



# COVID-19 Serologic Testing

## Implementation Guidance

Updated 6-5-2020



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## Overview

Trinity Health will offer serology testing, also known as an "antibody test," for SARS-CoV-2, the virus that causes COVID-19, in support of our Mission and our continued national and local response to the COVID-19 pandemic.

Trinity Health is launching serology testing for current patients, colleagues and outreach in local communities. For colleagues, it will be offered as a colleague benefit and administered locally. COVID-19 serological (antibody) testing remains in its earliest stages with many unknowns.

The antibody test can determine if someone has been infected with SARS-CoV-2 because antibodies develop after infection and can remain for weeks after a person has initial onset caused by SARS-CoV-2. It is not yet known if antibodies that result from SARS-CoV-2 infection will provide someone with immunity from a future infection.

People may want to know if they developed antibodies that *might* provide a level of immunity from COVID-19 infection in the future. Colleagues may want to know, too. Trinity Health colleagues can have one test done for free now through as late as Dec. 31, 2020. The end of the no-cost period could be earlier due to IRS regulation. The test is completely voluntary. For colleagues enrolled in a non-Trinity Health medical plan, testing may be available, according to their medical plan provisions. If they do not have access to a Trinity Health testing location and have no medical insurance, they will be referred to community resources for testing availability in their community.

This guidebook is intended to provide ministry leaders with information, templates, and education in order to successfully implement serology testing.

Trinity Health has identified the following guiding principles to structure the work surrounding serology testing.

## Guiding Principles

- Focus on tests/assays that have demonstrated high specificity
- Provide consistent education to all on interpreting results
- Testing strategy includes consideration of both colleagues and patients
- Outcomes of testing should improve colleague/patient health and safety and/or have operational implications
- Begin with testing groups/populations with medium or high prevalence of previous infection to minimize false positives
- Testing can support identifying those who might donate convalescent plasma

## Approach

The plan to offer serology testing for our patients and colleagues is being approached in three waves of activity and each wave will require specific actions that need to be completed to accomplish the intended goal. The waves are presented below, and the specific actions, tools and templates will be covered in the Preparing Operations section of the guidebook.

1. **Wave 1:** Patient and colleague testing accomplished through using Warde Reference lab. This is an interim plan to bridge the desire to provide serology testing now until our ministries can build in-house capacities for serology testing. In this wave:
  - a. Patient tests are ordered through your local EMR and all routine actions to obtain and result the specimen are to be followed. Your local lab team will follow their routine processes for sending the test to Warde Lab. Ministries that do not currently utilize Warde Lab will receive instructions for how to proceed.

- b. Voluntary colleague testing procedures will need to be established per your ministry teams. The good news is that once you have these procedures identified, they will be utilized during wave 2 in-house testing as well.
2. **Wave 2:** Patient and colleague testing that is accomplished through using in-house capacity. Each ministry will begin their in-house testing when:
  - a. Their voluntary colleague testing procedures have been established and communicated to the colleagues.
  - b. The informatics and IT builds are completed.
  - c. The lab analyzers and associated tests have received emergency use approval (EUA) from the FDA and the tests have been validated locally.
 Preparations for this work are covered in a later section of the guidebook.
3. **Wave 3:** Serology testing is available to Trinity Health outreach clinics and programs.

## Preparing Operations

In the unifying spirit of TogetherHealth, a team of System Office and Ministry colleagues of various roles prepared this guidance to help all Ministries implement serology testing. The purpose of this guidebook is to provide recommendations to guide decision making and actions, and others are requirements for Trinity Health system-wide standards.

In preparation for Ministry implementation, we are supporting you with this guidebook and in many ways, including:

- Ordering and resulting capabilities
- CDM build
- Supply chain process for needed supplies
- Other process direction
- Clinical guidance
- [Implementation plan template](#)
- Communications templates

## Action Needed

This effort requires local customization and to develop the appropriate processes and procedures that fit your Ministry needs and resources. Executive leaders should identify the accountable leader in your Health Ministry who will lead a team to implement this program. All questions regarding this work should be directed through the incident command structure with the local incident command leader escalating questions to the system incident command leader.

