



Becoming a Designated COVID-19 Testing Partner

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Background

To ensure equitable COVID-19 testing opportunities for the residents of Baltimore City, the Baltimore City Health Department (BCHD) will support testing efforts through a variety of clinical and community partners.

This testing initiative is in line with BCHD's core value of integrity-the provision of services through an equitable lens. It is intended to expand COVID-19 testing opportunities, thereby contributing to an efficient coordinated system of testing which ensures that every Baltimorean who wants and requires a test has equitable access to one, and receives a result and referral to health services (where necessary).

Testing Program Guidance

Goals of COVID-19 Testing Partnership:

In conjunction with mandated and recommended public health guidance, this program is intended to decrease the spread of COVID-19 in Baltimore City by:

- ❑ Ensuring that all Baltimoreans have equal access to COVID-19 testing
- ❑ Providing timely reporting of test results so that all tested are aware of their status in a timely manner
- ❑ Identifying individuals who are COVID-19 positive and providing referrals to care, case investigation, and contact tracing

BCHD is committed to providing COVID-19 testing services equitably across the city. Although we aim to provide services city-wide, we have particular interest in ensuring access to testing for those who otherwise have limited or no access to medical services.

Testing Pathways:

Currently, there are two different pathways by which BCHD can support partners in COVID-19 testing initiatives:

- (1) Pathway #1: BCHD provides test kits and samples are processed at the health department's Baltimore Disease Control (BDC) laboratory.
- (2) Pathway #2: BCHD provides test kits through a third-party vendor. Samples are processed at the third party vendor.

More details on each pathway are provided below.

BCHD does not provide staffing or deliver test results to patients for either of these pathways.

For both pathways, supplies may be limited, and may be dependent on national and international supply chains, federal and state testing guidance and coordination, and other factors beyond our control. Depending on demand, BCHD may not be able to fulfill 100% of requests. Policies for prioritization of supplies are detailed below.

BCHD will process requests as quickly as possible. However, it is possible that requests may take time to review if demand for test kits is high.

BCHD will do all in our power to maintain a constant supply of testing for our community partners, and will communicate with partners regularly as supply quantities vary.

Test kits that are provided will have FDA EUA approval. Test kits may be approved for specific collection sites (Nasopharyngeal, Mid-turbinate, Nasal, Oropharyngeal, etc.). Specific kits and collection directions may vary over time, per supply availability.

Point of care or rapid tests are currently not available through Baltimore City Health Department.

Baltimore City Health Department Testing Pathways		
	Pathway 1 (BDC lab)	Pathway 2 (Third party vendor)
Test kit materials provided	Swab Transport vial Transport media (VTM, saline, etc.) Specimen bags	Swab Transport vial Transport media (VTM, saline, etc.) Specimen bags
Collection Site	Anterior nares Oropharyngeal	Dependent on vendor availability
Lab processing samples	BDC Lab (BCHD public health lab)	Third party lab
Courier provided	Yes	Yes
Requisition form	Paper option available	Paper or online portal – vendor dependent
Ordering provider	Community partner	Health Commissioner or Health Secretary, with 'copy to' option for community partner
Results	Paper option available	Fax or online portal – vendor dependent

Testing Priorities

BCHD will prioritize testing partners with a focus on the following:

- Geographic areas of Baltimore City with:
 - High disease burden, defined by high incidence
 - Lower prevalence of testing per population
 - Evidence of clusters, outbreaks, or high levels of community transmission
 - Disproportionately fewer places to receive COVID-19 testing
 - High mortality rates due to COVID-19
 - High density of individuals at higher risk of complications due to COVID-19, either due to demographics or other underlying health issues
 - Ongoing evidence of health disparities
 - Higher potential for outbreaks (i.e. some congregate settings)
- Demographic groups within Baltimore City with:
 - Disproportionally higher rates of COVID-19 infection, hospitalization, and/or death
 - Evidence of high levels of transmission
 - Lower availability of or access to testing (this includes uninsured/underinsured)
 - Traditionally underserved/at risk populations
- Partners supporting BCHD in the investigation of outbreaks, testing in congregate settings, and other high priority testing settings

Eligible Partners:

BCHD's COVID-19 Testing Program is available to entities that provide clinical services and have the infrastructure and expertise to provide a clinical test. Community-based organizations requesting test kits must partner with a clinical group to be eligible to receive test kits.

