19 pandemic, the situation is fluid, and it is conceivable that we will be able to do more over time. Some of the COVID-19 work may ultimately be able to be done in conjunction with our CTU partners at BIDMC or BWH, but for the purposes of responding to the questionnaire, we have reflected what our Fenway CRS is capable of doing. For our CRS to do RNA testing in the long-term, we would probably need to install a Negative Pressure room. We believe that the technology of testing for COVID 19 will advance over time and that other methods of testing, such as sputum collection, will be available that do not create aerosolized particles. If that is indeed the case, we would not require a negative pressure room. Acquire additional PPE including; facial shields, gowns, masks, gloves and shoe covering. We can send our testing to Quest Dx, but at this time they are sending their samples to the West Coast which is causing a delay of 5 days to get results. Quest is working to set up a testing site on the East Coast which will reduce the length of time to received results. We will also explore other diagnostic labs, such as Molecular Testing Systems, whom we work with on an NIMH R0-1, but our clinical departments use Quest, so that is our usual go-to lab

University does testing. Already increasing testing for all kids and now parents. Can do drive by testing and it can be expanded. Needs are staff, swabs, reagents and kits. He isn't in charge of institution lab. Suggested contacting Tom Campbell.

Considering setting up outdoor testing facility. The health system has 3 drive-up testing sites that are not at capacity- so adding our site would not gain that much. I just want to be clear that not having us offering testing at our CRS is not currently a barrier to more testing being done at UCLA. With more resources our hospital lab could scale up further and we can get that info from you if helpful. (Currier) Limited by availability of swabs and PPE- and not being able to source them- but let me find out more. Our Health System is well positioned to be able to do more if we had more resources and we have a tremendous lab.

Currently the Hospital's clinical laboratory infrastructure is saturated, however our research laboratory facilities are available to conduct testing provided we can acquire additional funding for personnel and/or supplies and equipment. Equipment and supplies needed include extraction and PCR systems and reagents, media, and swabs. It will be best if all of these are provided by the sponsor.

Funding will help secure additional facilities and resources to modify the laboratory as well at the Hope clinic CRS. We are considering adding a mobile clinic in the parking lot to separate acutely infected COVID patients from the main clinic facilities. Securing adequate inventory of PPE is another important factor. Emory biosafety has recommended that the laboratory airflow be adjusted to add a negative pressure to one of the lab rooms to process acute COVID samples. The laboratory is a BSL2+ facility and the negative pressure is an optimization to the airflow.

I don't think the funding is the issue as much as operationalizing more outpatient testing in our area. I don't think that ACTG or our CRS ALONE could be able to do this even with more funding but that is my opinion

If we had additional personnel, we would train them to perform SARS COV-2 testing. We would buy PPE. We would need to set up a negative pressure tent (our institution has it). I need two research coordinators. We do need to get approval to hire additional staff. If NIH is willing to give funds for staff, we can definitely try to hire additional staff.

My sense is we will have the ability to have in person visits at our CRS once it is safe without any additional resources.

Our current initiative to expand our laboratory capacity to be able to perform molecular testing (PCR) for SARS-CoV-2. . Private laboratories expanded their testing facilities for molecular and serologic tests and have provided such testing to confirm cases on the island. Roche has given exclusive use of their reagents to one lab on the island; other labs are not able to use their Roche equipment.

Possibly.

PPE (now particularly gowns) still are limited resources. Additional funding would allow us to order some, but supplies are limited (might be able to get smaller quantities). Lab supplies (swabs are still limited); as with PPE, additional funding might help but in a limited way. I just learned we are trying to ramp up serologic testing.

Regarding the SARS CoV-2 screening needs we are setting up a drive through testing for our patients to meet those testing needs related to personnel. Additional funding from NIAID could be used to pay for SARS CoV-2 serologic testing and PCR testing of our cohort of children and adolescent/young adults with HIV and of possible research enrollees in preparation of resumption of research and to help with planning of re-opening other services.

Rush has been evaluating the purchase of two Abbott Alinity machines. These are high throughput integrated systems for molecular testing utilizing RT-PCR technology. They are a major improvement to two Abbott m2000 machines. They feature random access capability to limit reagent waste. If running a single assay it is estimated they can complete 300 results in 8 hours. Reagents are all lyophilized rather than frozen liquid reagents with the m2000 and other molecular systems. Because they are less labor intensive than the Abbott m2000 machines, our third shift staff can run them. Currently because we do not have enough qualified molecular technicians we cannot run our Abbott m2000 machines on 3rd shift. We understand Abbott SARS CoV2 assay is being submitted for EUA with anticipated status first/second week in May. WE believe we could get the Alinity machines sometime in June since we're close to their headquarters and thus easier install setup training. We have been quoted a cost of $305,500 for each machine including delivery. WE are currently running 470assays per day on 2 Abbott m2000 machines. With two Alinity machines we believe we can run 2000 PCR tests per day. Enhanced testing could

help us get staff aback to work and help us screen more patients prior to high risk procedures. Similarly it could make it safe to see our research patients again. Our medical center has also gone out to the community to help test patients at homeless shelters and long-term care facilities. We could expand these efforts too.

The issue is not just money-it is about availability of supplies

Washington University is considering implementing a plan to bring asymptomatic patients in for testing approximately 48 hours prior to planned visit. Can be done at a screening site near our CRS. It would be very useful to be able to do this in our HIV infected population as well as our ACTG/HPTN clinical trials population in order to facilitate safe visits for these participants. Staff would be utilizing universal masking as well as symptom based screening. If NIAID could support this by paying for testing costs and PPE it would enable us to start seeing HIV clinic patients and screen them for upcoming ACTG studies and our HPTN083 participants. Many do not have insurance coverage to cover testing costs.

We have several planned industry sponsored and investigator initiated COVID trials opening shortly so for us, we can open and enroll very easily at 4 of our sites

We should be able to address the needs stated in the survey. For now we are testing all who present with COVID like symptoms and are being admitted as a PUI. It would be great to offer testing to our CRS patients for protocols but also to our HIV population and smaller pediatric population w/ teens young adults and those not necessarily HIV infected but from general population who come to the hospital and ED asking for testing. At the hospital's daily COVID-19 committee meeting today, I met with the Physician in Chief who runs this meeting and he has said that the institution would support testing services and our efforts towards that end. We are able to start within a few days with PCR testing as currently the capacity of our Roche Cobas system is about 250/day and the hospital was utilizing up to 150 tests/day. We have excess capacity that we can access right away. As regards antibody testing, we will need to put the systems in place, with whichever antibody test (POC, finger prick, venipuncture) that you want to fund, once you let us know.

