

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

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The viral pandemic, COVID-19 /SARS-CoV-2, has presented unprecedented challenges to the entire reproductive community. Assisted Reproductive Technology (ART) Laboratories were affected in unique ways from being forced to completely shut down their laboratories and shelter in place while caring for precious frozen inventory, to opening up safely and maintaining quality of the patient care under social distancing and other safety guidelines. This committee is honored to acknowledge the outstanding performance of our community during these trying times. Once again, ART laboratory professionals demonstrated their unwavering commitment to our patients while operating under tremendous pressure. We came together as an even tighter community, as evidenced by the numerous educational initiatives, free exchange of experiences and ideas, and supporting one another in various ways. We believe that our collective experiences and amazing camaraderie will make us even stronger and better prepared for whatever future challenges we may face during these unprecedented times.

The following constitutes a 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 is an update to the initial guide created for reproductive laboratories seeking to attenuate the inherent risks posed by COVID-19 as their associated clinics resumed operations. In no way do the provisions outlined herein eliminate the risk of infection to either staff or patients, but instead, describe best practices according to our current understanding of the virus and pandemic as a whole.

Background:

The viral pandemic, COVID-19 /SARS-CoV-2, had a widespread impact on all aspects of daily life and significantly altered how reproductive medicine is practiced. The initial response to the pandemic varied among clinics from reducing patient volumes, limiting care only to urgent cases to ceasing all operations. Six months later, most clinics are fully operational. However, as the pandemic persists, ART labs must continue to protect both laboratory staff and patients' health and safety, which necessitates altered processes and procedures. It is critical that laboratories have strategies to deliver high-quality patient care while minimizing individual exposure risks and offer maximum protection for all staff and patients. To stay current and informed about COVID-19, laboratories should conduct ongoing reviews of recommendations from local authorities, CDC, ASRM, SART, CAP, and other pertinent sources. In addition, laboratories must have a plan in place should operational restrictions be reinstated.

This committee strongly recommends that each laboratory/clinic review and, if necessary, revise their current emergency protocols periodically as the situation and our understanding of the Coronavirus evolves. Laboratories should seek out other local programs to establish reciprocal support in the event one is unable to care for its patients or specimens. Additionally, laboratories should conduct individual risk assessments for all procedures offered and develop detailed operational strategies to minimize person-to-person transmission and contamination of the laboratory environment.

Elements for safe and effective operational strategy:

- 1) Limiting general person-to-person transmission
 - a. All staff should adhere to local and state COVID-19 regulations. The most significant risk to a laboratory is likely to come from exposure to contacts outside of the laboratory's controlled environment. 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. All patients and staff should be encouraged to wear a mask when entering and during their time at the laboratory/clinic. Recommend creating a policy specific to your laboratory/clinic of acceptable mask-wearing.
 - c. Each day before reporting to work, all staff should self-evaluate for any illness (see CDC guidelines for identification of COVID-19 symptoms). Institutional policy must be followed for any individual who has suspect symptoms or has contact with a confirmed COVID-19 case. The policy should include, who to report findings to, when to stay home, and for how long.
 - d. All patients should be screened before arriving at the clinic for consults, monitoring, and IVF procedures. There are many ways to screen patients, and each IVF program should choose a method that is best for their workflow and safety.
 - e. At the door screening (based on CDC guidelines) should be in place for all employees, patients, and visitors. All staff should wash hands frequently while ungloved and before putting on and after removing gloves and avoid touching your face, nose, or mouth.
 - f. Avoid eating or drinking in areas that do not accommodate physical distancing.
 - g. Disinfect all common areas used for eating or drinking when finished. Increased frequency of cleaning and additional disinfection of staff restrooms and locker rooms is recommended.
- 2) Limiting staff exposure inside the laboratory
 - a. It is recommended that staff change into scrubs as soon as they arrive at the laboratory and have any potentially soiled scrubs laundered appropriately.
 - b. Staff should use appropriate Personal Protective Equipment (PPE) in the laboratory. This should include bonnets/caps (embryology laboratory only), surgical masks, scrubs, and gloves. The committee recommends laboratories that opt not to require gloves for activities without risk of exposure to body fluids be cognizant of the need for frequent hand washing and surface cleaning. It is recommended that masks be used not only within the laboratory space but worn according to your laboratory/clinic acceptable mask-wearing policy while on-site. **It is the clinic's responsibility to ensure the availability of adequate PPE for the staffing and patient volume anticipated. In the absence of adequate PPE, this committee recommends that services be delayed until PPE is available.**
 - c. As possible, 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 team members should be treated as potentially infected and should be screened and tested for COVID-19 before returning to work. Rotations will depend on individual laboratory needs; however, periods of 4-7 days are generally ideal. The committee recognizes that this team approach may not be possible for all laboratories, especially as IVF volume has increased at many clinics.

