



Updated Interim Non-Emergent Pre-Procedure COVID-19 Testing Guidance

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Applicability

This guidance is intended to provide hospitals and ambulatory surgical treatment centers (ASTCs) with a general framework for performing COVID-19 testing prior to non-emergent surgeries and procedures (collectively referred to as “procedures”) and is aligned with guidance from the Centers for Disease Control and Prevention (CDC), American College of Surgeons, American Society of Anesthesiologists, and the Anesthesia Patient Safety Foundation.^{1,2,3,4,5,6}

Non-discrimination Statement

It is essential that health care institutions operate within an ethical framework and consistent with civil rights laws that prohibit discrimination in the delivery of health care. Specifically, in allocating health care resources or services during public health emergencies, health care institutions are prohibited from using factors including, but not limited to race, ethnicity, sex, gender identity, national origin, sexual orientation, religious affiliation, age, and disability. For additional information, refer to [Guidance Relating to Non-Discrimination in Medical Treatment for Novel Coronavirus 2019 \(COVID-19\)](#).

Current Status

Since May 11, 2020, Illinois hospitals and ASTCs have been permitted to perform non-emergent procedures when specific regional, facility, and testing criteria were met. This allowed for needed non-COVID-19 care to be safely provided, including during the second surge of October 2020 – January 2021. Currently, COVID-19 cases are on the rise in Illinois, necessitating ongoing vigilance. Patients infected with COVID-19 are more likely to have perioperative morbidity and mortality.^{7,8} In addition, certain procedures place health care workers at higher risk of infection. A universal screening and testing program to identify patients infected with COVID-19 prior to performing non-emergent procedures is essential.⁹

Regional COVID-19 Resurgence Criteria for Performing Non-emergent Procedures

As of May 11, 2020, DPH permitted hospitals and ASTCs to perform outpatient and inpatient procedures only if specific criteria were met. This guidance provides additional flexibility to hospitals and ASTCs to determine, on their own, whether to perform non-emergent inpatient and outpatient procedures. The decision for a hospital or ASTC to perform non-emergent procedures should be informed by regional COVID-19 epidemiologic trends, regional hospital utilization, and facility-specific capacity. Experience over the past year has shown that health systems become seriously stressed when regional staffed adult med-surge bed or intensive care unit (ICU) bed availability drops below 20%.

Regardless of whether a hospital or ASTC decides to perform non-emergent inpatient and outpatient procedures, hospitals and ASTCs must continue to monitor daily regional resurgence criteria, consistent with the Restore Illinois Plan, and regional hospital resource utilization, to assess the current and potential demand on resources. The four metrics that must be monitored daily are listed below and can be located at [Illinois Regional Resurgence Metrics](#) and [Illinois COVID-19 Hospital Resource Utilization](#).

- Consecutive days with regional staffed ICU bed capacity below 20%.
- Consecutive days with regional staffed adult med-surge capacity below 20%.
- Consecutive days of increased COVID-19 hospitalized patients.
- Test percent positivity rate above 8%.

A hospital or ASTC's decision to perform non-emergent inpatient and outpatient procedures should be dependent upon ensuring the appropriate number of ICU and non-ICU beds, personal protective equipment (PPE), testing reagents and supplies, ventilators, and trained staff are available to treat all patients without resorting to a crisis standard of care. Hospitals and ASTCs must ensure capacity to respond to a surge of patients needing care if COVID-19 activity increases in the region. (Joint Statement, American College of Surgeons, American Society of Anesthesiologists, Association of Perioperative Registered Nurses, American Hospital Association).²

General Requirements Regardless of Setting

Non-emergent procedures may be performed if a facility fulfills the following conditions:

1. Written policies and procedures that at a minimum provide a screening procedure, COVID-19 risk assessment and testing protocols for each patient.^{10, 11}

2. Case setting and prioritization

Each facility should convene a surgical review committee, composed of representatives from surgery, anesthesiology, nursing, epidemiology/infection control and administration to provide oversight for the prioritization of non-emergent procedures. This committee should lead the development and implementation of guidelines that ensure sufficient capacity is maintained to respond to a surge in patients and are fair, transparent, and equitable.

3. Personal Protective Equipment (PPE)

Facilities may perform procedures if there is adequate PPE with respect to the number and type of procedures that will be performed, and enough to ensure adequate supply if COVID-19 activity increases in the region within the next 14 days.

