EC.02.04.03
The laboratory inspects, tests, and maintains laboratory equipment.

Elements of Performance (EPs) for EC.02.04.03

35. The embryology laboratory maintains the following:
- Incubators with remote alarm systems and emergency power backup
- Records of daily monitoring of incubator temperature and gas content using calibrated instrumentation before first opening the embryology laboratory
- Microscopes suitable for oocyte recovery, semen analysis, determination of fertilization, manipulation of oocytes or embryos
- General laboratory supplies suited to the size of the laboratory
Note: Audible alarms for refrigerators are not required; however, always discard specimens from refrigerators that experience equipment failure. Both audible and remotely monitored alarms are required for incubators and liquid nitrogen storage tanks used for cell and tissue storage.

36. The embryology laboratory equipment is maintained and operated according to manufacturers’ instructions and is decontaminated prior to calibration, as needed. Deviations from manufacturers’ instructions are documented with proper rationales to safeguard against negative impacts to the quality and safety of laboratory operations and specimens.

EC.02.06.01
The laboratory establishes and maintains a safe, functional environment.

Elements of Performance (EPs) for EC.02.06.01

47. Embryology laboratories have the following special space requirements:
- The laboratory is physically isolated from other activities. Use of toxic chemicals or radioisotopes, including toxic cleaning materials, in the laboratory is not permitted.
- The laboratory is in proximity to the procedure room, and if not, necessary conditions are in place so that embryo viability is not compromised.
- Incubators and their chamber space have sufficient volume for the positive identification of specimens.
- “Wet areas” are separated from the area in which oocytes and embryos are handled.

HR.01.02.03
One or more qualified professionals direct pathology and clinical laboratory services.

Elements of Performance (EPs) for HR.01.02.03
9. A qualified individual directs embryology services. The director of the embryology laboratory has the following qualifications:
- A doctoral degree and sufficient training and experience in biology, biochemistry, the physiology of reproduction, as well as clinical laboratory sciences and their operation.
- Two years of documented experience in a laboratory performing in vitro fertilization and assisted reproductive-technology procedures.
Note: The director of the embryology laboratory who is not a physician or doctoral scientist, but who was functioning as the director on or before July 20, 1999, is considered qualified.

9. A qualified individual directs embryology services. The director of the embryology laboratory has the following qualifications:
- A doctoral degree and sufficient training and experience in biology, biochemistry, the physiology of reproduction, as well as clinical laboratory sciences and their operation.
- Two years of documented experience in a laboratory performing in vitro fertilization and assisted reproductive-technology procedures.
- Effective January 1, 2006, new embryology laboratory directors hold either High-Complexity Clinical Laboratory Director (HCLD) or Embryology Laboratory Director (ELD) certification from the American Board of Bioanalysis (AAB) or an equivalent board certification.
Note 1: The director of the embryology laboratory who is not a physician or doctoral scientist, but who was functioning as the director on or before July 20, 1999, is considered qualified.
Note 2: If the embryology laboratory is also performing andrology and other testing specialties under the Clinical Laboratory Improvement Amendments of 1988 (CLIA ‘88) guidelines, the laboratory director also meets CLIA qualifications. (For more information on the qualifications of the laboratory director, refer to HR.01.02.03, EP 1)
Note 3: If the medical director also serves as the laboratory director, he or she designates a laboratory supervisor. (For more information on embryology laboratory supervisor qualifications, refer to HR.01.03.01, EP 4)

10. When the embryology laboratory director is off-site, he or she is available at all times to staff by phone, email, or fax and also performs the following functions:
- Establishes frequency of director on-site visits (minimum visits of once every quarter) to the laboratory that is actively treating patients
- On-site review of accreditation procedures and on-site presence during The Joint Commission accreditation survey, if possible

HR.01.02.07

The laboratory determines how staff function within the organization.

Elements of Performance (EPs) for HR.01.02.07

15. Embryology laboratory testing personnel have the following qualifications:
- Bachelor’s or master’s degree in chemical, physical, biological, medical technology, clinical, or reproductive laboratory science from an accredited institution
- Documented training that includes performing at least 30 assisted reproductive technology procedures under supervision
- Documented annual proficiency training as established by the laboratory director
**HR.01.03.01**

Staff are supervised effectively.