We will use the funding to expand testing with active epidemiological surveillance in the community. With current resources we can ramp up the test in our community to up to about $4000 tests/week immediately. With additional funding we hope to test 5000/day for the next month. We would like to utilize the funding to develop an additional sustainable infrastructure that active testing will be available at all time even when we establish new normal and during influenza season.

When I think about expanded testing on the scale you are discussing I think of our experience doing HIV testing where on a busy day we could test 100-200 individuals out of our mobile van. In those instances, we are doing POC testing, so we have to track and report positives (which happen at a much lower rate), but the information we gather from each individual is minimal. We are not registering them as patients, we aren't collecting their insurance information, and we are not billing their insurance on the back end. Right now the testing that we are doing is all through our clinic. So, patients have to register as a new patient and then come in and are seen for a medical visit and testing which is billed through their insurance or on a sliding fee based on income if they are uninsured (which is another set of information we have to gather or have patients attest to). This is a cumbersome process and appropriate for those who are more symptomatic and ill since we can assess their need for symptomatic treatments, other causes (i.e. flu which we are still seeing), or a higher level of care but it is probably not needed for those that are less or minimally symptomatic, lower risk, or if you want to expand testing to asymptomatic individuals. And when you are talking about testing 1000+ individuals a week I believe this is where you are going.

With increased support for staff and test kit acquisition we should be able to increase our screening within a few weeks. For the present we have a good access of supplies but we remain wary about how robust the supply chain is and our ability to dramatically increase testing based on supply logistics.

One of our greatest needs is swabs for NP testing. These are not easy to come by. So all of the money in the NIH budget may not make a difference with that.

Need to procure PPE as appropriate and testing supplies such as swabs and transport media.

Additional funding for testing would allow us to buy more kits, reagents, and swabs. However, I am told that as of today, our suppliers are shipping as fast as we can buy. Identify additional suppliers or have them increase their output. Short on PPE for those doing the testing, and the shortage of PPE is also affecting our ability to do clinical trials

Drive-up and walk-up testing is occurring on a very limited basis now and could be expanded with personnel and available tests. We are poised to expand with support. Need to piece together other personnel needs. Ready for another qPCR machine and automated RNA extractor (two would be useful).

Funding would definitely help supplementing testing kits availability.

Will research lab or clinical lab is to be used?

Additional funding, would shorten the time to get the Luminex up and running (as well as other testing) and we would be able to greatly expand the bandwidth of our testing. All could be implemented within a matter of days 3-5 once funding was received.

Yes, we could. Please understand however that the resources would be substantial; we would need to contract/rent an additional space for designated COVID-symptomatic/suspected individuals. We likely could transiently redeploy existing staff to work in this location while we sought additional staffing for the expanding research domains, but it's a designated space issue that is the central/pressing need. Importantly, as you well know, the DAIDS approval process for the use of such space is also a complicated one, and the rate-limiting-step for operations commencement would likely be a DAIDS approval.

I assume this question is asking about testing for coronavirus with NP or OP swabs or saliva-based specimens in acutely infected people. We could start seeing a limited number of acutely infected patients in the next 2 to 4 weeks in the late afternoon/evening hours in the main clinic building to minimize contamination during the peak business hours. To scale up the process, we will need to expand to a mobile clinic mentioned in answer #1 and will need sufficient quantities of PPE.

Currently, we are enrolling COVID convalescent patients at the Hope clinic through an investigator-initiated protocol to assess serology and cellular immune responses. The Hope clinic is also participating in a DMID vaccine trial for COVID and has been continually open and conducting face to face research since the pandemic began.

We would be able to cover the cost of training, additional clinical staff to collect specimens, as well as the cost to collect specimens at an alternative testing site (within the SFDPH) or at the participants home through a mobile study visit team.

University does testing. Already increasing testing for all kids and now parents. Can do drive by testing and it can be expanded. Needs are staff, swabs, reagents and kits. CRS Site Leader isn't in charge of institution lab. Lab Masnager states they are underutilized and could do more. Not getting enough samples to run. Could use an Abbott M2000 and one person to increase capacity. Have one drive through and could open 1-2 more. PPE is an issue because ORs are going to open again soon. Limited availability of PPE. With additional funding they could do much more.

Comments of the negative respondents.

No- as all COVID-19 testing at our site is implemented by the central UCLA Laboratory, we are not able to modify the frequency or volume of testing in the laboratory. The testing is not under out direct control. With our current machines and testing platforms, we can perform 2000 NP swabs tests daily. However, we are in need of reagents/test kits and additional personnel to reach this capacity. I am not certain if it is a funding issue per se. The major issue is a lack of availability of reagent and test kits not a lack of funds to buy the reagents

Not currently- we are desperately looking for reagents and supplies for rapid testing. Anticipate that in May, we will be opening up all of our OPD areas so could easily operationalize it then- obtaining supplies, material etc. would need to go

through Eric.spitzer@stonybrookmedicine.edu.

Reagents, test kits and personal protective equipment are difficult to obtain, and many companies are declining to ship such items to Puerto Rico, alleging their priority is the mainland USA. PR Health Department Laboratory has lagged in testing capacity due to issues with the delay in the availability of CDC test primers and tests. The Medical Sciences Campus entered late in this response due to lack of equipment, lack of reagents, difficulties in purchasing testing kits, need to validate tests, etc. Our lab has equipment that would need Roche reagents, therefore was unable to even start performing molecular testing.

We would need to be able to set up outside where people could walk/drive up without an appointment and there would be a minimal registration process. Ideally, testing would be paid for through grant support, so there would be no collecting of payment or insurance information. We don't have access to POC testing, so unless this was provided through NIAID we would need to continue to use LabCorp. This would be dependent on LabCorp being able to supply us with enough testing kits - they have been allocating kits based on prior volume - so this would have to been seen. And we would need funding for staffing to support this volume of testing. In terms of PPE, if it is outside and we are doing extended wear we would have some increase in the amount of PPE we would need, but not a ton; so I feel this is less of a barrier. We would also need city support for this as well, which I believe is obtainable. This would not be something we could turn on in days, but I do think that we could stand this up in 2-3 weeks if appropriately supported. We have the staff at our institution to do this, many of whom can't do their normal jobs. Happy to flesh out a more detailed proposal and budget if this is something that NIAID would want to support.

