Beth Israel Lahey Health

System-wide Recovery Guidelines

Team: **Testing**
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Introduction

This document offers a set of guidelines relating to COVID-19 testing to help BILH sites plan for the resumption of elective services.

The Testing guidelines are organized into the following categories:

I. Testing indications for symptomatic and asymptomatic staff and patients, including pre-operative and pre-procedural testing

II. Recommendations for expanding testing capacity across the system by site, including needed technology and information system interfaces

III. Strategy for ensuring sufficient supply of necessary test supplies and analytic redundancy for future surge capacity

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I. Testing indications for symptomatic and asymptomatic staff and patients, including pre-operative and pre-procedural testing

Testing Guidelines

BILH has previously developed guidelines to outline the indications for use of COVID-19 testing including use of PCR and serology (antibody) assay. These guidelines have been updated by a multidisciplinary team including BILH Infectious Diseases (ID), Infection Control/Hospital Epidemiology, Pathology, and Primary Care. Our guidance was informed by the Massachusetts Department of Public Health (MA DPH), the Centers for Disease Control and Prevention (CDC), and professional society guidelines, and further modified based on local factors to optimize use of testing to protect our staff and patients and to ensure the preservation of personal protective equipment (PPE).

General Testing Guidance

- BILH SARS-CoV-2 PCR Testing Prioritization for Patients and Staff
- BILH SARS-CoV-2 Molecular & Serology (Antibody) Testing Recommendations by Symptom Onset

Pre-Operative and Pre-Procedure Testing

BILH sites are establishing processes and workflows specifically for pre-operative and pre-procedure patients for whom COVID-19 testing is indicated, with the goal of ensuring that tests are completed within 48-72 hours prior to the operation or procedure.

- BILH Interim Pre-procedure Evaluation for COVID-19 and PPE in the Setting of Non-OR Procedures
- BILH Interim Perioperative Evaluation for COVID-19 and PPE in the Setting of Surgical Procedures

Resources are available to assist providers in identifying the appropriate sites for pre-operative and pre-procedure COVID-19 testing, depending on the need for other testing and patient preference:

- BILH COVID-19 PCR Offsite Testing Provider Checklist
- BILH COVID-19 PCR Testing Sites and Operational Details

At this time, all pre-operative and pre-procedure COVID-19 tests should be performed locally at a BILH laboratory (as feasible), in order to ensure timely turnaround prior to the operation or procedure. Leaders throughout BILH are addressing the feasibility of increasing testing capacity at local BILH facilities. BILH in-house testing turnaround times currently average less than 24 hours from specimen collection to result, whereas turnaround times at commercial labs average about 48 hours.

Given the logistical complexity of implementing pre-operative and pre-procedure testing, leaders at all BILH sites should review the feasibility of centralizing pre-operative and pre-procedure testing in conjunction with other pre-admission testing requirements and processes.

*Use of Rapid Testing (*Analytical Turn Around Time < 2 hours*)*

Currently, the availability of rapid SARS-CoV-2 molecular diagnostics testing is limited due to test kit supply constraints. Several facilities have access to a small number of test kits

per week, which they are allocating with local ID provider input. In general, the use of rapid testing will have highest impact for patients with severe illness to guide access to clinical trials or emergency access use of therapeutics, to inform a risk assessment of emergent high-risk procedures, to help guide PPE utilization and bed flow management within the emergency room or procedure areas, such as Labor and Delivery and the operating room. Due to limited data on short-term capacity, system-wide guidance cannot be formulated at this time. Additional guidance regarding best usage of rapid tests kits will be forthcoming as supplies improve.

Use of Serology (Antibody) Testing

SARS-CoV-2 commercially manufactured antibody tests are or are expected to become available at most BILH laboratories. Depending on the type of antibody-test method, positive test results may indicate whether an individual has been previously exposed to SARS-CoV-2 and could be used for providing information for epidemiologic studies. However, at the present time, there are limited data to inform their use as diagnostic assays. In order to provide detailed guidance, more information is needed on the performance characteristics of serologic testing, the immune response to COVID-19, and the timing/duration and protective nature of the antibody response. Concurrent molecular testing with SARS-CoV-2 PCR should be obtained whenever feasible.