It is our goal to increase access to testing as widely as possible across Baltimore. It is imperative that as we expand testing services, we maintain the safety of staff and patients, maintain the quality and accuracy of the testing process, and ensure accurate test results are returned to patients in an efficient manner.

All entities applying for this program must identify a clinical entity to take responsibility for the testing and resulting process. This includes, at a minimum:

- A clinical provider with credentials to legally order medical tests in the state of Maryland;
- This provider assumes the medical and legal responsibilities of COVID-19 testing, including documentation of medical malpractice insurance covering the testing activity (see below);

- ❑ A thorough process for providing results to patients that is efficient and HIPAA compliant;
- ❑ Documentation of patients providing consent for testing;
- ❑ Documentation of patients who are tested, the test result, and the status of patient notification; AND
- ❑ Expertise to ensure testing is conducted in a safe manner, which reduces the chances of transmission of COVID-19 to staff, patients, or the public

Examples of eligible partners may include:

- ❑ Community clinics, including but not limited to Federally Qualified Health Centers
- ❑ Private physician offices in a clinic setting
- ❑ Individual private physicians in a clinic setting
- ❑ Clinical groups coordinating with community-based organizations (non-clinical settings)
- ❑ Hospitals or hospital clinics
- ❑ We may also consider other settings such as: School health clinics, pharmacies, University/college health clinics, drug treatment centers and correctional institutions
- ❑ Other entities may be considered on a case by case basis

Both ongoing and one-time testing events will be considered, taking available logistical support into account.

Testing must take place within Baltimore City.

The request form for community-based testing is found on the COVID-19 test kit distribution website: <https://coronavirus.baltimorecity.gov/covid-19-test-kit-distribution-program>, and in the appendices to this document. Please email completed and signed request forms to: COVIDTesting.BDCLab@baltimorecity.gov. Please call the BDC lab with questions: 410-396-7894.

If the specific standards outlined in this document are met, a BCHD representative will call the point of contact to discuss the request in more detail. The agency will be notified in writing of a decision within 5 working days from the discussion. Requests that are approved as a testing site will be expected to sign a written agreement stipulating the terms of this partnership.

BCHD will process requests as quickly as possible. However, it is possible that requests may take time to review if demand for test kits is high.

Testing Clinical Criteria

Clinical entities are expected to use test kits in alignment with testing criteria and priorities established by the Centers for Disease Control and Prevention (CDC) and Maryland Department of Health (MDH). The clinically responsible party is expected to remain up to date with current testing guidelines, and follow these guidelines when using test kits.

Current testing guidance from Maryland Department of Health can be found here: https://phpa.health.maryland.gov/Documents/2020100101_MDH%20Order_Amended%20Various_Health_Care_Matters_Order%20POC2.pdf

Billing

Test kits provided to the clinical partner by BCHD and lab testing performed by BCHD on behalf of a clinical partner are not billable to the patient's insurance payer or U.S. Department of Health and Human Services (HHS).

Clinical partners are eligible for reimbursement of office visits, telemedicine visits, and treatment of a suspected or confirmed COVID 19 diagnosis. Applicable co-pays, co-insurance, and deductibles are suspended during the Governor's State of Emergency. These out-of-pocket costs should not become a barrier to care or treatment. For uninsured patients, as part of the FFCRA, PPPHCEA, and (CARES) Act, the U.S. Department of Health and Human Services (HHS), will provide claims reimbursement to health care providers generally at Medicare rates for testing uninsured individuals for COVID-19 and treating uninsured individuals with a COVID-19 diagnosis. More information for uninsured patients can be found here: <https://coviduninsuredclaim.linkhealth.com/coverage-details.html>