**Elements of Performance (EPs) for HR.01.03.01**

4. The embryology laboratory supervisor has the following qualifications:
   - Bachelor’s or master’s degree in chemical, physical, biological, medical technology, clinical, or reproductive laboratory science from an accredited institution
   - Documented training that includes performing at least 60 assisted reproductive technology procedures under supervision
   - Documented annual proficiency training as established by the laboratory director
   - Twelve hours annually of accredited continuing education credits

**LD.04.05.09**

The laboratory director is responsible for developing, implementing, and maintaining policies and procedures that guide and support the provision of services.

**Elements of Performance (EPs) for LD.04.05.09**

11. The embryology laboratory director is responsible for no more than five separate laboratories of any type and is responsible for the following activities:
   - Developing policies specific to the scope of embryology laboratory services
   - Communicating with the medical director on patient progress related to laboratory aspects of treatment
   - Upholding safe laboratory environmental conditions
   - Maintaining patient confidentiality throughout the embryology laboratory’s assisted reproductive technology process
   - Verifying that staff are trained on assisted reproductive technology laboratory procedures and obtain the required number of annual continuing education hours for the laboratory procedures performed

**QSA.10.01.01**

Embryo laboratory procedures provide for accurate results.

**Embyrology laboratory procedures provide for accurate results.**

**Elements of Performance (EPs) for QSA.10.01.01**

1. The embryo laboratory has written procedures for each laboratory test performed.
1. The embryo laboratory follows its written procedures for each laboratory test performed and follows recommendations from the American Society for Reproductive Medicine (ASRM) for embryo transfer. If not following ASRM recommendations, documentation of reasons for deviation are provided.
2. **The embryo laboratory’s procedures address the following:**
   - Infectious disease assessments
   - Evaluation and assessment of oocyte morphology and maturity, fertilization, and embryo quality
   - Insemination schedule relative to oocyte maturity
   - Volume, numbers, and quality of sperm used for insemination of each oocyte
   - Disposition of oocytes with an abnormal number of pronuclei
   - Disposition of excess oocytes
   - The time period following insemination for examination of oocytes to determine fertilization
   - Micromanipulation of oocytes and embryos, such as intracytoplasmic sperm injection, oocyte and embryo biopsy, and assisted hatching
   - Cryopreservation of specimens
   - Embryo transfer procedures, which include the following: the length of time embryos are cultured before transfer, the media and protein supplementation used for transfer (as applicable), disposition of excess embryos, types of catheters available (with circumstances for use of each), methods of transfer, and technique for posttransfer catheter check
   - Confirmation of patient identity and the identification of gametes and embryo samples
   - Obtaining informed consent

2. **The embryology laboratory’s procedures address the following:**
   - Infectious disease assessments
   - Evaluation and assessment of oocyte morphology and maturity, fertilization, and embryo quality
   - Insemination schedule relative to oocyte maturity
   - Volume, numbers, and quality of sperm used for insemination of each oocyte
   - Disposition of oocytes with an abnormal number of pronuclei
   - Disposition of excess oocytes
   - The time period following insemination for examination of oocytes to determine fertilization
   - Micromanipulation of oocytes and embryos, such as intracytoplasmic sperm injection, oocyte and embryo biopsy, and assisted hatching
   - Cryopreservation of specimens
   - Embryo transfer procedures, which include the following: the length of time embryos are cultured before transfer, the media and protein supplementation used for transfer (as applicable), continuous monitoring of results that minimizes multiple pregnancies, disposition of excess embryos, types of catheters available (with circumstances for use of each), methods of transfer, and technique for posttransfer catheter check
   - Confirmation of patient identity and the identification of gametes and embryo samples
   - Sperm preparation protocols that include an abstinence period, type of container used, facilities for collection, and time period and conditions for sample collection
   - Preparation and labeling of biopsy samples and selection of a reference laboratory for genetic testing
   - Chain of custody throughout the process (For more information, refer to QSA.10.03.01, EP 3)
   - Obtaining informed consent for all procedures prior to performance

4. **The embryo laboratory follows its procedures for each laboratory test it performs.**

4. **The number of embryos transferred is agreed upon by the physician and the treated**
patient(s), and patient(s) are provided with an accounting of the disposition of all sperm, eggs, and embryos consistent with the documentation in the laboratory’s record.

