Point-of-care rapid antigen testing in the community setting to reach populations disproportionately affected by COVID-19

BACKGROUND

Black and Latinx communities continue to be some of the most heavily affected by the COVID-19 epidemic in the United States.[1,2] Testing for COVID-19, and isolation and contract tracing for those who test positive, are effective strategies to reduce transmission and allow states to safely reopen.[3] However, many health departments are experiencing delays in processing laboratory specimens, making it difficult to provide timely results and initiate isolation and contact tracing. Further, data from several jurisdictions[4] indicates that persons in Black and Latinx communities may be less likely to visit brick-and-mortar sites to get tested for COVID-19 and face a myriad of challenges in accessing care and maintaining isolation. Therefore, there is a need to develop targeted testing strategies to reach Black and Latinx communities in high prevalence areas and provide wrap-around support services.

APPROACH

To address racial and ethnic COVID-related health disparities and reduce transmission of COVID-19, this program will support health departments and community partners to provide point-of-care rapid antigen (POC rAg) testing in non-traditional settings. Through an Emergency Use Authorization (EUA),[5] the FDA has authorized use of the Becton Dickenson (BD) Veritor POC rAg test for persons who have symptoms of COVID-19. The BD analyzers can process specimens within 15 minutes[6]; thus, persons testing positive can be notified of their results, counseled about isolation, assessed for wrap-around service needs, and interviewed to elicit contact information, all during the testing encounter.

The program proposes to use the BD Veritor POC rAg test to test persons with or without symptoms in Black and Latinx communities with relatively high positivity rates and among COVID-exposed persons identified through contact tracing. With an estimated 84% sensitivity and 97% specificity,[7] this test will accurately identify most persons infected with COVID-19. Although testing asymptomatic patients is not included in the EUA for the BD Veritor POC rAg test, the program will also collect specimens to conduct confirmatory laboratory-based PCR testing, regardless of the initial POC rAg test results (Figure 1). The program will partner with laboratories that have capacity to provide PCR test results with 48 hours.

In accordance with CDC guidelines,[7] persons who test positive on the POC rAg test will immediately receive counseling on isolation. Information will also be collected for all contacts based on CDC criteria. Negative results on the POC rAg test will be considered presumptive until confirmed with a PCR test; persons that test negative and are symptomatic or have a known exposure to a person confirmed to have COVID-19 will be advised to isolate until they receive PCR confirmatory results. This approach will ensure that persons who are infected, but were not detected with the POC rAg test, are identified.

The program will support three testing models:

Priority population testing: Health departments will partner with community-based organizations (CBO) to coordinate COVID-19 testing in areas with emerging infections (e.g., churches, workplace settings). Staff from the CBOs will support contact elicitation, ensure language access, and facilitate a 'warm handover' to support services (e.g., alternative housing, food and nutrition, daily check-in phone calls, linkage to medical and social services).

Testing of identified contacts: As part of the broader contract tracing strategy, health departments will work with partner CBO to deliver POC rAg testing services to identified contacts. Tracers will arrange for contacts to be tested, prioritizing clusters for on-site testing. CBO staff will also be available to offer support services.

Testing in community health centers: The program will also support POC rAg testing in community health centers (CHC) that provide primary care services to populations with limited access to health care. CHC staff already coordinate care for patients requiring clinical, preventive and support services, and will also provide counseling on isolation and initiate contact elicitation.

The main outcomes of this program are to (1) increase testing among persons in Black and Latinx communities, (2) reduce time to isolation of persons with COVID-19 and elicitation and notification of their contacts, and (3) reduce transmission of COVID-19 in these communities.

PARTNERS

Vital Strategies collaborates with health departments in the United States to develop and scale local COVID-19 response programs. Building on those partnerships, this program will support state and county health departments to implement innovative COVID-19 testing models, with a focus reaching on Black and Latinx communities. This program will complement on-going state and county activities to reach vulnerable populations, fill a gap in COVID-19 testing services, and support a continuum of prevention and care.

REPORTING

Contact information, demographics (age, sex, race, ethnicity, and zip code), risk information, and additional variables required by the state will be collected during intake and reported to the appropriate health department. The BD Veritor 'synapsys' function can link to the web and electronic health records to automate reporting of results and provide health departments with real-time information about testing. All results (POC rAg test and the PCR confirmatory test) will be reported to the health department, per jurisdiction reporting requirements.

INNOVATION

This program is innovative in that it will offer COVID-19 testing in non-traditional settings to make services accessible to communities that may otherwise not have access. Antibody POC tests do not detect acute COVID-19 infections and PCR laboratory-based testing may take several days or weeks to process—potentially missing the opportunity to identify cases in the initial period when individuals are most infectious. This program will use POC rAg testing to detect early infections and provide results that are clinically meaningful during the testing encounter. As there are also delays in reporting test results to health departments, particularly for POC tests, the program will also leverage the 'synapsys' function on the BD Veritor to send results to health departments and allow for real-time monitoring of results and case management.

ASSUMPTIONS/ RISKS

There are several key considerations for program implementation. Implementation needs full buy-in of local health departments. As the program model emerged from needs identified by state and county health departments, we anticipate the program will have cooperation at both levels. The program also presumes that BD and distribution partners will have sufficient equipment to supply to program. Given the high demand for COVID-19 testing, it is likely that it will continue to be a challenge to procure tests. Finally, to be effective, testing models must be designed and delivered in a way that resonates with Black and Latinx communities. Given the history of biomedical testing in these communities, and concerns about involvement

with government entities, jurisdictions will work closely with community partners to ensure that the program is culturally competent and responds to community needs.

REFERENCES

1. Millett GA, Jones AT, Benkeser D, et al. Assessing differential impacts of COVID-19 on Black communities. *Annals of Epidemiology.* 2020.
2. Rodriguez-Diaz CE, Guilamo-Ramos V, Mena L, et al. Risk for COVID-19 infection and death among Latinos in the United States: Examining heterogeneity in transmission dynamics. *Annals of epidemiology.* 2020.
3. Frieden T, Shahpar C, McClelland A, Karpati A. *Box It In: Rapid Public Health Action Can Box In Covid-19 and Reopen Society.* Resolve to Save Lives;2020.
4. Bilal U, Barber S, Diez-Roux AV. Early Evidence of Disparities in COVID-19 Testing in US Cities. *medRxiv.* 2020(Preprint).
5. BD Veritor™ Veritor System for Rapid Detection of SARS-CoV-2. *Food and Drug Administration Emergency Use Authorization* https://www.fda.gov/media/139752/download.
6. BD Veritor™ Plus System for rapid COVID-19 (SARS-CoV-2) testing. https://www.bd.com/en-us/offerings/capabilities/microbiology-solutions/point-of-care-testing/bd-veritor-plus-system-for-rapid-covid-19-sars-cov-2-testing.
7. Interim Guidance for Rapid Antigen Testing for SARS-CoV-2. https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html.

BUDGET

ITEM	UNIT COST	# UNITS	TOTAL COST
BD Veritor Plus System Each	$ 275.00	4	$ 1,100.00
BD InfoSync to scan bar codes + sync data	$ 398.00	0	$ -
BD Veritor SARS-CoV-2 Test Kit	$ 32.50	8500	$ 276,250.00
Printer cable for BD Veritor	$ 27.00	4	$ 108.00
Training and installation		0	$ -
TOTAL			**$277,458.00**