We would just need more manpower to take on additional studies if needed: e.g. lab, data management, administration and study coordinator % FTE as appropriate for trials which I assume would be covered in budget. Probably would need additional supplies.

The other 3 sites have less infrastructure and we are setting them up now to expand. They do not have research processing labs yet so we have to use couriers.

If protocols require more frequent testing than what is SOC, would just need reimbursement for costs"

It appears that the NYBC will not have the capacity to assist our research site, NYBC CRS DAIDS #31801, with the expansion of SARS-CoV-2 testing. The prior survey was completed with my misunderstanding of the nursing staff capacity of the greater NYBC to partner with our research site.

Additional funding would shorten the time to get the Luminex up and running (as well as other testing) and we would be able to greatly expand the bandwidth of our testing. All could be implemented within a matter of days 3-5 once funding was received:

- Luminex FlexMap-3D instrumentation for in-house serological test development
- Luminex supplies (beads, proteins, antibodies) required for serological test development
- Cepheid instrumentation expansion at SMH STAT Lab for PCR testing
- Nanodrop Spectrophotometer for measuring nucleic acid concentrations
- Cell counter
- Specimen collection kits for PCR testing –swabs
- PPE

If NIAID provided additional funding to your CRS, how soon could you implement expanded SARS-CoV-2 RNA at your CRS or Institution? Please quantify this response.

1-14 days- 12

15-28 days- 5

>29 days- 2

Unknown- 1

Other responses: most citing external conditional factors

Further expansion would depend on the type of assistance, level of support and buy-in from stakeholders. Meaningful scale up might require several weeks. Our community outreach efforts are already expanding.

We will be able to implement expanded SARS Co-V testing at our site. In addition to the cost of the testing it would be helpful to get collection kits and PPE to help support it. Timeline for expanded testing will depend on when Governor changes stay at home order. Based on the information from New Jersey state data the country where CRS is located has highest mortality in the state of 8% and is one of the 48 counties identified in End the Epidemic. Based on current admissions data it may be 2-4 weeks minimum. Will know more in two weeks.

Not sure at this time but will let us know once they have more information.

If extraction and PCR systems and reagents are supplied we could ramp up testing immediately within 2-5 days. However if not supplied we would need time to investigate and purchase instrument and reagents prior to begin ramping up- it will be about 2-4 weeks.

Outpatient testing availability at our hospital/CRS is still limited to certain symptomatic persons; asymptomatic persons testing is not permitted. Even symptomatic persons can only be tested under certain high risk situations such as living in congregate care settings or high risk illness in high risk populations (age: 65 w/ chronic medical conditions. Additional funding that would allow our CRS to establish outpatient tent plus allow us to send RNA testing outside of our hospital system could potentially be implemented in less than a week.

We would be able to expand rapidly (2 weeks) as we have existing connections through the SFDPH COVID-19 testing infrastructure.

Appendix 2: Short survey to CRS Site Leaders who did not respond to the initial survey:

Responses were received on the secondary survey from 46/54 Clinical Research Sites who did not respond to the initial survey.

What would your CRS need from DAIDS to support expanded SARS-CoV-2 RNA testing at your CRS or Institution?

In order to support additional SARS-CoV-2 RNA based testing we would need additional supplies to perform the testing. This includes both collection kits- most commonly nasopharyngeal swabs and viral/ universal transport media and testing system supplies. The testing system supplies in our case include additional test cartridges for the Cepheid instrument. Currently, we are significantly hindered in whom we offer testing too. We have a high capacity instrument so we could accommodate additional testing easily.

At this point, I would say that our Respiratory Viruses Laboratory will ultimately plan to conduct both COVID PCR testing and COVID serology (though many current COVID serologic assays are problematic, as you no doubt have heard--but my hope is that the shortcomings will be addressed in the coming months). We will plan to conduct these assays in the context of our research studies. At this point, we are not specifically planning for larger scale testing, although that is not entirely out of the question.

Additional reagents for the provision of testing.

More swabs would be helpful too.

We can build our own platform for testing if we can secure the reagents. WE have built and validated the platform but we need more reagents that could be secured with additional funds."

Additional reagents for varied systems (see above). In addition support for 2 research assistants to supplement our existing personnel.

Additional supplies.

As of yesterday, UTMB had performed just over 15,000 tests. A large number of employees have been screened and 1.3% of the asymptomatic are positive. (3.6% of symptomatic people, not just employees, are positive). Our leadership is not planning widespread employee screening due to the low percentages among employees and the community members. The institution is slowly reopening face to face services including non-COVID research. If all goes well, non-COVID human trials will restart mid-May. UTMB seems to have surplus RNA testing capabilities at this time.

Serology testing would be useful in managing the institutional workforce. UTMB is working obtaining this capability.

If there will be support offered for serology, then I will contact institutional leadership for further input.

We appreciate NIAID interest in supporting our institutional efforts."

Financial support to cover the cost of testing and the added precautions (personal protective equipment and logistics) that will be required to conduct the testing.

Funding to expand testing would help

Funding to pay for staff and testing—provision of PPE and swabs would be appreciated

"I do think that we have tremendous need to get help to support expanded SAR-Co-2RNA testing for resumption of operation not only for Positive Health clinic but also all other system clinics, not only for research but also regular clinics.

Additional funding won't help.

If protocol required, would need funding for completing the tests and test supplies

