



Laboratory guidance for commencing or continuing ART operations during the ongoing COVID-19 pandemic.

The following constitutes a consensus document created by representatives of the **Society for Assisted Reproductive Technology (SART)**, the **College of Reproductive Biology (CRB)**, and the **Society for Reproductive Biologists and Technologists (SRBT)**. This document was created to guide reproductive laboratories seeking to attenuate the inherent risks posed by COVID-19 as their associated clinics resume or continue operations. In no way do the provisions outlined herein ensure against infection of either staff or patients, but instead describe best practices according to our current understanding of the virus at this time.

Background:

The viral pandemic, COVID-19 /SARS-CoV-2, has had a widespread impact on all aspects of daily life, and has significantly altered how reproductive medicine is practiced. In response to the pandemic, clinics have either ceased routine operation or significantly reduced patient care volumes. As reproductive medicine laboratories deliver patient care during the COVID-19 pandemic, several changes are required to protect the health of laboratory staff. It is therefore critical that laboratories have strategies to deliver high quality patient care while minimizing individual exposure risks, limiting the risks to the entire staff, and adjusting daily operations in a manner that provides maximum protection to all parties. In order to stay current and informed about COVID-19, each laboratory should conduct ongoing review of existing recommendations and guidance documents provided by local authorities, CDC, ASRM, SART, and other pertinent sources. Laboratories must have a plan in place should local government reinstitute mandatory stay at home orders.

This committee strongly recommends that laboratories review and, if necessary, revise their current emergency protocols. Laboratories should communicate with other programs in the area about commitment to reciprocal support in the event one is unable to care for patients or support one's laboratory. Additionally, laboratories should conduct individual risk assessments for all procedures offered and develop detailed operational strategies aimed at minimizing person-to-person transmission and contamination of the laboratory environment.

Elements for safe and effective operational strategy:

- 1) Limiting person-to-person transmission
 - a. Laboratorians should adhere to local and state COVID-19 regulations. The greatest risk to all staff is likely to come from exposure to contacts outside of the controlled environment provided by the laboratory. Encourage staff to practice physical distancing (6-foot separation) and COVID-19 hygiene measures outside work. Each laboratory should consider having policies and procedures to protect staff who are at higher risk for severe COVID-19 illness or live with a person who is at higher risk.
 - b. Before resuming operations and as a routine measure each day of operation, all staff should self-evaluate for any indication of illness and report or discuss findings with a supervisor. Evidence of infection should be documented and followed by a review of



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- symptoms and referral to an appropriate provider for testing if symptoms are consistent with COVID-19 (Fever, difficulty breathing, cough, etc. – refer to [CDC](#) recommendations for a complete list). In the absence of adequate testing, individuals demonstrating COVID-19 symptoms should be quarantined for 14 days and seek care and testing when it becomes available. Only healthy, symptom-free technicians should be present in the clinic.
- c. At the door screening procedures should be in place for all employees, patients and visitors.
 - d. It is recommended that staff should change into scrubs as soon as they arrive at the laboratory and remove scrubs before they leave. Clothes worn to and from the laboratory should be washed immediately when they arrive home.
 - e. Personal protective equipment should always be used in the laboratory. This should include bonnets/caps (embryology laboratory only), surgical masks, scrubs and gloves. The committee recommends laboratories that opt to not require gloves for activities without risk of exposure to body fluids be cognizant of the need for frequent hand washing and surface cleaning. The use of gloves will protect not only the wearer, but also reduce the need for decontamination and cleaning of instruments. It is recommended that masks be used not only within the laboratory space but worn continuously while on-site. **It is the responsibility of the clinic to ensure the availability of adequate PPE for the staffing and patient volume anticipated. In the absence of adequate PPE, this committee recommends that resumption of services be delayed until such resource may be procured.**
 - f. Discourage sharing of laboratory and clerical tools, such as pipettes and pens.
 - g. Wash hands frequently while ungloved and before putting on and after removing gloves.
 - h. Avoid touching your face, nose, or mouth.
 - i. Avoid eating or drinking in areas that do not accommodate physical distancing.
 - j. Disinfect all areas used for eating or drinking when finished.
- 2) Limiting staff exposure
- a. Laboratory staff should be strongly encouraged to report any signs of illness and seek testing or medical care if symptoms are consistent with COVID-19. While it is not always practical, staff members exhibiting signs of any communicable illness should be encouraged to remain at home until the symptoms pass.
 - b. Laboratory staff should be divided into non-overlapping teams of a size sufficient to provide clinical care appropriate to the volume of patients being seen. Should one member of a team become ill, all members of that team should be treated as potentially infected and should be screened and, if possible, tested for COVID-19 before returning to work. Rotations will depend on individual laboratory needs; however, periods of 4-7 days are generally ideal.
 - c. At a minimum, all surfaces should be disinfected by the current team at the end of the rotation. Teams also may opt to disinfect all surfaces at the beginning of the rotation.



