Reproductive Laboratory Accreditation Program

Standards for Accreditation

2004 Edition
Standards for Accreditation

PREAMBLE

Embryology laboratories are an integral part of In Vitro Fertilization (IVF), Gamete Intrafallopian Transfer (GIFT), Tubal Embryo Transfer (TET), and Zygote Intrafallopian Transfer (ZIFT) programs. These are collectively known as Assisted Reproductive Technologies (ART). Embryology laboratories are not referral laboratories but maintain specific affiliation with a physician group(s). Embryology laboratories perform some or all of the following: culture medium preparation, examination of follicular aspirates with oocyte identification, oocyte quality and maturity grading, sperm preparation, insemination of oocytes, determination of fertilization and zygote quality evaluation, embryo culture and embryo grading, embryo transfer, oocyte/embryo/sperm cryopreservation, and micromanipulation of human oocytes and/or embryos.

Andrology laboratories perform some or all of the following procedures: semen analysis, semen biochemical tests, tests for sperm survival, sperm viability and sperm membrane integrity, sperm antibody testing, sperm penetration assays, sperm cryopreservation, preparation of sperm for intrauterine insemination, and computer assisted semen analysis (CASA).

Reproductive laboratories shall be able to meet the needs of patients and their physicians. Specific functions shall include the proper identification, transportation, storage, processing, and examination of human gametes with subsequent reporting of results. Each reproductive laboratory shall provide appropriate educational and scientific opportunities for the medical and technical staff.

The following are adapted from the "Revised Minimum Standards for Practices Offering Assisted Reproductive Technologies" published in Fertility and Sterility (September, 2003) and the CAP Standards for Laboratory Accreditation, 1997 edition.
STANDARD I
Laboratory Director and Personnel Requirements

The reproductive laboratory shall be directed by a physician or qualified doctoral scientist. The director must have expertise in biochemistry, biology, and the physiology of reproduction and experience in experimental design, statistics, and problem solving.

There should be sufficient personnel to provide reproductive services as needed in a timely manner with a mechanism in place to provide back-up for the laboratory personnel. Staffing should be appropriate for the size and volume of the program.

The location, organization, or ownership of the laboratory shall not alter the requirements of this Standard, its interpretation, or its application.

INTERPRETATION

A. Qualifications, Responsibilities, and Role of the Director

To function effectively in fulfilling the duties and responsibilities as director of the reproductive laboratory service, the laboratory director, who may or may not be the medical director, should possess broad knowledge of the biochemistry, biology, and physiology of reproduction, and laboratory operations. Directors in laboratories performing testing covered by CLIA '88 must meet CLIA laboratory director requirements for high-complexity testing, including board certification for doctoral scientists. Directors of embryology laboratories who are not physicians or qualified doctoral scientists but who were functioning as directors on or before July 20, 1999 will be considered to be in compliance with this Standard. Effective January 1, 2006, all new laboratory directors should hold HCLD (High Complexity Laboratory Director), ABB-ELD (American Board of Bioanalysis Embryology Laboratory Director) certification or its equivalent. Laboratory directors grandfathered in are strongly encouraged to seek HCLD or ELD certification. The director of the embryology laboratory should have two years documented experience in a laboratory performing IVF or ART related procedures. The director of the andrology laboratory should have two years documented experience in a laboratory performing andrology procedures. This experience should include familiarity with quality control, quality assurance, inspection, accreditation and licensing procedures, and detailed knowledge of tissue cultures, ART, and andrology procedures performed in the laboratory.

The director should have appropriate training and background to assume responsibility for the overall operation and administration of the laboratory including hiring competent personnel, formulating laboratory policies and protocols, and communicating regularly regarding patient progress and patient protocols as they affect laboratory aspects of treatment. The laboratory director must be accessible to the laboratory to provide on-site, telephone or electronic consultation as needed.
The director should be able to discharge the following responsibilities:

1. Medical Significance, Interpretation, and Correlation of Data – Make judgments about the clinical significance of laboratory data and communicate effectively in interpreting laboratory data and relating correlations to referring physicians as appropriate.

2. Consultations – Provide consultations to physicians regarding the medical significance of laboratory findings as appropriate.

3. Interaction with Physicians/Patients/Administrators/Agencies – Relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the medical community, and the patient population served.


5. Personnel – Ensure that there are sufficient qualified personnel with adequate documented training and experience to supervise and perform the work of the laboratory.

6. Educational Responsibilities – Provide educational direction for the medical and laboratory staff, and participate in educational programs of the institution as appropriate.

7. Safety Responsibilities – Promote a safe laboratory environment for personnel and other occupants.

B. Personnel

The director should assure that all laboratory personnel are qualified by education and experience to perform the responsibilities they have been assigned. Definitive training programs should be provided for all procedures; personnel participation should be documented. Provision should be made for all personnel to further their knowledge and skills through participation in training courses, educational programs, and technical meetings.