4. Infection control practices⁴

- Instruct patients to notify their provider by phone if they develop symptoms of COVID-19 prior to the procedure.
- Do not penalize patients for cancelling or missing appointments because they are ill.
- Establish facility cleaning and disinfection policies that follow established infection control protocols for all areas along the continuum of operative care.
- When possible, facilities should establish non-COVID-19 care zones for screening, temperature checks, and pre-procedure waiting areas.
- Place visual alerts, such as signs and posters in appropriate languages, at entrances and in strategic places providing instructions on hand hygiene, respiratory hygiene (including the use of cloth face coverings), and cough etiquette ([Stop The Spread of Germs](#))
- Set up waiting rooms to allow patients to be at least 6 feet apart. If your facility does not have a waiting area, then use partitions or signs to create designated areas or waiting lines.
- Reduce crowding in waiting rooms by asking patients to remain outside (e.g., stay in their vehicles or in a designated outdoor waiting area), if feasible, until they are called into the facility for their appointment. Another option is to set up triage booths to screen patients safely.

5. Visitors

Facilities should develop policies and procedures for visitors and caretakers accompanying patients. Visitors should generally be restricted in regions where community transmission is high. Visitors necessary for an aspect of patient care or as a support for a patient with a disability should be pre-screened in the same way as patients (as described below). Facilities may also decide to test all visitors using an approved SARS-CoV-2 test.

6. Pre-procedure screening

Providers should consider using telemedicine for pre-procedure visits. All patients should be clinically screened on the day of the procedure for symptoms of COVID-19 (new cough,

shortness of breath, fever in the last 7 days, known exposure to a COVID-19 positive person). An oral temperature of 100.4 °F or less is required in order to proceed with a non-emergent procedure.

7. Pre-procedure testing for SARS-CoV-2

- Pre-procedure testing is required for all patients who are not fully vaccinated prior to the planned procedure.
- Universal pre-procedure testing is recommended for all patients, regardless of vaccination status, given the duration of protection from vaccination, and the efficacy against emerging variants is unclear.
- Patients are considered fully vaccinated for COVID-19 two weeks after they have received the second dose in a two-dose series (Pfizer-BioNTech or Moderna), or a single-dose vaccine (Johnson and Johnson/Janssen).
- Testing must be completed within 72 hours of a scheduled procedure using a test authorized for emergency use by the U.S. Food and Drug Administration (FDA) for the detection of SARS-CoV-2. Tests with emergency use authorizations (EUAs) can be found on the [FDA website](#).

Following testing, patients should be instructed to self-quarantine as much as possible, to avoid close contact with people other than immediate household members, and to notify their medical provider immediately if they have close contact with someone with COVID-19. Self-quarantine minimizes the risk of exposure before the procedure. If a patient is unable to self-quarantine, they must continue to practice social distancing, wear a mask, and practice good hand hygiene.

Type of COVID-19 test based on procedure risk of transmitting COVID-19

1. High-risk procedures

Patients undergoing high-risk procedures listed below (Appendix A) must be tested using a Nucleic Acid Amplification Test¹² (NAAT). For purposes of this guidance, all procedures that involve the upper aero-digestive tracts and lower respiratory tract, including anesthesia administered by mask or intubation, should be considered high risk. NAATs may be point of care (POC) tests, including rapid POC tests, which should be performed according to CDC POC guidelines¹³.

2. Low-to-moderate risk procedures

While a NAAT remains the gold standard for SARS-CoV-2 testing, patients undergoing low-to-moderate risk procedures may, based on clinical judgment, be tested using a rapid POC antigen test. For purposes of this guidance, low-to-moderate risk procedures are those that do not involve the upper aero-digestive tracts and lower respiratory tract, and do not involve anesthesia via mask or intubation (e.g., procedures conducted under local or regional anesthesia outside the high-risk areas).

Under certain conditions, described in the IDPH Guidance for Interpreting Viral Test Results for SARS-CoV-2¹⁴, a confirmatory NAAT may be needed to validate positive antigen tests. Per IDPH guidance, results from rapid antigen tests should be interpreted based on the test sensitivity and specificity, whether the individual being tested has symptoms, and the level of transmission in the community.