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- d. Minimize the overlap of specific laboratory duties during this time to reduce the risk of cross-contamination should a staff member become infected. Assigning specific tasks to individual technicians also allows for a practical level of physical distancing within the confines of the laboratory.
 - e. Limit patient interactions to the minimum needed to achieve appropriate levels of care and patient identification. Where possible, assign a single individual to interact with patients and restrict communication to physical distancing standards. Private rooms may be utilized to ensure patient confidentiality. Whenever patient contact occurs, PPE directly involved in the encounter should be changed, with sanitizing and handwashing measures employed as needed.
 - f. Laboratory staff should be encouraged to limit working hours to those necessary to accomplish their respective duties and to return home when those duties are completed. The laboratory should consider remote options for all non-bench activities such as data entry, meetings and telephone calls.
- 3) Patient care strategies – adjustments to operating protocols designed to ensure optimal care while limiting patient time-on-site, patient-to-patient exposure, and patient-to-clinician exposure.
- a. Patients should arrive and be treated alone when possible. Only under extenuating circumstances should a partner, friend, or attendant be allowed to accompany the patient into the laboratory.
 - b. Patients should be encouraged to wear a mask or other face-covering at all times while at the laboratory facility, except when under anesthesia. Patients should only be admitted to the laboratory with a mask or other face-covering that is worn in an effective and appropriate manner.
 - c. Patients should not be admitted if temperature is 100°C or greater. Physician should be immediately notified for guidance.
 - d. Patient scheduling
 - i. Patients should be scheduled in a manner that limits the number of patients on-site at any one time. This may mean altering the established procedure flow (retrievals in the morning, transfers in the afternoon, etc.) to increase time between procedures. These approaches must be coordinated with the clinical staff to be effective and avoid disruptions in care.
 - ii. Laboratories should consider off-site semen specimen collection if possible. To facilitate at home semen collection, laboratories must have policies and procedures in place to assure that patients receive specimen collection instructions, specimens are properly labeled, samples containers are stored in a secondary container during transport and specimen transport does not compromise semen quality. Men collecting specimens offsite must be screened in the laboratory or the clinic's COVID-19 triage area and present a valid form of identification when delivering the specimen to the laboratory.



For on-site collections, the laboratory must develop a strategy for patient scheduling that allows ample time to clean collection rooms between patients.

- e. When possible, patients coming for laboratory services should be brought into a treatment room immediately, minimizing the use of waiting rooms. Centers that have parking nearby should create a virtual waiting room that allows patients to stay in their cars until they can be escorted to the laboratory specimen collection, blood draw area or procedure room.
 - f. If use of the waiting room cannot be avoided, seating should be structured to facilitate physical distancing among waiting room occupants. Magazines and other media should be removed from waiting and collection rooms to reduce opportunities for cross-contamination.
 - g. Patients should be encouraged to communicate any symptoms or diagnoses of COVID-19 experienced up to 14 days after their laboratory appointment. Upon receipt of such notification the laboratory should monitor any individuals who were in direct contact with the patient for related symptoms. If appropriate precautions were followed throughout the visit, further action is unlikely to be required.
 - h. The laboratory should establish a clear boundary between its functional areas and the remainder of the clinical space if they are in proximity. All non-laboratory staff, patients, and physicians be counseled to remain outside of this area at all times.
 - i. Laboratories should develop practices that involve physical distancing and PPE use for the acceptance of specimens delivered to the laboratory (blood, sperm, etc.).
- 4) Minimizing risks during laboratory procedures
- a. This committee recommends that risks associated with laboratory procedures be evaluated by laboratory leadership. Laboratory leadership must ensure personnel are provided training focused on risk mitigation in IVF laboratory during COVID-19 pandemic and documented policies and procedures are read and, if possible, signed by all laboratory personnel.
 - b. Targeted risk assessments for all laboratory procedures should focus on the areas where aerosol formation (e.g. working with large amounts of follicular fluid, centrifugation and pipetting of sperm, etc.) and other risks of contamination may exist.
 - c. Additionally, laboratory leadership should determine safe case volume for their laboratories given the workflow and staffing changes during the COVID-19 pandemic. Laboratory leadership must collaborate with their clinical partners to ensure safe and efficient workload for laboratory teams.
 - d. In the absence of definitive information about presence and survival of the COVID-19 virus within IVF laboratory culture systems and cryogenic storage, this committee recommends that individual reproductive laboratories review their universal precautions and labeling practices in order to mitigate infection and cross-contamination risks.



5) Cleaning and Disinfecting

- a. Due to the variety of cleaning products employed by various clinics, it is the responsibility of each clinic to establish a written policies and procedure on the method of disinfection which is both effective against viral agents and safe for use within the setting of a reproductive laboratory.
- b. All clinical areas should be cleaned and disinfected thoroughly between exposures to patients.
- c. Restrooms and collection rooms should be disinfected following patient use.
- d. Increased frequency of cleaning and additional disinfection of staff restrooms and locker rooms is recommended.
- e. Common areas should be disinfected at the end of each working day.
- f. Laboratory space should be cleaned at the end of each working day. Surfaces and equipment at risk for contamination should be disinfected. The use of gloves while in the laboratory space should greatly reduce, but not eliminate, the extent to which equipment may need to be disinfected.
- g. Laboratory leadership must exhibit heightened awareness of the methods used both during operational hours, as well as by custodial staff, to disinfect the laboratory. These may introduce volatile organic compounds to the laboratory with a detrimental impact on embryo development. Attention to quality control trends, as well as the increased use of contamination monitors may be warranted.
- h. Packages delivered to the laboratory may be contaminated. PPE should be worn when handling packages. When possible, allow the package to remain undisturbed outside the laboratory area to decontaminate for a set amount of time prior to unpacking. If a holding area outside the laboratory is not available or immediate unpacking is required wipe the exterior with disinfectant prior to bringing it into the laboratory.