5. For tissue banks, policies and procedures address the following special circumstances:
- Consent forms indicate that the tissue bank transfers specimens in and out of its facility
- Limits of responsibility with the use of common package carriers used for transport
- Documentation of the type of specimen, prefreeze quality and quantity, and identification of the gamete sources
- Instructions for the thawing/warming of the specimens
- Documentation of infectious disease status for all specimens to be stored
- Assessment of the condition of transport containers before and after receipt of specimens
- Storage of reproductive tissues in either liquid nitrogen or in the vapor phase of liquid nitrogen
- Monitoring of oxygen level for improperly ventilated rooms that are used for storage of liquid nitrogen tanks


QSA.10.02.01

The embryology laboratory has a process for method validation.

Elements of Performance (EPs) for QSA.10.02.01

5. The embryology laboratory participates in the Centers for Disease Control and Prevention’s (CDC) National Assisted Reproductive Technology Surveillance System (NASS).

Note: Information on NASS is available at https://www.cdc.gov/art/nass/index.html#collaborative.

QSA.10.03.01

The embryology laboratory maintains records during all phases of testing and reporting.

Elements of Performance (EPs) for QSA.10.03.01

2. The embryology laboratory records include the following:
- Each patient’s assisted reproductive technology cycle
- Semen assessment before and after processing and concentration for insemination
- Outcome of insemination or micromanipulation procedures (for example, fertilization)
- Outcome of any culture (for example, cleavage)
- Relative timing of protocol events (for example, incubation hours)
- Assessment of the developmental status and quality of all embryos at transfer
- Verification that no embryos remain in the catheter following completion of transfer
193 - The identity and lot numbers of media and media supplements used in each phase of the procedure
194 - The identity of the laboratory staff who handled the specimens and performed the procedures

2. The embryology laboratory records include the following:
197 - Each patient’s assisted reproductive technology cycle
198 - Semen assessment before and after processing and concentration for insemination
199 - Outcome of insemination or micromanipulation procedures (for example, fertilization)
200 - Outcome of any culture (for example, cleavage)
201 - Relative timing of protocol events (for example, incubation hours)
202 - Assessment of the developmental status and quality of all embryos at transfer
203 - Verification that no embryos remain in the catheter following completion of transfer
204 - The identity and lot numbers of media and media supplements used in each phase of the procedure
205 - The identity, training, and evaluations of the laboratory staff who handled the specimens and performed the procedures

3. The embryology laboratory’s protocols for chain of custody include the following:
211 - Handling of all specimens throughout the procedure, including the movement of all specimens and proper identification to match every item with the right patient
212 - Documentation of written confirmations with a double-check by a different staff member prior to cycle events (for example, insemination and embryo transfer) for accurate identification of gametes and confirmation that embryos match the correct patient
213 - When electronic witnessing is used, the method is validated and all gamete sources are included
214 - Audit trail of all equipment used for each tissue and identity of the individual(s) handling each tissue
215 - Disposal of all cells and tissues including the identity of the individual(s) performing the procedure
Note: Chain of custody should be traceable and patient identification verifiable at all phases of specimen handling and during culture, storage, and disposition.
217

4. When sample processing is performed in another laboratory that is not part of the accreditation survey (for example, a separate andrology laboratory), the processing laboratory is CLIA-certified and incorporated into the chain of custody protocols.
Note: If the embryology laboratory refers testing to another accredited reference laboratory, the embryology laboratory must document current accreditation status of all its reference laboratories, including laboratories used for preimplantation genetic testing.

QSA.10.04.01

The embryology laboratory documents quality control methods for the media it uses.

The embryology laboratory documents quality control methods for the media it uses.