Our institution currently is able to perform approximately 1,000 PCR tests per day and nearly that many serology tests, and utilization is not at that level so the institutional labs have additional capacity for testing right now. Any physician in the community can order testing through our institutional laboratories. However, our research programs have been given lower priority for obtaining testing in the context of research studies. We are able to access screening tests for recruitment of people who are COVID-19 positive into clinical trials but are not able to obtain frequent serial tests to monitor participants in clinical trials. We can obtain follow-up tests within certain time periods, i.e., weekly tests to determine when someone converts from positive to negative, but our commercial laboratories are not set up to give us a "cycle threshold" report that allows us to serially monitor viral load over time such as might be needed to assess a new antiviral drug's activity. We do have some capacity to do this through our research labs, e.g., Davey Smith's CFAR Translational Virology laboratory can do this type of serial testing for us in the context of a clinical trial or research study to estimate viral load over time or to test other types of specimens such as saliva, CSF, blood, etc. The major challenge to us is not so much the actual testing but safely obtaining specimens to test in our research unit. For example, we have community-based testing being done in drive-through testing centers and people who test positive are being referred to UCSD's COVID-19 clinic or the hospital if needed for follow-up, so we can recruit from these testing sites and through our Division clinic and the hospital. At our own research unit, the AVRC, however, we have only limited PPE supplies, enough for A5395 but these are being prioritized at the hospital and the institution's outpatient clinics, so we have to wait sometimes for long periods to obtain supplies of PPE that would be required for expanded testing within our CRS. In addition, our CRS is off-site (across the street from) the hospital and is administratively managed through the main campus, not the hospital. What this means for us is that we cannot have our exam rooms cleaned with the type of enhanced cleaning procedures necessary to eliminate fomite contamination by SARS-CoV-2. The hospital does not take responsibility for cleaning our facility, and the campus has limited capacity for enhanced cleaning procedures. We can call the hospital's environmental services to do this in an emergency, but this may take 4-6 hours for someone to come. For this reason, we have tried to limit our use of the CRS facilities to a single exam room in which we see potentially infected participants. We keep them isolated outside of the facility (fortunately we have an outside covered patio where they can wait) or we have them wait in their cars until their appointment time, and all patients must be masked with a surgical mask and staff must have PPE to see them. The participants immediately leave the facility after a visit. For those types of in-person visits, we currently are only allowing people in the CRS facility or the designated exam room for a quick targeted exam, vital signs, and blood draws. We currently are not doing nasopharyngeal or oropharyngeal swab or saliva testing inside the facility because they are often more invasive procedures that cause people to cough or have the potential to contaminate the space with saliva or secretions. We have arranged to do those sampling procedures outside in our participant parking lot through what is effectively our own drive-through testing facility supported by our CRS. We have a mobile van with a tent set-up whereby participants can drive up, park next to the van, they stay in their vehicle while one of our staff, wearing PPE, performs the swab testing as the participant sits in their car (they can also have blood drawn there), and then the participant drives home. All participants, if they come for testing through that process are asked to wear a mask when they drive up.

Our institution needs more reagents for rapid testing. We have many instruments for rapid testing but have difficulty obtaining reagents.

Our site is greatly motivated to assist in any way we can. Currently we do not have a PCR machine but have the space in our dedicated lab. If NIAID provided funds we would be able to implement serology testing. We could also be a sample collection site. We have more than thirty clinics in our organization that could also be a part of the expansion. Please feel free to reach out with any questions, concerns.

The 2 areas of testing are PCR and serology. PCR has been limited by availability of swabs with VTM and tests. Tests are now available but swab kits have uncertain availability. Additionally, while we do self-swabbing, provider swabbing entails risk that require substantial time constraints to protect HCW that limit the number of swabs that can be performed as part of population based surveillance. Serology tests are becoming available but there remain safety considerations that reduce the efficiency of performing phlebotomy from pre-COVID routines. And we do not yet have interpretative guidelines for serologic thresholds.

The biggest need for testing at our site the preferred gene x-pert swab in viral culture media. The supply is very low at our institution and attempts to acquire more have been difficult due to the national shortage.

The Bronx CRS will need funding to cover staff time (including dedicated couriers), the cost of testing and testing supplies and the cost of PPE.

We could offer testing for SARS-CoV-2 but would need resources to train staff, or hire part time staff to do this if current staff does not feel comfortable as well as funding for PPE to do this.

We could potentially need to increase our lab staffing and testing equipment to meet a greater volume than what we currently have or else contract out for additional support.

We currently are doing COVID-19 IRB-approved research, and are likely to submit additional proposals for funded research to NIAID or NHLBI in the near future. We currently have the capacity to do additional testing, although test kits and reagents are in limited supply.

We have the ability to order RNA tests. However we would need funding to cover tests that may not be covered by patient insurer's (asymptomatic patients). We would also need funding for personnel expenses due to additional effort.

We would be very excited to work on expanding the capability for RT-PCR testing.

It would be helpful to have funding to cover/provide for

The cost of the RT-PCR assay which is done through our CLIA certified clinical/hospital laboratory. Such an assay has been implemented at the site clinical laboratory

Assistance with procuring swabs [with VTM] for the testing

Assistance securing N95 masks just to ensure that there is a supply on had

Support for expanded staffing infrastructure (clinical and laboratory) to be able to meet the need and support expanded capacity in terms of identification of individuals for testing, specimen collection, processing , result notification

In some instances, especially for faster turnaround time, the Abbott PCR machine would be a good adjunctive tool

We would need additional staff for specimen processing

We would need support for a research coordinator, specimen acquisition staff and lab support for performing PCR and serology tests, plus all related consumable supplies.

We would need instrumentation to run high throughput assays; supplies (including swabs and transport medium) in order to be able to obtain the necessary samples; and additional personnel in order to be able to run tests at least two shifts per day plus weekends; informatics support to track samples and report results. In addition, we would need support to perform the validation studies necessary to perform these tests under CLIA.

We were not planning on testing volunteers unless that is being added to the protocol. If so we would need assistance to conduct the studies. The institutions do testing per the institution's protocol for employees. There have been delays due to lack of reagents and kits in the past. We are still on a stay at home order in the city of St. Louis until May 15.

The Bronx CRS will need funding to cover staff time (including dedicated couriers), the cost of testing and testing supplies and the cost of PPE.

Increased funding to secure more RNA test kits or provision of additional test kits directly and funding for more PPE for staff members carrying out testing.

We are absolutely interested in additional funding to support SARS-CoV-2 testing expansion.

If NIAID provided additional funding to your CRS, could you address the identified needs?

Yes- 24

No- 2

Comments:

This would assume we could purchase the additional supplies with the additional funding. Currently, we are receiving many of these components from national/ VA wide contracts- in particular Cepheid test cartridges. If in addition to the funding, this could result in a re-distribution or acquisition of additional test cartridges outside of the national contract that could greatly facilitate expanded testing.

We can build our own platform for testing if we can secure the reagents. WE have built and validated the platform but we need more reagents that could be secured with additional funds.

No. We have the necessary funds to order supplies, but everything is on back-order.

It would enable the NM system to accelerate testing. The priority now is for inpatients, followed by persons coming for scheduled outpatient procedures. Ambulatory testing as would be needed for clinical trials participants and their clinic contacts is lower on the priority. If we had dedicated funds we could open up testing related to the CRS and open up clinical research safely faster.