- BILH COVID-19 Serology (Antibody) Testing Interim Recommendations
- BILH COVID-19 Serology (Antibody) Testing Frequently Asked Questions for Clinicians
- BILH COVID-19 Serology (Antibody) Testing Frequently Asked Questions for Patients

SARS-CoV-2 Diagnostics – Specimens Other than Nasopharyngeal Samples

Nasopharyngeal swabs are the preferred specimen type for SARS-CoV-2 PCR testing.

Under certain clinical circumstances, use of an oropharyngeal swab is also reasonable, including for pediatric patients or if obtaining a nasopharyngeal swab is not feasible. In addition, if initially a nasopharyngeal swab is negative on serial testing (2 samples obtained 12 hours apart) and clinical concern for lower respiratory tract infection exists, obtaining a sample by bronchoalveolar lavage for testing is feasible for processing at a site which has validated this assay. Please see the BILH COVID-19 Testing Matrix by Specimen Type for further details.

II. Capacity across the system by site, method, and technology and recommendations for expansion

BILH system capacity for SARS-CoV-2 should be defined by the following:

1. High-throughput analyzers
2. Cartridge-based, open-access rapid-testing analyzers

Current System Capabilities and Capacity

High-throughput testing capabilities for the BILH system are concentrated at BIDMC, with an estimated daily capacity of 1,200 tests per day. Additional sites have existing high-throughput analyzers for which SARS-CoV-2 testing is in development or upgrades of existing equipment would be enable future testing capacity.

Most BILH sites utilize a random-access, rapid testing analyzer: two sites are using the Genmark Diagnostics, Inc., ePlex system (analytical TAT 90 minutes), and all sites are/will be utilizing the Cepheid, Corp., GeneXpert (analytical TAT 45 minutes). Both types of analyzers are modular, allowing for random access for testing. However, the utility of these analyzers may be limited by number of positions (i.e., not high-throughput) and uncertainties of availability of test kits and timing of supply shipments.

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Key:
Current analyzers
Completed or planned purchase
Potential future options

	Analyzer – High Throughput/Capacity				
Hospital Lab	**Abbott Alinity-m**	**Abbott m2000**	**Hologic Panther***	**Hologic Panther Fusion**	**Roche 6800**
Anna Jaques					
Beverly/Addison Gilbert			1		
BIDMC	1 (pending)	4	1		
BID-Milton			1		
BID-Needham			1		
BID-Plymouth			1		
LHMC			1		1 (pending)
Mount Auburn			1	1 (pending)	
NEBH			1		
Winchester					
Total	**1 (pending)**	**4**	**8**	**1 (pending)**	**1 (pending)**

*The Hologic Panther is currently awaiting "Emergency Use Only" approval by the FDA and is a potential future option for sites that currently use this analyzer for other testing.

	Analyzer – On Demand/Cartridge-Based	
Hospital Lab	**Cepheid GeneXpert**	**GenMark ePlex**
Anna Jaques	1	
Beverly/Addison Gilbert	1	
BIDMC	1	1
BID-Milton	1	
BID-Needham	1	
BID-Plymouth	1	
LHMC	1	1
Mount Auburn	1 (pending)	
NEBH	1	
Winchester	1	
Total	**10 (1 pending)**	**2**

The analytical TAT for the Cepheid SARS-CoV-2 Xpress test RT-PCR test is 45 minutes.

The analytical TAT for the ePlex SARS-CoV-2 RT-PCR test is 90 minutes.

Current SARS-CoV-2 Testing Volume

Of note, the current SARS-CoV-2 RT-PCR testing volume is addressing the geographic spread of active transmission, in particular referral from high-risk congregate settings. Over the next few months, we anticipate a shift in testing demand to include expanded screening of patients prior to admissions, and patients requiring procedures and/or immunosuppressive therapies. Thus, while the demographics of testing to date are helpful to inform a minimal capacity need, future test volume estimates should not be based on historical data but rather on estimates of anticipated admissions, procedures, and broad screening to monitor for a resurgence of COVID-19 infection.