- 3. Caution should be exercised in patients with serious B-cell immunodeficiency** (e.g., acute lymphocytic leukemia, lymphoma, rituximab treatment), even after receiving vaccination. Several cases of persistent/relapsing SARS-CoV-2 infection in these patients have been documented and these patients should be retested before every high-risk procedure.

Patients who have previously tested positive for SARS-CoV-2

Persons who previously had confirmed SARS-CoV-2 infection, should have procedures postponed until 10 days after a positive test and until they are asymptomatic. They may continue to test positive by a NAAT for up to 12 weeks but are unlikely to have reinfection. The decision to test should be based upon the following:

- Within 90 days after the date of symptom onset or positive test for COVID-19
 - Persons who remain asymptomatic do not need to be retested.
 - For persons who develop new symptoms consistent with COVID-19, retesting may be warranted if alternative etiologies for the illness cannot be identified.
- 90 days or more after the date of symptom onset or positive test for COVID-19
 - Persons who remain asymptomatic should be tested before a non-emergent procedure as outlined above. If they test positive, the determination of whether the patient is contagious to others should be made on a case-by-case basis.
 - Persons who develop new symptoms consistent with COVID-19 should be retested. If positive, this should be documented and discussed with the local health department, so that the possibility of reinfection can be investigated. In the interim, they should be considered infectious and remain isolated. Specimens from these potential reinfections should be saved and the local health department notified to allow possible sequencing for variants of concern on these “breakthrough” isolates.

Clinical Laboratory Improvement Amendment (CLIA) Waiver Required for POC Testing

According to the Centers for Medicare & Medicaid Services (CMS) rules¹⁵, in order to conduct POC antigen testing, a facility must first obtain a CLIA Certificate of Waiver. COVID-19 POC antigen test systems are authorized for use in patient care settings that operate under a CLIA Certificate of Waiver. Information on how to obtain a CLIA waiver is located on the [CMS](#) or the [IDPH CLIA Program](#) websites.

Facilities with a valid CLIA certificate that would like to add COVID-19 testing to the services they may perform, must email DPH.CLIA@illinois.gov and provide their CLIA#, request to add COVID-19 testing, and provide the specific test system(s) that will be used.

Under CLIA rules, staff who perform POC tests must be appropriately trained to perform the test and must use appropriate PPE when handling samples. Facility administrators and testing personnel new to CLIA-waived testing will find it useful to complete CDC's [online training module \(continuing education available\) at https://www.cdc.gov/labtraining/training-courses/ready-set-test.html](https://www.cdc.gov/labtraining/training-courses/ready-set-test.html).

Reporting of POC Testing

Facilities that perform POC testing must report each individual positive and negative test result to IDPH, per federal and state requirements. Facilities not currently sending electronic laboratory reporting files to IDPH must report to IDPH according to the instructions below.

- Register in IDPH's reporting system with the facility's CLIA certificate number at <https://redcap.link/dph.illinois.gov.pocovid19registration>.
- You will need your CLIA number, ordering provider, facility name, address, phone number, the type of testing platform, and the point of contact email and phone number.
- Once the facility's registration has been processed, the individual who submitted the registration will receive an email with a link to begin reporting. This link is unique to the facility and can be shared with facility staff who will be reporting results.
- Each positive and negative test result must be reported to the IDPH system within 24 hours.
- If you have questions, please email: dph.elrresp@illinois.gov

Pediatric Procedures. Non-emergent procedures for pediatric patients are not subject to the "Regional COVID-19 Resurgence Criteria" but are subject to the "General Requirements."

Appendix A: Examples of high-risk procedures requiring a NAAT

- All thoracic surgery requiring lung isolation or tracheal/pulmonary resection.
- Flexible bronchoscopy of lower airways through ETT – Diagnostic (DLT and blocker placement), BAL, brushing, biopsy, transbronchial biopsy, or similar.
- Upper GI endoscopy, TEE, ECT, cardioversion.
- Scheduled cesarean section or other planned regional anesthetic with high likelihood of requiring conversion GA (mask or intubation).
- Any procedures on the glottis, oropharynx, nasopharynx, mastoid, or sinuses.
- Any ENT/OMFS procedures using cautery, laser, drill, or saw within airway/oral cavity.
- Any procedures utilizing operative rigid laryngoscopy or rigid bronchoscopy.
- Any procedures on the subglottic airway involving incision of the airway (tracheostomy), dilation of the airway, or laser or electrocautery debridement of the airway.