I will discuss with our Allegheny Health Medicine Institute COVID19 team to come up with a reasonable plan and address our immediate, short term and long-term need.

Yes, with the caveat that I am not sure what the supply chain for test kits and supplies will be in the future. Test availability is expanding in our region, but still very limited

The functional activities for which we would need additional funding would be to support PPE supply, to support the payment for the actual testing, whether that would be in our institutional lab or in our CFAR labs, and to support potentially contracting for environmental cleaning services. We are also incurring additional costs for support of the testing van, tent and parking lot testing facility. Lastly, we would likely need supplemental funding to support staff who are obtaining the specimens and the biohazard materials that would be needed to dispose of contaminated PPE and/or to put contaminated specimens into for transport or storage.

Obtaining reagents. We have funding for the reagents, but just can't get them from the manufacturers. If NIAID could assist in working with the manufacturers to make the reagents accessible, that would allow expanded testing.

The most useful addition would come in the form of addition personnel support at a nursing level. Assurance of swab supplies would also alleviate uncertainty.

Our CRS does not perform the testing ourselves but the institution we are affiliated with (John H. Stroger Jr Hospital of Cook County) runs the test in house. The ability to expand testing at the institution is based on how quickly we can obtain the appropriate test kits.

Yes we could address this and our clinic is looking to do this with offsite testing/driving to our patient's homes via a testing team and doing testing in the field. Could the testing be done off site so as part of a mobile testing unit with research staff participating in testing?

Yes, additional funds would make that possible.

Yes, assuming we could purchase additional kits, reagents.

Absolutely. As the testing was being introduced at the institution, and as capacity expands, I have been working closely with the institutional laboratory and Infection Prevention and Control leadership on the implementation and availability of testing. This has evolved into a very fruitful partnership and collaboration between the NewYork Presbyterian (NYP) clinical laboratory and our Division. Currently, a Roche and Cepehid platforms are available through this CLIA certified clinical NewYork Presbyterian (NYP) Laboratory.

Furthermore, research labs in our division and in the department of medicine have developed and implemented q-RT-PCR assays for research studies initiated by CRS investigators. And if there is interest in supporting the development and validation of new assays, our CRS investigators and faculty in the

Absolutely, we are prepared to respond.

No. We have the necessary funds to order supplies, but everything is on back-order.

Yes, we could do this but would need funding.

Additional funding won't help.

Within 5 days of having IRB approval. Of note, the Columbia University Medical Center IRB is fast-tracking all COVID research.
Given the need to acquire equipment, hire staff and perform appropriate validation studies it would take us 4-6 weeks at a minimum.

If NIAID provided additional funding to your CRS, how quickly could you implement expanded SARS-CoV-2 RNA testing at your CRS or Institution?

1-14 days- 11

15-28 days- 4

>29 days- 4

Comments:

Would largely depend on availability of resources. We already have testing system- expanded supplies would help us test more. If achievable the time to impact would be short (weeks)

We are running samples now and it would just be how quickly NIAID and VACT could hammer out the details. If you want us to run the samples at Yale it may take 1-2 months as currently we have pressing patient issues (>450 patients in-house).

Additional funding won't help.

We have fully capability to expand testing given a five day lead if we have guaranteed funding. We have systems set for testing, linkage to our Department of Heath for data reporting, notification and contact tracking. As part of a community testing program we are leading, we tested 950 persons (PCR and antibody) yesterday.

I would say, it can be flexible. Also, it will depend on if the test can be a point of care test or send-out test. Who can do the test. Normally, if this can be done without research consent process, without IRB approval. For my positive Health clinic, we can start as soon as staff been trained to perform the test. That would be less than 2 weeks. I would think that it will be the same for other clinics or Emergency department or other units

Additional testing up and running within a month I agree with Carlos except that I think we could get expanded testing up running in less than a month. We already have the Abbott and Roche PCR platforms running so it should be straightforward to validate a new machine if we can get one. We also have the Genexpert running and could do more if we had cartridges. For serology reagents for the Abbott architect would allow us to do more.

We could implement within a few weeks, pending IRB approval and receipt of supplies

We could provide expanded testing within 2 weeks (really could do so earlier, we would just need the time to organize staff schedules, the parking lot tent drive-through facility staffing, and PPE to get it started).

We have COVID testing. Additional support would permit expansion for needed surveillance.

Depends on availability of materials

Within 5 days of having IRB approval. Of note, the Columbia University Medical Center IRB is fast-tracking all COVID research.

Time frame would be 1 month if this is in the setting of a study then maybe a little longer due to needing to obtain IRB approval though we can try to expedite this

Our clinical CLIA-certified New York Presbyterian hospital lab which is co-localized with the CRS, already has SARS-CoV-2 RNA testing available – the primary systems are Roche & Cepheid. This is the lab through which our CRS conducts local safety labs for all of our interventional studies. Depending on the additional volume needed we could ensure expanded testing quickly since the platform is in place.

Additionally, there are research labs in the ID Division which have validated qRT- RNA testing on NP swabs, saliva

Expanded PCR testing can begin immediately upon added NIAID support.

The Duke team has been considering activities that would include testing all Duke employees, Durham-area first responders, a Duke Network-Targeted Strategy for Efficient Community SARS-COV-2 Sampling and a program aimed at testing individuals who are homeless or in shelters. Several Duke School of Medicine Faculty have been leading these planning activities and we would leverage these concepts to immediately activate an aggressive COVID-19 testing program in the Durham, N.C. region.

The laboratory team supporting this work currently has the Abbott m2000 PCR testing platform designed for high throughput testing. Using this system, we have been supporting COVID-19 clinical research and health system testing for surge capacity. This platform can test 400 samples/day utilizing a 24/7 approach. The lab team also has a Cepheid Gene Xpert testing platform that can test about eight samples/two hour period for lower testing needs. PCR testing is validated and on line and can expand immediately upon NIAID funding support.

Given the need to acquire equipment, hire staff and perform appropriate validation studies it would take us 4-6 weeks at a minimum.

If NIAID provided additional funding to your CRS, could you implement or expand serology testing at your CRS or Institution?

Yes- 21

No- 1

Comments:

We have initiated the request from Roche to acquire the testing platform for serologic (IgM and IgG testing for SARS-CoV-2. If additional funding could be secured we could purchase more testing kits to run on our automated chemistry analyzer. In addition, funding to support a contracted medical technologist to assist with running any specimens if above and beyond current workload would also be of assistance.