## Serology Testing Process Guidance

### Patients/Consumers

The process for ordering a lab test, obtaining the specimen, and resulting the test is well known in acute-care settings. This standard process will be followed for all patients regardless of the wave of activity.

### Colleagues

Because of this unique offering of voluntary serology testing to our colleagues, there are some changes that will need to be made to accommodate this program that are different than the process routinely followed for patients.

The document, [COLLEAGUE Q & A](#), provides answers to colleague questions regarding testing, how and where to receive the test, obtaining results, and where to go for follow-up questions.

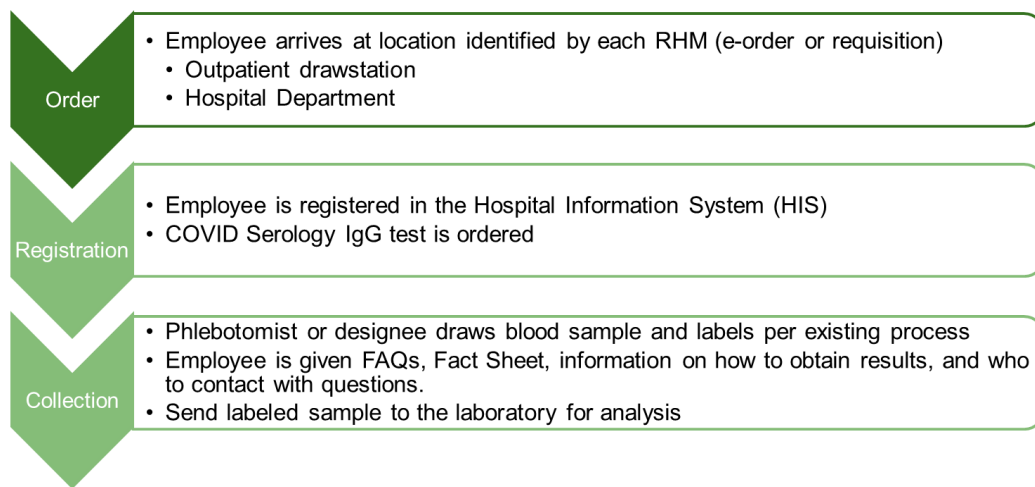
Lab processes are most efficient when automated and so ministries should be employing their digital technology whenever possible when designing their solutions. The guidance below supports the use of technology for serology testing.

Voluntary colleague testing may generate a high volume of serology tests. To expedite the signoff on the test orders, the administrative signoff process may be employed; the administrative signoff is defined below.

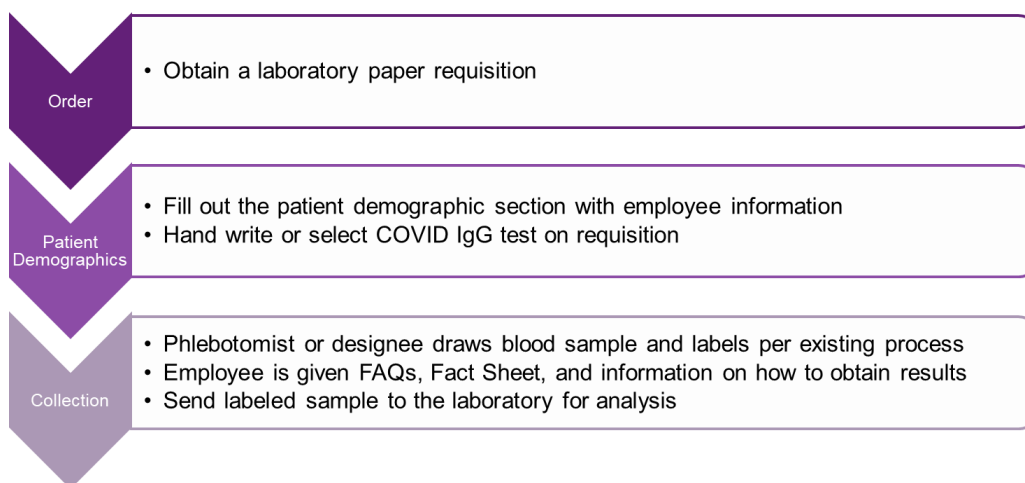
Administrative signoff means the approval of an action by direction of management for efficient operations including direction to the administrator of the electronic health record system to automate the approval for a series of an order for COVID-19 serology lab tests that are ordered for Trinity Health colleagues and medical staff members and which are not billed to third-party payors.