Expectations for Baltimore City COVID-19 Testing Partnership

All entities applying for this partnership must adhere to operational standards and quality assurance measures. Entities applying for this support agree to the following:

Infection Control and Personal Protective Equipment

- The clinical entity has a plan for how to conduct COVID-19 testing following current infection control guidelines set forth by MDH or CDC. The clinical entity provides the name of a qualified individual with appropriate professional credentials who develops and oversees the workflow and ensures infection control practices are being met. This includes: a safe location for testing that decreases likelihood of transmission during the testing session, social distancing for patients in waiting rooms, an appointment schedule for ill patients to be tested, a plan for minimizing transmission of COVID-19 in waiting areas or other clinical areas, a training program to ensure all individuals staffing the clinic know how to appropriately don and doff PPE. Non-appointment based programs are also expected to have in place and implement appropriate infection control guidelines.

- ❑ The clinical entity demonstrates a plan for ensuring quality control for infection control, including safety of individuals staffing the clinic.
- ❑ The clinical entity demonstrates adequate supply of Personal Protective Equipment (PPE) for all staff involved with COVID-19 testing. BCHD can assist with a limited number of PPE, however, supplies are limited and are not guaranteed. To request PPE from BCHD, entities must submit a formal PPE request per routine BCHD protocols. These requests are processed separately from the testing program and should be sent to medresourcerequest@baltimorecity.gov

Courier

- ❑ Test kits will be delivered to approved partners via BCHD courier.
- ❑ The designated BCHD staff and courier will be notified of daily batch pick up requirements. Partners may send collected COVID 19 specimens to the Baltimore Disease Control (BDC) laboratory via the BCHD courier for processing at no charge. The BDC laboratory will provide faxed and/or electronic laboratory reporting of all results to the ordering provider.
- ❑ Courier services will be provided by BCHD for delivery of test kits and specimens collection; courier services are available from 8:30 a.m. to 3:30 p.m. Monday through Friday
- ❑ Test kits must be received by BDC lab by 3:30 p.m. Monday through Friday. Specimens collected after this time must be properly stored until pickup on the next business day.
- ❑ BCHD must be notified of specimens collected over the weekend (Saturday and Sunday), and on holidays; they must be picked up on the next business day

Specimen Collection

- ❑ All COVID-19 tests conducted with kits from BCHD will be completed by trained healthcare personnel who have received the necessary training, per the clinical entity's guidelines
- ❑ The Aptima Multitest Swab collection kits (**ORANGE LABEL**) are only to be used for oropharyngeal (OP) and nasal mid-turbinate sampling (the size of the tips of these swabs prohibit use for Nasopharyngeal (NP) sampling). Sample collection should follow instructions on the package insert.

Specimen Storage

- ❑ The test kits received from BCHD will be properly stored according to the specifications on each kit

- ❑ Specimens in the Aptima Multitest Tube (**ORANGE LABEL**) may be stored as follows: -2°C to 30°C and must be transported to the BDC Lab within 24 hours or no later than the first business day following a weekend or a holiday
- ❑ The clinical entity ensures that staff have been properly trained to break the swabs at the indicated score-mark so that they will fit securely into the collection tubes and not impede closure of the caps. Note: Incorrectly closed caps will result in leakage of tube contents and the specimens within will not be tested. In such cases the clinical entity will be notified and the patient's specimen will need to be recollected.

Requisition Forms

- ❑ Complete the required BDC laboratory requisition form (Appendix B), and labeling of test tubes.
- ❑ If the paper requisition form is used, complete it such that all three copies are legible and complete. Failure to complete all fields of the test requisition may result in cancellation of the test. One copy of the requisition should be retained by the clinical entity, the other two placed in the bag with the specimen and transported to the BDC Lab for testing.
- ❑ All specimens **MUST HAVE TWO** patient identifiers, name and date of birth, legibly written on the specimen tube. Unlabeled specimens will not be tested.