- d. 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. When rotating teams are not possible, the lab should implement a routine disinfectant of all surfaces
- e. 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 physical distancing level within the laboratory's confines.
- f. Limit in-person 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.
- g. 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. Ideally, only patients who need to be seen in person should be allowed in the clinic, and partners should only accompany them under extenuating circumstances to reduce risk to staff. No additional persons should be allowed in the clinic or laboratory facility. Patients should always be required to wear a face-covering while at the laboratory facility, except when under anesthesia. Patients should only be admitted to the laboratory with a mask or other appropriately worn face-covering.
- b. 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 the 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 to ensure that patients receive specimen collection instructions, specimens are appropriately labeled, and chain of custody is followed, samples containers are stored in a secondary container during transport and specimen transport does not compromise semen quality.

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

- c. When possible, patients coming for laboratory services should be brought into a treatment room immediately, minimizing the use of waiting rooms. Centers with 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.
- d. If the waiting room use 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.
- e. 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.
- f. Laboratories should develop practices involving physical distancing and PPE use to accept 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 a safe and efficient workload for laboratory teams.
- d. In the absence of definitive information about the 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 to mitigate infection cross-contamination risks.

5) Cleaning and Disinfecting

- a. Each lab should establish written policies and procedures on the frequency and method of disinfection, which is effective against viral agents and safe for use within the setting of a reproductive laboratory.
- b. All clinical procedure rooms should be cleaned and disinfected thoroughly between exposures to patients as per standard protocols.
- c. Collection rooms should be disinfected following patient use.
- d. 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 and the increased use of contamination monitors may be warranted.

6) Adequate staffing -It has been the experience of many clinics, including those that are reopening and those that have continued operations, that patient volume has increased in recent months to levels often exceeding those experienced before the pandemic. Combined with the complexities of current operating conditions, increased prophylaxis, and individual stressors, this additional burden creates a far more challenging work environment than has been present in the past. It is, therefore, the recommendation of this committee that the following guidelines be observed:

- a. Staffing within the laboratory should be maintained at levels appropriate to the workload being issued, with due consideration for additional sanitizing efforts. For clinics utilizing rotational shifts, this may require adding clinical laboratory staff to ensure that each shift has an appropriate number of qualified technicians.
- b. Clinics that have reduced FTEs due to COVID-19 measures should restore staffing to original levels before initiating a full patient schedule.
- c. Clinics should be cognizant of shifts in procedure-to-technician ratios, which may create unforeseen challenges, particularly with double identification of specimens.
- d. Prior to resuming full schedules, clinics that have utilized periods of reduced clinical demand to attend to housekeeping tasks should plan appropriately so that completion of these projects does not impact patient care.
- e. In the event clinics are required to cease operations due to COVID-19 outbreaks, adequate time to complete time start-up protocols, and QC measures before initiating procedures again should be allowed.
- f. Provide lab staff resources for emotional well-being, such as access to support groups, informational materials, and adequate time for recuperation following strenuous work periods. A physically healthy team only operates effectively if the members are emotionally supported.