All laboratory personnel must be in compliance with applicable federal, state, and local laws and regulations. Any physician shall maintain a current medical license issued by the state in which the laboratory is located.
STANDARD II
Resources and Facilities

The laboratory should have adequate space to ensure safe and comfortable working conditions and be of a design that is appropriate for the volume of procedures performed. The laboratory must maintain or have access to all equipment necessary to perform those services offered.

INTERPRETATION

The embryology laboratory should be in a low-traffic, secure area; the andrology laboratory may share physical space with other laboratory activity. Any activity requiring sterile technique should be performed in an area that is physically isolated from other laboratory activities. Use of toxic chemicals or radioisotopes is not permitted. The laboratory should be conveniently located. Intercom communication is recommended where direct communication with the procedure room is not possible. Separate office space should be provided for administrative functions. Appropriate reference materials should be available to the laboratory staff. Laboratory construction, space utilization, ventilation, and safety facilities should be appropriate for the performance of high quality laboratory work. The laboratory should have sufficient equipment for the procedures performed including incubators, hoods, thermometers, centrifuges, microscopes, pipettes, and warming devices. Disposable materials should be used for steps that involve exposure to tissue and body fluids; any material that comes in contact with eggs, embryos, or sperm being prepared for cryopreservation or intrauterine insemination must be non-toxic. All chemicals and reagents must be properly labeled and stored.

There should be a manual(s) in the laboratory describing all procedures in sufficient detail to assure reproducibility and competence in the handling of mammalian gametes. Procedure manuals detailing all laboratory procedures must be available in the laboratory. These manuals should be in substantial compliance with the National Committee for Clinical Laboratory Standards (NCCLS) Guidelines for Procedure Manuals (GP-2A or GP-2A2). Maintenance manuals for all laboratory equipment should be maintained in the laboratory. Policy manuals including policies for record keeping, result reporting, laboratory communication, and disposition of business/billing procedures shall be maintained in the laboratory.
STANDARD III
Quality Control/Quality Assurance

Each laboratory shall have a quality control program that demonstrates the reliability and medical usefulness of laboratory procedures. There shall be an ongoing quality assurance program designed to monitor and objectively evaluate the quality of care provided by the laboratory.

INTERPRETATION

All procedures should be reviewed and updated by the director or his/her designee at least annually. Equipment should be maintained and calibrated as appropriate. All new protocols should be validated. All reagents should be dated; outdated reagents should not be used. Positive and negative controls should be used as appropriate. The quality of all media and protein supplementation should be tested with bioassay systems or quantitative sperm motility or viability assay. Sterile technique should be used as appropriate. Water purity should be verified and documented prior to preparation of each batch of media. Written records of all laboratory procedures should be maintained.

The quality assurance program should include a mechanism to review and analyze data in order to identify problems related to the quality of care provided by the laboratory. This should include using mechanisms to detect clerical or analytical errors, monitoring data (including turnaround time for reports and consistency of service) gathered from the laboratory to identify and resolve problems, and maintaining a file of adverse reactions.

The reproductive laboratory shall participate in the College of American Pathologists’ Interlaboratory Comparison (Surveys) Program when appropriate Surveys are available or in a CAP-approved alternative proficiency testing program. If any proficiency testing results are unsatisfactory according to the criteria established by the Surveys program, the cause of the unsatisfactory result should be investigated and the problem resolved. The findings of the investigation and the corrective measures instituted shall be recorded, dated, and signed by the responsible staff person and the director of the laboratory.
STANDARD IV
Inspection Requirements

A laboratory that desires accreditation shall undergo periodic inspections and evaluations as determined by the CAP/ASRM Laboratory Accreditation Program.

INTERPRETATION

The application will be initiated by submission of a completed application containing the necessary information, evidence of enrollment on the appropriate proficiency testing programs, and payment of fees. Laboratories will be evaluated in accordance with the Standards for Accreditation – Reproductive Laboratory Accreditation Program of the College of American Pathologists and the American Society for Reproductive Medicine.

The laboratory must submit to periodic on-site inspection. The conduct of inspections and evaluation of results shall be in accordance with the policies and procedures of the Commission on Laboratory Accreditation.

Laboratories undergoing a change in directorship, location, or ownership are subject to inspection and evaluation in accordance with applicable policy.

Laboratories enrolled in the Reproductive Laboratory Accreditation Program are required to perform periodic self-evaluations. When deficiencies are noted, the laboratory shall take appropriate corrective action that shall be documented and subject to review by the Commission on Laboratory Accreditation. Uncorrected deficiencies at the next on-site inspection shall be considered recurrent. The Commissioner will review deficiencies detected during the self-evaluation. Corrective action responses from the laboratory director may be required.

Recurrence of the same deficiencies in consecutive inspections is considered a serious problem and is subject to review by the Commission.