Resulting and follow up

- ❑ The clinical entity takes full responsibility of patient notification of results in a timely manner. This includes ensuring all samples that are sent to the laboratory are resulted, and results are communicated to patients in a timely manner, and in a language they understand. The partner will ensure the provision of timely COVID-19 test results to all patients with particular attention paid to reaching clients with positive COVID-19 results
 - Provision of a hard copy of results to patients is the responsibility of the clinical partner
- ❑ Actively link all persons diagnosed with COVID-19 to medical care and services, including the provision of guidelines for isolation of cases, and quarantine of close contacts (especially household members)
- ❑ Provide sufficient follow up for patients who are positive and who might develop worsening of symptoms and require additional clinical attention
- ❑ Ensure that persons who are diagnosed with COVID-19 are notified of referral to their local health department for contact tracing

- ❑ **Provide thorough guidance and instructions at the time of testing on isolation and quarantine.** Information can be found here:
<https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine-isolation.html>

<https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/isolation.html>

and here: <https://coronavirus.baltimorecity.gov/information-clinicians-0#Isolation%20and%20Quarantine%20Instructions>

Reporting

- ❑ Provide weekly and monthly reports as requested to BDC including, but not limited to, data on:
 - Total number of individuals tested
 - Demographics
 - Test results
 - Presence of symptoms
- ❑ The clinical entity will report all positive cases to BCHD, per clinician reporting guidelines
- ❑ BDC Lab will report all results to Maryland Department of Health, as required for reportable diseases

Compliance

- ❑ Comply with all Maryland state laws and regulations regarding COVID-19 testing including:
 - Obtaining and documenting informed consent
 - Delivering clinical results
 - Agrees that there are no Clinical Laboratory Improvement Act (CLIA) requirements to collect swabs for COVID-19
 - Adhere to all data collection and handling protocols to maintain client confidentiality
 - Complies with all requirements issued by the Maryland Department of Health (MDH) and BCHD for reporting of COVID-19 positive patients to the state and city surveillance system

- Physicians licensed in the state of Maryland will be the ordering provider on the tests and are solely responsible for the administering of the COVID-19 test and implications for the patient, similar to any other clinical order. **All partners, including those associated with community-based sites, must provide evidence of medical malpractice insurance that covers this activity, including a certificate of coverage for COVID-19 testing events.**

Cost

- Clients will not be charged for the cost of the COVID-19 tests provided by BCHD, in either pathway 1 or 2

Communications and Monitoring

- Entities receiving test kits from BCHD must designate a staff member for contact with BCHD should questions arise about the collected specimen
- Entities receiving test kits from BCHD must be available for testing coordination meetings as agreed upon by BCHD and the clinical entity
- Entities must agree to a site visit and review of all of the above protocols and criteria within 48 hours' notice by BCHD

Community-based testing

Entities interested in community-based testing, must demonstrate all of the above, in addition to having a clinical partner with a prescribing provider. The request for community-based testing is found on the COVID-19 testing kit distribution website: <https://coronavirus.baltimorecity.gov/covid-19-test-kit-distribution-program>, and in the appendices. Please email completed and signed request forms to: COVIDTesting.BDCLab@baltimorecity.gov

All partners, including those associated with community-based sites, must provide evidence of medical malpractice insurance that covers this activity, including a certificate of coverage for COVID-19 testing events.

BCHD Responsibilities

- A.** For test kits and laboratory services through BDC lab (Pathway 1), BCHD will supply
 - Swab, transport media, tube
 - Specimen bag
 - Lab results (paper fax, with the possibility of electronic portal in the future)
 - Courier service (test kit drop off and once daily specimen pick up)
- B.** For test kits only (Pathway 2), BCHD will supply:

- ❑ Swab, transport media, tube
- ❑ Specimen bags
- ❑ Mechanism for lab requisition (paper or electronic, depending on third party lab)
- ❑ Courier service (to drop off requested test kits)

Note: The clinical partner will be responsible for getting lab results from the third-party lab (i.e. portal, fax, CRISP, etc.)