Colleagues will need to present their Workday ID number when arriving for their serology test; for colleagues employed by IHA or from our Waterloo locations, please use your local identification information.

### Core steps utilizing the EHR for ordering and lab processes



Not all ministries and or locations will be able to use technology to support their serology processes. The guidance below provides support for those sites that need to use paper processes.



Each ministry will identify the lab requisition slip that they will be using; a sample is provided that incorporates the test and charge codes. Please add the colleague identification number to the lab requisition.

**SAINT JOSEPH MERCY HEALTH SYSTEM**  
A Member of Trinity Health

St. Joseph Mercy Ann Arbor  
St. Joseph Mercy Chelsea  
St. Joseph Mercy Livingston  
St. Mary Mercy Livonia  
734-712-3141 | 800-528-8755

Patient Street Address  
City, State, Zip  
Social Security No.  
Subscriber Name & Date of Birth  
☐ Spouse  
☐ Patient  
☐ Guardian

**Laboratory Requisition**

Primary Insurance Contract Group Patient Name - Last First M.I. ☐ CALLED IN ☐ PATIENT DROP OFF  
Secondary Insurance Contract Group Sex Birthdate Patient Phone Collection Date & Time  
Provider Signature ☐ STANDING ORDER ☐ BILL TO Special Account Physician Name & Address  
199xxx Mary Doe MD  
1234 Medical Office Building  
Anytown, MI 48xxx  
STAT ☐ Call ☐ Fax  
Page ☐ WebX  
Ph #  
Fax #  
Specify Tests  
Copy of Report to: (Please indicate physician's first and last name)  
ICD-10 Diagnosis Codes (Enter all that apply) Z20.828 2. 3. 4. 5. 6.

**SARS-COV-2 ANTIBODY IGG, LOCAL REFERENCE LAB [LAB7993]**

### Information to be included on the requisition:

Colleague name, birth date, sex

Colleague ID number

Collection date and time

Ordering physician

Test: SARS-COV-2 ANTIBODY IGG

ICD-10 Diagnosis Code: Z20.828

Each of the actions that support voluntary colleague testing have been reviewed and the following guidance is provided for operationalizing the serology testing processes. For each component, we offer suggestions for how the ministry could approach the work; we also provide some documents for utilization.

### Clinical Team Responsibilities

1. Identify the accountable clinical executive (It is recommended that the Chief Medical Officer) and email the name of this leader to your ministry's Incident Command leader.
2. Prioritize colleague populations for first rounds of testing
3. Partner with clinical leaders and lab directors to determine colleague testing process (unit based, outpatient draw stations, etc.)
4. Determine process for ordering test
  - a. Identify clinician(s) responsible for ordering test. This person will order for all Trinity Health colleagues within their state, including System Office, Continuing Care and National Health Ministry colleagues. If your region covers multiple states, you will need to identify an ordering clinician in each state.
  - b. Determine process for ordering (blanket order in EMR, paper requisitions, etc.)
5. Confirm reporting via EHR as primary method as preferred method of sharing results with colleagues; identify secondary method should colleague not have portal
6. Identify resource for responding to colleague questions regarding results
7. Partner with local National Health Ministry leaders to ensure that their colleagues are included within the prioritization of colleague cohorts and that they have the necessary testing location and timing information to communicate to their local colleagues.
8. Partner with local communications team to include specifics of ministry processes into standard templates and communicate effectively.

### National Health Ministry (NHM) Leader Responsibilities

1. Identify the accountable national clinical executive for your ministry and the local leader for each location who will coordinate the process.
2. Partner with HM Clinical and Human Resources teams to ensure colleague testing plans are aligned.

### 3. Communicate serology testing process information to colleagues

#### Human Resources Team Responsibilities

1. HM Human Resources leaders should be aware of plans and ensure they meet colleague needs and any applicable legal requirements.
2. Partner with NHM local Human Resources leaders to ensure that their colleagues' needs are met.