Yes, we have also developed a broad array of Ab testing, including neutralizing and blocking antibodies.

Yes, at VACT we already have the Abbott SARS-CoV-2 up and running.

Also possible since we have in-house testing almost ready.

This would be our goal to expand serology testing to our CRS and institution.

Think so. We have a LDT at Emory that has recently been launched and are starting testing with the Abbott test at Grady

Yes- we have other investigators working on serologic testing. We are currently working with Scanwell technologies. I am not familiar with a commercially available serologic test

Yes, we have capability now for serology testing at our institution. We would need to pay for the tests.

Ready to expand rapid testing immediately as soon as reagents are available.

We have been hesitant to expand serology testing because test performance unknown and unclear if seropositivity has clinical impact. When a validated and IDSA-accepted as clinically useful serologic test is identified, we would hope to expand testing. We would likely appreciate funding at that time."

Yes. Our capacity is limited by throughput for obtaining specimens.

Yes we would implement/expand serology testing if we receive additional funding.

Yes, additional funds would make that possible.

Yes, as above, we would be very excited to work on that. Serology testing has been validated and implemented at our CLIA-certified New York Presbyterian hospital lab. As is the case with RT-PCR testing, I have been working closely with the NYP/Columbia laboratory on testing, and this resulted into a very fruitful partnership and collaboration with the NYP/clinical laboratory and our Division. And with additional funding there would be opportunities to expand the testing at the CRS/institution in support of research protocols.

The Duke Human Vaccine Institute of the Duke School of Medicine is home to the NIAID DAIDS Immunology Quality Assessment Program (IQA), NIAID DAIDS External Quality Assessment Program Oversite Testing Laboratory (EQAPOL) and the NIAID DAIDS Virology Quality Assessment Program (VQA). This laboratory is College of American Pathologists (CAP)-accredited, CLIA-approved and audited yearly for GCLP compliance. This team is currently working with the ACTG laboratory leadership to evaluate potential utilization of different sample types (e.g., saliva) for testing support and is well prepared to support a regional testing program.

We are certainly capable of implementing serology testing in our lab, given appropriate funding.

We are certainly capable of implementing serology testing in our lab, given appropriate funding.

What would your CRS need from DAIDS to support expanded serology testing at your CRS or Institution?

In addition to funding for serologic testing supplies, known positive patient serum/ plasma from those exposed to SARS-CoV-2 would be helpful in validation studies.

Expanded serology testing at your CRS or Institution?

Funding for continues provision of reagents. We have laboratory staff who are underutilized currently.

Funding for the kits (~$5.50 per test) and support for research personnel to supplement existing lab staff.

Plan to start serology testing in the next week or two and supplies will be the primary issue.

Financial support to cover the cost of testing and the added precautions (personal protective equipment and logistics) that will be required to conduct the testing.

Funding would be the most practical since testing is centralized with the rest of the hospital system.

Funding to pay for staff and testing—provision of PPE and swabs would be appreciated

I would think “test kits”, “training” “data collection” and “funding support”

Financial support to cover the cost of testing and the added precautions (personal protective equipment and logistics) that will be required to conduct the testing.

We would need to do phlebotomy so PPE will be important

Test kits or supplies

Currently, the biggest drawback with serologic testing is having an accurate serology test. The lateral flow point of care tests do not have sufficient sensitivity, specificity or accuracy in terms of false positive and false negative rates to be effectively used for epidemiologic or individual diagnostic testing, so our institutional tests are laboratory based ELISA assays. They expect to have high throughput commercial assays from Abbott, Roche, and other large diagnostics companies within the next week or two, and once those are in place they can expand their serologic testing further. For now the institution estimates that with the current ELISA kits they have they could perform up to 800-1000 tests per day, although these tests right now are being prioritized for healthcare workers and expanded campus student screening. However, they are not currently working at full capacity, so we could expand serologic testing now and within 2-3 weeks will have much more capacity. I am told by our laboratory people that the only major challenge is the availability of reagents, and part of what has been happening recently is that the federal government has been diverting reagents and kits to their own federal stockpiles or to send to areas that do not have adequate testing yet. I expect this will be a short-term problem.

Personnel who can be dedicated to testing including documentation of relevant clinical data is the greatest need.

The Bronx CRS will need funding to cover staff time, the cost of testing and testing supplies and the cost of PPE. If aliquoting of plasma from whole blood on site is necessary, we would need funding for a biosafety cabinet (hood) at the site. Our site has enough space for this equipment.

We would need some funding to allocate for research nurse/phlebotomist to do lab draws depending on the volume of patients DAIDS is interested in testing.

Funding

The needs to expand serology testing are the same as expanding RNA testing: funding for tests not covered by the patient's insurer and funding to cover additional personnel efforts.

It would be helpful to have support for the infrastructure needed to ensure smooth expansion of serology testing: including additional personnel [especially with staggered hours] to conduct phlebotomy, handle specimens, enter data and

communicate results to participants; funding to cover the cost of the consumables; if feasible, lab personnel to assist with expanding the serology testing capacity.

We have a serology test (a rapid lateral flow immunoassay) that we are currently validating so we would need kits and some personnel (1 -2 people) to get serology testing up and running at our site

Multiple, population-based cohorts across the state are being initiated under Duke leadership and with NIAID support, expanded testing could be initiated in a very broad manner.

The lab team identified above under #4 is currently working with Duke clinical investigators to determine COVID-19 antibody responses as part of a prospective cohort study and a pilot emergency room COVID-19 seroprevalence study. For this project, we have used a non-EUA ELISA IgG and IgA assay (Euroimmun). For expanded serological testing, we would request funding for the Abbott Alinity Analyzer to support serology testing on the Abbott EUA-approved IgG test. Abbott will commit to providing an instrument to us within two weeks of Duke issuing a purchase order. If NIAID-approved, we could utilize lab support from one of the above noted programs to rapidly acquire the Alinity instrument. Additional NIAID support would be required to provide test kit reagents and related consumable supplies.

We thank you for the opportunity to respond to this call and are certain that we have the institutional support to operationalize an expanded SARS-COV-2 testing program with budgetary support from NIAID. Our existing NIAID funded programs should facilitate a process for supplemental funding if you agree with our plan. We are happy to discuss this on a call and prepare more detailed plans and budgets upon request.

Plan to start serology testing in the next week or two and supplies will be the primary issue. We have reagents now but would need more protein antigens (maybe plasmids) for serology.