(Note: The list of procedures considered high risk is based on guidance issued by the University of Nebraska Medical Center <https://www.nebraskamed.com/sites/default/files/documents/covid-19/perioperative-guidelines-for-patients-requiring-perioperative-services.pdf>).

Endnotes

¹American Society of Anesthesiologists and the Anesthesia Patient Safety Foundation *Statement on Perioperative Testing for the COVID-19 Virus*. December 8, 2020. <https://www.apsf.org/news-updates/asa-and-apsf-joint-statement-on-perioperative-testing-for-the-covid-19-virus/>

² *Joint Statement: Roadmap for Resuming Non-emergent Surgery after COVID-19 Pandemic*. American College of Surgeons, American Society of Anesthesiologists, Association of periOperative Registered Nurses, American Hospital Association. April 17, 2020. <https://www.asahq.org/about-asa/newsroom/news-releases/2020/04/joint-statement-on-non-emergent-surgery-after-covid-19-pandemic>

³ Centers for Disease Control and Prevention. *Framework for Healthcare Systems Providing Non-COVID-19 Clinical Care During the COVID-19 Pandemic*. June 30, 2020. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/framework-non-COVID-care.html>

⁴ Centers for Disease Control and Prevention. *Healthcare Facilities: Managing Operations During the COVID-19 Pandemic*. March 17, 2021. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-hcf.html>

⁵ Centers for Disease Control and Prevention. *Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic*. February 23, 2021. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html>

⁶The Joint Commission. *FAQs and Revisions for the Position Statement: Preventing Nosocomial COVID-19 Infections as Organizations Resume Regular Care Delivery – June 22, 2020*. <https://www.jointcommission.org/-/media/tjc/documents/covid19/faqs-and-revisions-to-position-statement-on-preventing-nosocomial-infections-0623.pdf>

⁷ Haffner MR, Le HV, Saiz AM, et al. Postoperative In-Hospital Morbidity and Mortality of Patients With COVID-19 Infection Compared With Patients Without COVID-19 Infection. *JAMA Network Open*. 2021;4(4):e215697. doi:[10.1001/jamanetworkopen.2021.5697](https://doi.org/10.1001/jamanetworkopen.2021.5697)

⁸ Knisley A, Zhou ZN, Wu J, et al. Perioperative Morbidity and Mortality of Patients With COVID-19 Who Undergo Urgent and Emergent Surgical Procedures. *Ann Surg*.2021;273(1):34-40. doi:[10.1097/SLA.0000000000004420](https://doi.org/10.1097/SLA.0000000000004420)

⁹ Kothari AN, Trans AT, Caudle AS. Universal pre-procedure SARS-CoV-2 testing can facilitate safe surgical treatment during local COVID-19 surges. *Br J Surg*.2020; doi: [10.1093/bjs/znaa062](https://doi.org/10.1093/bjs/znaa062)

¹⁰ Hamilton BCS, Kratz JR, Sosa JA, Wick EC. Developing Perioperative Covid-19 Testing Protocols to Restore Surgical Services. *NEJM Catalyst Innovations in Care Delivery*. June 19, 2020. DOI: 10.1056/CAT.20.0265 <https://catalyst.nejm.org/doi/pdf/10.1056/CAT.20.0265>

¹¹ University of Nebraska Medical Center. *COVID-19 Contingency Procedure Guidelines*. June 24, 2020. <https://www.nebraskamed.com/sites/default/files/documents/covid-19/perioperative-guidelines-for-patients-requiring-perioperative-services.pdf>

¹² Centers for Disease Control and Prevention, *Nucleic Acid Amplification Test (NAAT)*, March 28, 2021. <https://www.cdc.gov/coronavirus/2019-ncov/lab/naats.html>

¹³ Centers for Disease Control and Prevention, *Guidance for SARS-CoV-2 Point-of-Care and Rapid Testing*, March 12, 2021. <https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html>

¹⁴ Illinois Department of Public Health. *Rapid Point-Of-Care Testing for COVID-19 in Community Settings and Schools*. <https://www.dph.illinois.gov/covid19/community-guidance/rapid-point-care-testing-covid-19>

¹⁵ CMS, Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency related to Long-Term Care (LTC) Facility Testing Requirements and Revised COVID19 Focused Survey Tool (QSO-20-38-NH). <https://www.cms.gov/files/document/qso-20-38-nh.pdf>