#### Marketing and Communications Team Responsibilities

1. Amend standard templates to reflect ministry processes
2. Localize brand as needed on templates and materials
3. Develop cadenced communications to colleagues
4. Provide communications to colleagues

Email final communication and timing for communication to Jody Lamb and Rachel Nelson of System Office Communication, as this information will be posted on the COVID-19 info page for convenient access for System Office and NHM colleagues who live near your Health Ministry testing location.

#### *Communication Files*

[Colleague Q & A](#)

[Colleague Announcement Template](#)

[Intranet Article Template](#)

Colleague Handouts

[Understanding the Test](#)

[Process of Getting Tested](#)

[Understanding Your Results](#)

[Clinician Information Handout](#)

[Consumer Patient Handout](#)

#### Lab Team Responsibilities

1. Set up orders and results functionality (LIS/EMR), submit request to IT
2. Order reagents from vendor
3. Notify the PM by email when the reagent has been received
4. Add new test to analyzer test menu
5. Validate new test method per policy
6. Test orders interface to validate results reporting
7. Test code and charge code validation
8. If EUA, patient and provider sheets need to be distributed in the communication.
9. Affirm the results reporting processes

#### Finance Responsibilities

1. All colleague testing should be charged to the 81205-COVID-19 cost center.
2. Follow the [Billing and Accounting Guidance for Serology Testing for Colleagues file](#).

#### Health Informatics and IT Team Responsibilities

1. Confirm/update applicable process flows and related documentation
2. Conduct or participate in end-user testing and validation efforts in collaboration with lab team
3. Create/update any site-specific job aids or EHR end-user functionality guides

4. Communicate process changes to key stakeholders in the RHM
5. Assess and evaluate end-user readiness and adoption of change

## Colleague Testing

Through the COVID-19 global health crisis, Trinity Health colleagues answered the call to serve our Mission in our communities' time of need. Colleagues may want to know if they developed antibodies that *might* provide a level of immunity from COVID-19 infection in the future, although it is still unknown if antibodies provide immunity and for how long.

A template has been developed to support local activities; it is intended to provide the ministries with a checklist and project plan for local leaders should they need it; while there is not an expectation that this plan would be submitted to a system oversight team, it may be useful for the incident command team.

All Trinity Health colleagues who want to receive serological testing will have the opportunity to do so, over time. Initially, testing will be prioritized for key populations including:

- Patients and health care workers who have recovered from confirmed COVID-19 infection.
- Health care workers who have worked in COVID-19 units and FURI clinics.
- Emergency department health care workers.
- Senior community colleagues and patients/residents in communities that have experienced outbreaks.

## Guiding Principles for Colleague Testing

- Participation in the serology testing program is voluntary; colleagues are not required to be tested as a condition of employment. Results will be provided in the patient portal and available to the colleague, PCP (if applicable), and other authorized provider(s). Individual results will not be provided to any representative of the employer, including Employee Health.
- We would not change our PPE guidance on the basis of results
- We would not change care assignment on the basis of the results
- We would not use these results in the determination of patients and COVID-free zones

Colleagues will have many questions regarding the testing process – how I get the test and where – and what the results mean regarding antibody detection or the lack of antibody detection. Please use the document titled – COVID Antibody Testing for Colleagues – to provide answers to the questions that we expect colleagues to have.

The instructions for the patient portal vary by EHR; ministries should use their locally-developed communication materials to assist colleagues who want to establish a portal account to obtain their results.

## COVID Serology Testing Availability to Outpatients and Other External Client Bases

When a Health Ministry is operationally ready with enough capacity, serology testing may be offered widely to the community.

1. To open COVID Serology testing to our outpatient patient population the first step will be to create a technical bulletin that details:



- Test description
  - When is testing available?
  - Specimen to be collected
  - Ordering
  - Result interpretation
  - Storage and transport of the specimen
  - Billing
  - Who to call if there are questions related to this testing?
2. HMs with an active lab marketing teams across Trinity Health will be gathered to brainstorm other outreach opportunities beyond their existing outpatient client base and develop Health Ministry specific marketing plans to ensure that the communities that we serve are aware and have access to this new testing.
  3. This same group should explore what infrastructure would be required to support direct-to-consumer marketing of this new test.