Equipment, supplies, informatics and staffing.

Additional funding to secure more serological test kits or direct provision of the tests kits and reagents needed.

The Bronx CRS will need funding to cover staff time, the cost of testing and testing supplies and the cost of PPE. If aliquoting of plasma from whole blood on site is necessary, we would need funding for a biosafety cabinet (hood) at the site. Our site has enough space for this equipment.

Same as for RNA testing: We would need instrumentation to run high throughput assays; supplies in order to be able to obtain the necessary samples; and additional personnel in order to be able to run tests at least two shifts per day plus weekends; informatics support to track samples and report results. In addition, we would need support to perform the validation studies necessary to perform these tests under CLIA.

Additional context and/or comments

I want to provide a little background as it may help with your questions. VA Connecticut was originally a separate REPRIEVE site from Yale (I was/am the PI at both sites - VACT & Yale) but we transferred the patients from the VA to Yale at the suggestion on NIAID. I am reporting this because at VACT we have the capacity to run SARS-CoV-2 RT-PCR with Cepheid, DiaSorin and the Roche cobas systems (2,000 samples a week). We are running them for the New England VISN and the region; VACT is a reference laboratory for the region. The State of CT also asked FEMA about obtaining additional cobas reagents so that VACT could possibly help CT with its testing. We are helping the City of New Haven with testing for the homeless. I am also the Chief of Staff at VA Connecticut where I have my research virology laboratory which is embedded within the VACT reference virology lab - this allows me to help with these decisions. I am reporting this because at VACT we

have the capacity to run SARS-CoV-2 RT-PCR with Cepheid, DiaSorin and the Roche cobas systems (2,000 samples a week). We are running them for the New England VISN and the region; VACT is a reference laboratory for the region. The State of CT also asked FEMA about obtaining additional cobas reagents so that VACT could possibly help CT with its testing. We are helping the City of New Haven with testing for the homeless. I am also the Chief of Staff at VA Connecticut where I have my research virology laboratory which is embedded within the VACT reference virology lab - this allows me to help with these decisions.

This is not limited to Positive Health Clinic (the REPRIEVE participant) and this potentially can be a big collaborative task between AHN and NIH.

I think that it can help our institution if this can be integrated into our health system re-opening plan.

If there is a rapid PCR screen test available (result less than 20 minutes)

- Rapid screen for all urgent care patients with COVID19 related signs/symptoms or seeking care with potential COVID19 exposure history
- Rapid screen prior to face to face visit in out-patient clinic, especially, patients with respiratory signs/symptoms or signs/symptoms to be considered as COVID19
- Screen test for any patients for patients prior to undergo surgical, GI or interventional procedures. (OR normally is “positive pressure”, therefore to rapid screen patients for COVID19 is extremely necessary)
- Rapid screen test for Health care staff at high potentially expose to COVID19 patients, such as ED, ICU, anesthetists, surgeons…
- Homeless, underserved populations screening for COVID 19
- If possible, all patients has potential contacts with COVID19 will need to have rapid test prior to face to face visit.

Appendix 3: DAIDS HIV/AIDS Network CRS Survey: SARS-CoV-2 Testing

DAIDS HIV/AIDS Network Clinical Research Site (CRS) Survey: SARS-CoV-2 Testing

Thank you for taking the time to respond to the **DAIDS HIV/AIDS Network Clinical Research Site (CRS) Survey: SARS-CoV-2 Testing in the United States**.

The purposes of this survey are:

1. To identify opportunities to support expanded SARS-CoV-2 testing at DAIDS Clinical Research Sites to help meet needs for expanded community testing in the United States as well as needs for future DAIDS research studies.
2. To understand current capacity for testing.
3. To understand potential challenges with testing.
4. To understand current/potential linkages to other organizations in support of testing, if any.

Instructions

This survey has been sent to DAIDS HIV/AIDS Network CRS Leaders at US-based clinical research sites for completion. Please submit **ONE** survey response per clinical research site by **Thursday, April 23**.

* 1. CRS Name

* 2. CRS Number

3. Name of respondent completing survey

4. Email contact for respondent completing survey

DAIDS HIV/AIDS Network Clinical Research Site (CRS) Survey: SARS-CoV-2 Testing

Current Capacity Performing SARS-CoV-2 RNA Testing at CRS

* 5. Is SARS-CoV-2 RNA testing currently being conducted at your CRS and/or at your CRS Institution?

- ☐ At the CRS
- ☐ At the institution that the CRS is affiliated with
- ☐ Neither at the CRS or affiliated institution

If testing is done at the institution that the CRS is affiliated with, please write in the name of institution.

1

6. Please indicate the labs your **CRS** is sending samples to for SARS-CoV-2 PCR RNA testing. Select all that apply.

- [ ] Not Applicable (our CRS is not sending out any samples for testing)
- [ ] Commercial Labs (i.e. Quest, LabCorp)
- [ ] Your Hospital Clinical Lab
- [ ] State Health Department
- [ ] Other (please specify)

7. Please indicate the labs your **Institution** is sending samples to for SARS-CoV-2 PCR RNA testing, if known. Select all that apply.

- [ ] Unknown
- [ ] Not Applicable (our Institution is not sending out any samples for testing)
- [ ] Commercial Labs (i.e. Quest, LabCorp)
- [ ] Your Hospital Clinical Lab
- [ ] State Health Department
- [ ] Other (please specify)

8. What is the turnaround time for results for the labs selected in Q6 and Q7?

	Turnaround time for results
Commercial Labs (i.e. Quest, LabCorp)	
Your Hospital Clinical Lab	
State Health Department	
Other	

9. If the turn-around time for results is >2 days, what is the main cause of delay?

- [ ] Not applicable (turn-around time for results is 2 days or less)
- [ ] Back log at the lab
- [ ] Difficulty in transport of samples to lab
- [ ] Difficulty in transmission of test results from lab to clinic
- [ ] Other (please specify)

DAIDS HIV/AIDS Network Clinical Research Site (CRS) Survey: SARS-CoV-2 Testing

Patient Access at CRS

10. Please describe the patient populations that are able to get tested for SARS-CoV-2 RNA testing at your CRS or Institution. Select all that apply.