Current SARS-CoV-2 Testing Volume by Resulting Lab – Week of May 4

	Resulting Lab				
Hospital Lab	**In-House**	**BIDMC**	**Commercial**	**Other**	**Total**
Anna Jaques	62	194	40	0	**296**
Beverly/Addison Gilbert	0	509	386	0	**895**
BIDMC	N/A	2,318	0	0	**2,318**
BID-Milton	11	180	86	0	**277**
BID-Needham	27	146	71	0	**244**
BID-Plymouth	37	687	0	0	**724**
LHMC	29	592	70	0	**691**
Mount Auburn	0	332	88	0	**420**
NEBH	0	52	0	0	**52**
Winchester	0	487	73	0	**560**
Non-BILH	N/A	287	N/A	N/A	**287**
Total	**166**	**5,784**	**814**	**0**	**6,764**

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Potential Weekly Additional SARS-CoV-2 Testing Volume from Procedures

	Current OR Weekly Volume Difference from Budget		Non-OR Historic Weekly Procedure Volume	
Hospital Lab	**IP OR Cases**	**OP OR Cases**	**IP Non-OR Procedures**	**OP Non-OR Procedures**
Anna Jaques	14	58	13	68
Beverly/Addison Gilbert	30	107	18	173
BIDMC	123	213	154	707
BID-Milton	34	40	1	65
BID-Needham	1	59	4	2
BID-Plymouth	48	50	17	12
LHMC	93	244	121	545
Mount Auburn*	32	125	17	83
NEBH	154	83	0	0
Winchester	6	98	19	90
Total	**535**	**1,077**	**364**	**1,743**

*Estimate based on 5% of system total

Urgent Capacity Expansion Recommendations

In order to ensure adequate testing capacity for the projected needs of BILH, we recommend the following approach:

- Add as soon as possible, the addition high-throughput analyzers for molecular diagnostics of COVID-19 to solidify the near-term (within 2 months) testing needs
  - The flow of samples within the BILH system should be directed by:
    - Regional geography
    - Information systems linkages for ordering/resulting
- Ensure SARS-CoV-2 PCR testing is available for urgent needs at all network sites through the expansion of access to cartridge-based, rapid testing analyzers and supplies to all sites
- Continue to pursue redundancy in the BILH system for high-throughput and cartridge-based rapid testing analytic capacity such that testing is not based on a single manufacturer supply chain

High-Throughput Analyzers

- LHMC has signed a contract with Roche to obtain a high throughput analyzer, which would add capacity for an estimated 1,200-resulted tests per day. The current projection is that this system may not be available until July, when considering

delivery and validation. We would recommend that all actions be taken to bring this system online as soon as feasible, preferably within 4 weeks.

- Assess the feasibility of upgrading existing Hologic Panther systems to Panther Fusion vs. obtaining validation of Hologic assay on existing equipment over next 1-3months, if FDA approval occurs within the next 1-2 weeks as expected.

Cartridge-Based Rapid Testing Analyzers

- Enhance the system strategy for obtaining assurance of a regular supply of testing kits allocated by Cepheid and GenMark
- Prioritize the BILH system supply of rapid test kits for:
  - Use of rapid testing analyzers at sites without an alternate platform for testing for urgent indications (i.e. eligibility for emergency use therapeutics, eligibility for transplant, to inform high-risk procedures when outpatient pre-operative/pre-procedure screen not able to be performed due to urgency and within the emergency room to aid urgent patient disposition

Clinical Information Systems Dependencies

Information Systems at BILH sites should be configured to support a closed loop ordering and results process. This means that:

1. From the perspective of a clinician, order entry and result notification and display should all occur within the ordering clinician's local EHR. Magic buttons provide a useful adjunct but should not replace notification and results viewing in the local EHR.
2. From the perspective of the local laboratory, tests should be logged into the local LIS and then processed in one of the following ways based on testing capacity and BILH guidelines:
   - Processed locally
   - Sent to BIDMC for processing
   - Sent to a commercial lab for processing

This approach provides optimal support for clinical care, but requires manual transcription and data entry when the test is processed externally and there is no electronic interface between the sending lab and the reference lab that does the processing. The receiving lab must manually enter the patient and order into their system, and the sending hospital must manually enter the results into their system. This

is an established process in all labs in their current state and allows for the closed loop process described above however leads to a high burden of work on the lab staff for the process of accessioning and resulting which must be done manually.