APPENDICES

Appendix A: COVID-19 Partnership Request Form

Appendix B: Sample BDC Laboratory Specimen Collection Form

Appendix A: COVID-19 Partnership Request

(see next page)

COVID-19 Testing Partner Request

Instructions: Please answer all questions. Scan and email the completed request form to: COVIDTesting.BDCLab@baltimorecity.gov

Applicant Information

Name of Entity Submitting Request: _____ **Request Date:** _____

Address: _____
Street Address Suite/Unit #

City State ZIP Code

Is this the primary applicant a clinical entity? YES NO

If the primary applicant is not a clinical entity, please indicate the name of your clinical partner here:

Authorized Point of Contact for this Request: _____ **Tel:** _____
Last, First MI

Email: _____ **Fax:** _____ **Website:** _____

Program Description

Please provide brief, but complete answers to the following questions.

1. Describe why your organization is applying to this program. Responses must include: identified community need, a description of the area(s) of the city where COVID-19 testing will occur (location(s), priority population(s), etc.
2. Describe your clinical workflow for COVID-19 testing in each setting where testing will occur. Responses must include: a description of the physical location(s) where testing will occur (including entry and exit), client/patient access (appointment, walk up, or drive up), registration including any foreseen testing costs to the client, isolation guidance, etc.
3. Describe your COVID-19 testing staffing structure for each type of location where testing will occur. Responses must include the total number of staff involved with COVID-19 testing, and training provided to conduct the test.
4. What infection control measures will you have in place when testing beings? Responses must include information on: infection control for staff and patients/clients, cleaning agents, social

distancing measures for staff and patients/clients, types and amount of personal protective equipment (PPE) for each staff member.

- Describe your proposed chain of custody and storage of collected specimen.
- Describe your plan for providing clients/patients with results. Responses must include: system for the provision of results to patients/clients, reporting of positive cases for investigation and contact tracing, guidelines for isolation or quarantine if necessary.
- Who will be the ordering physician for COVID-19 testing?

Last, First MI Degree

Tel: _____ Email: _____

- Who will be the infection control supervisor for COVID-19 testing?

Last, First MI Degree/License

Tel: _____ Email: _____

- Who will be responsible for data reporting to BCHD?

Last, First MI

Tel: _____ Email: _____

- Is this an request for a one-time testing event? YES NO

- Will your clinic need BCHD's courier service to drop off test kits and pick up collected specimens? YES NO

- Please provide the address/es where COVID-19 testing will be conducted. Include the day(s) of the week and time(s) of the day.

13. Expected Start Date: _____ Expected End Date: _____

14. Estimated number of tests to be conducted per day: _____

Disclaimer and Signature

I certify that I am authorized to submit this request on behalf of my organization.

Name: _____ Signature: _____

Appendix B. Lab Requisition Form (example)*

LABORATORY TEST REQUISITION

Please print clearly

Date of collection- _____ Time of collection _____ Facility Name _____

PATIENT DEMOGRAPHICS

Patient Name _____ Date of Birth _____
(Last) (First)

Patient Address _____

Patient Phone _____

*MANDATORY

City _____ State _____ Zip _____

Sex: Male Female Transgender M to F Transgender F to M
Race: Black or African American Caucasian Hispanic Native American Asian Other _____

TESTING INFORMATION

Choose test: SARS-CoV2
Specimen source: (choose 1)
 nasopharyngeal (NP) anterior nares (nasal swab) Nasopharyngeal wash/aspirate
 oropharyngeal (OP) nasal mid-turbinate Other _____

PROVIDER INFORMATION

*Results will be faxed to this provider

Ordering Provider Name _____ NPI # _____

Facility Address _____

Provider Phone _____ Fax number for results _____

All fields must be completed in order to perform testing**

Samples with incomplete forms cannot be processed.

Questions: Call 410-396-7894