- [ ] Unknown
- [ ] Symptomatic patients (within the community)
- [ ] Asymptomatic patients requesting testing
- [ ] Close contacts – based on health department contact tracing
- [ ] All hospital admissions
- [ ] Health care workers
- [ ] First responders
- [ ] Other (please specify)

11. Please describe any barriers at your CRS to accessing patient populations for SARS-CoV-2 RNA testing.

DAIDS HIV/AIDS Network Clinical Research Site (CRS) Survey: SARS-CoV-2 Testing

Linkages to Organizations Within Your Community

12. Does the CRS have existing linkages to the following types of institutions in order to test patients for SARS-CoV-2? Select all that apply.

- [ ] Long term care facilities
- [ ] State and county health departments or state and county run clinics
- [ ] Outpatient clinics
- [ ] Home health agencies
- [ ] Hospitals
- [ ] Jails and/or prisons
- [ ] Other (please specify)

13. For the institutional linkages selected in Q12, please describe the nature of the relationship in the corresponding textbox below.

Long term care facilities	
State and county health departments or state and county run clinics	
Outpatient clinics	
Home health agencies	
Hospitals	
Jails and/or prisons	
Other	

DAIDS HIV/AIDS Network Clinical Research Site (CRS) Survey: SARS-CoV-2 Testing

Challenges and Opportunities with SARS-CoV-2 RNA Testing

14. What are your barriers to expanding SARS-CoV-2 RNA testing at your CRS? Rank the top 3 in order of importance with #1 as most important barrier.

	Is this a barrier?	Importance rank
Insufficient personal protective equipment (PPE)		
Insufficient clinical consumables (i.e. swabs)		
Insufficient testing kits		

	Is this a barrier?	Importance rank
Insufficient reagents		
Personnel limitations (i.e. not enough trained personnel to obtain, transfer, or process specimens)		
Staff concerns about personal safety		
Lack of safe collection facilities (i.e. availability of negative pressure rooms, availability of drive thru to obtain specimens outside, other facility challenges)		
Changing or limited criteria for who gets tested		
Inadequate linkages to potential pool of patients		
System/software incompatibility between clinic and testing lab		
Not an approved testing lab (i.e. CLIA certified)		
Inadequate funding		
Lack ability to bill for services		
Reimbursement provided does not cover expenses		
Institutional rules/policies constraining testing		
Our CRS is not interested in/capable of performing testing		

Other (please specify)

5

15. If you responded **"Yes"** to **insufficient personal protective equipment (PPE)** as a barrier in the previous question, please specify the types of PPE that are relevant. Select all that apply.

- [ ] Face shields
- [ ] N-95 masks
- [ ] Surgical masks
- [ ] Gloves
- [ ] Protective clothing
- [ ] Other (please specify)

16. For each of the items recorded as barriers in Q14, please elaborate on the challenge in the corresponding textbox below.

Insufficient personal protective equipment (PPE)	
Insufficient clinical consumables (i.e. swabs)	
Insufficient testing kits	
Insufficient reagents	
Personnel limitations (i.e. not enough trained personnel to obtain, transfer, or process specimens)	
Staff concerns about personal safety	
Lack of safe collection facilities (i.e. availability of negative pressure rooms, availability of drive thru to obtain specimens outside, other facility challenges)	
Changing or limited criteria for who gets tested	
Inadequate linkages to potential pool of patients	
System/software incompatibility between clinic and testing lab	
Not an approved testing lab (i.e. CLIA certified)	
Inadequate funding	
Lack ability to bill for services	
Reimbursement provided does not cover expenses	
Institutional rules/policies constraining testing	
Our CRS is not interested in/capable of performing testing	
Other	

17. If these barriers could be overcome, how many more tests could be performed at your CRS per week?

- ◯ <1000
- ◯ 1000 to 2000
- ◯ >2000 to 3000
- ◯ >3000 to 4000
- ◯ >4000

* 18. If your CRS was going to start performing SARS-CoV-2 testing as part of gradual entry back to normal operations, can you do so immediately?

- ◯ Yes
- ◯ No

DAIDS HIV/AIDS Network Clinical Research Site (CRS) Survey: SARS-CoV-2 Testing

Challenges and Opportunities with SARS-CoV-2 RNA Testing (Part A)

19. If yes, please describe what additional support would help.

DAIDS HIV/AIDS Network Clinical Research Site (CRS) Survey: SARS-CoV-2 Testing

Challenges and Opportunities with SARS-CoV-2 RNA Testing (Part B)

20. If no, what would your CRS need to get testing going?

DAIDS HIV/AIDS Network Clinical Research Site (CRS) Survey: SARS-CoV-2 Testing

Challenges and Opportunities with SARS-CoV-2 RNA Testing

21. Is there something that NIAID/DAIDS can do quickly, including any of the items addressed previously, to help support increased SARS-CoV-2 testing at your CRS?

- ◯ Yes
- ◯ No

If yes, please describe.

DAIDS HIV/AIDS Network Clinical Research Site (CRS) Survey: SARS-CoV-2 Testing

Serology Testing for anti SARS-CoV-2 Antibodies

* 22. Does your CRS or affiliated lab(s) currently offer serologic testing for COVID-19?

- ◯ Yes
- ◯ No

DAIDS HIV/AIDS Network Clinical Research Site (CRS) Survey: SARS-CoV-2 Testing

Serology Testing for anti SARS-CoV-2 Antibodies (Part A)

23. If yes, please describe the purpose of the testing.

DAIDS HIV/AIDS Network Clinical Research Site (CRS) Survey: SARS-CoV-2 Testing

Serology Testing for anti SARS-CoV-2 Antibodies (Part B)

24. If no, is it because the available serologic tests have not been determined reliable enough by your local institution?

- ◯ Yes
- ◯ No

DAIDS HIV/AIDS Network Clinical Research Site (CRS) Survey: SARS-CoV-2 Testing

Serology Testing for anti SARS-CoV-2 Antibodies

25. If serologic testing is made available, what are your barriers to providing serologic testing through the CRS/affiliated lab? Select all that apply.

- [ ] Not enough personnel
- [ ] Not enough/inadequate clinic facilities
- [ ] Not enough lab capacity
- [ ] Unclear compensation
- [ ] Other (please specify)

26. For each of the items recorded as barriers in the previous question, please elaborate on the challenge in the corresponding textbox below.

Not enough personnel	
Not enough/inadequate clinic facilities	
Not enough lab capacity	
Unclear compensation	
Other	

27. Would having testing on demand capability help with your site plans for reopening and re-engaging participants with face to face visits?

- ○ Yes
- ○ No

If yes, please elaborate on your response.