When BIDMC began processing tests for other hospitals, implementing multiple interfaces between BIDMC and other hospitals was not an option because of the urgent need to make testing available. Electronic interfaces take time to implement (typically three months), require lab and IT resources to participate in the implementation, and are not typically done to handle results for a single or small number of tests. Interfaces between hospitals and outside reference laboratories are typically implemented when the hospital intends to use the reference laboratory for a significant volume of tests over a period of time.

Because capacity is expected to increase at other BILH sites and send-out patterns are therefore expected to change, it would not make sense to kick off a lengthy process of building a series of new interfaces to support current patterns. As expansion continues, however, we should continue to look for opportunities to increase automation, and to evaluate the pros and cons of supporting referral patterns with manual data entry in labs versus implementing new interfaces. As part of this evaluation, consideration will also need to be given to the potential impact on any other planned lab-related interface projects. Any potential re-prioritization should include an analysis of the clinical and financial impact.

These options will continue to be vetted through the Testing Work Team and Laboratory Medical Directors, specifically to consider the following when developing strategies and recommendations for urgent expansion of testing capabilities:

- Current analyzers/technology and potential capacity
- Supply availability, specifically for rapid test kits
- EHR alignment for ordering and resulting
- Future expected test volume, particularly for OR/procedural volume
- Staffing needs/constraints for expansion
- Geography to facilitate access to a high-throughput system

III. Strategy for ensuring supply of necessary test kits and reagents

At this time, nasopharyngeal swab remains the preferred specimen for SARS-CoV-2 testing, as well as additional respiratory pathogens such as influenza A/B. While we are

pursuing alternate options for specimen collection, having a secure supply of swabs that may be used for nasopharyngeal collection will remain critical.

Commercially Available Flocked Nasopharyngeal Swabs

Commercially available flocked swabs remain our preferred supply given their ability to be utilized across all testing platforms and commercial labs. In addition, they remain at a preferable price-point compared to flocked swabs produced by novel manufacturing technologies. A priority list for commercial flocked swabs has been developed and will continue to be updated based on available supplies.

Nasopharyngeal Swabs Manufactured by Novel Techniques

Several manufacturers' prototypes have been validated on the BIDMC Abbott m2000 system; however, these swabs have not been validated for either Cepheid GeneXpert or the Genmark ePlex systems. For these swabs to be utilized across the system to their full capacity, additional validation would be required across platforms, including other cartridge-based tests (e.g., influenza, respiratory pathogen panel). The availability of these swabs will serve a critical need to secure our ability to ensure a robust stock of supplies for potential future surge capacity as well as increasing capacity of supply across the marketplace to reduce overall supply constraints.

Continued Review of Alternate Specimen Collection Techniques

As additional information is obtained on the utility and validation of nasal and buccal/saliva swabs, recommendations for supply management will be provided as appropriate.

Specimen-Collection Media

*Viral Transport Media (VTM)**:*** VTM remains the preferred specimen transport media given its use across test platforms within the system and via commercial labs. Due to commercial production supply disruption, BILH has been forced to produce its own VTM during the COVID-19 surge. As normal operations return, this will no longer be feasible via the existing pathways due to staffing and supply constraints. While a contingency plan needs to remain in place to allow for continuing this production if required (including a continued secured supply of required reagents), actions should be taken to secure a robust supply of VTM moving forward.

Sterile Phosphate Buffered Saline (PBS): Use of PBS has been validated for SARS-CoV-2 testing on the BIDMC Abbott m2000 analyzer and at Quest. Additional validation should be considered across future BILH high-throughput analyzers to inform the potential use of this technique if future VTM supply disruption occurs.

Supply Redundancy/Preparation for Future Potential Surge

- We recommend that 30-60 days of testing supplies (swabs, media and analyzer reagents) be kept on hand in preparation for future additional disruption of supply chains.
  - This volume estimate should include the capacity to test all admissions and meet pre-procedure/pre-operative testing needs.
  - We recommend including a review of our supply of influenza (A/B) and respiratory pathogen panel testing kits in preparation for a potential fall/winter surge.
- All attempts should be made to secure supply across platforms given the unpredictable nature of reagent supply.
- BILH should develop a strategy for centralizing the production of test kits (swabs + media) as well as strategies for distribution and supply chain management.