Elements of Performance (EPs) for QSA.10.04.01

1. The embryology laboratory documents the following for the media it uses:
1. The embryology laboratory documents the following for the media it uses:
   - Procedures for preparation and quality control of culture media
   - Completion of a visual check for physical damage to the media container and evidence of media contamination before its use
   - For each batch of culture media prepared in-house, the pH, osmolality, and culture suitability using a bioassay system appropriate for performing these activities
   - The lot number, the date prepared, the method of sterilization, and the expiration date for each batch of media
   - For each batch of commercially prepared culture media, evidence that media undergo a quality control process using a bioassay system appropriate for performing these activities, unless documentation of quality control performed by the manufacturer meets this requirement
   - Evidence that manufacturers' specifications for using media are followed
   - Any media supplementation testing (for example, protein) using a bioassay system, when needed, unless documentation of quality control performed by the manufacturer meets this requirement
   - Blood-based media supplements (for example, human fetal cord serum) prepared in-house and used in testing for human immunodeficiency virus (HIV), Type 1; human immunodeficiency virus (HIV), Type 2; hepatitis B virus (HBV); hepatitis C virus (HCV); human T-cell lymphotrophic virus (HTLV), Type 1; and other diseases that may be deemed appropriate according to the laboratory's written procedures

QSA.10.05.01

The embryology laboratory has a method of tracking cryopreserved specimens.

The embryology laboratory has a method of tracking cryopreserved oocytes, sperm, embryos, and other human tissues.

Elements of Performance (EPs) for QSA.10.05.01

2. The embryology laboratory maintains documentation in duplicate log books or files for each liquid nitrogen storage tank.
2. The embryology laboratory maintains documentation in duplicate log books or files for the following:
   - Each liquid nitrogen storage tank with physical inventory at least annually
   - Sample type (oocytes, sperm, embryos, and other human tissue)
   - Sperm and oocyte sources
   Note: Duplicate log books are kept at a site separate from the location of nitrogen tanks containing reproductive tissues.

QSA.10.06.01

The embryo laboratory uses policies and procedures for the receipt or transfer of cryopreserved specimens that maintain specimen identification and integrity.

The embryology laboratory follows its policies and procedures for maintaining specimen identification and integrity during the receipt or transfer of cryopreserved oocytes, sperm, embryos, and other human tissues.

Elements of Performance (EPs) for QSA.10.06.01

2. The embryo laboratory policies and procedures for the receipt or transfer of cryopreserved specimens include the following:
   - Methods to maintain specimen identification and specimen integrity
   - Methods of transportation
   - Method for verifying the identification and number of cryopreservation containers received or transferred

3. The embryology laboratory policies and procedures for the receipt or transfer of cryopreserved oocytes, sperm, embryos, and other human tissues include the following:
   - Methods to maintain specimen identification and specimen integrity
   - Methods of transportation
   - Method for verifying the identification and number of cryopreservation containers received or transferred
   - Plan to provide for continuation of patient care in the event of an emergency or natural disaster

4. The embryo laboratory follows its policies and procedures for the receipt or transfer of cryopreserved specimens.

4. The embryology laboratory’s policies and procedures for the continuation of patient care in the event of an emergency or natural disaster includes the following:
   - Emergency transfer of specimens to designated alternative storage facilities that are continuously monitored for stability in the event of mechanical failures or loss of coolant
   - Timely notification to patients regarding the location and status of their cryopreserved specimens
   - Methods used in the event of equipment failure, including back-up tanks
   - Physician’s final decision on the course of treatment
   - Communication with the patient and partner on embryo transfer options; cryopreservation of oocytes, zygotes, or embryos; or abandonment of the cycle altogether
   Note: The most prudent course of action in the event of a disaster may be to discontinue treatment for that cycle.
QSA.10.07.01

The embryo laboratory retains its records.
The embryology laboratory retains its records.

Elements of Performance (EPs) for QSA.10.07.01

3. The embryology laboratory’s electronic records have safeguards against data loss.
   Note: When automated data processing is used, procedures are established to prevent inaccurate input or output of data and programming errors.

4. The embryology laboratory’s clinic and patient records are copied (paper) and backed up (electronic) periodically. If both paper and electronic records are maintained, copied paper records are kept in a secure (preferably remote), predetermined location.
   Note: Revisions to any records have an audit trail that identifies all altered information, date of revision, and the individual who made the revision.