Standards for Reproductive Laboratory Accreditation
2013 Edition
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).

Specific functions of a reproductive laboratory 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 four Standards for Accreditation (Standards) in this document constitute the core principles of the College of American Pathologists (CAP) Reproductive Laboratory Accreditation Program (RLAP). The objective of the Standards is to ensure that accredited reproductive laboratories meet the needs of patients, physicians, and other practitioners. The CAP accredits reproductive laboratories that conform to the Standards. The specifics of how the Standards are applied to laboratories are found in the CAP Accreditation Checklists and Terms of Accreditation.

The CAP is committed to helping laboratories comply with the Standards through peer-based education. However, the ultimate responsibility for compliance rests with the laboratory director and the laboratory organization.

Standard I – Director and Personnel
The reproductive laboratory shall be directed by a qualified board-certified pathologist, other qualified physician, or scientist with doctoral-level or commensurate qualifications that meet or exceed requirements or applicable law. (Exception: The embryology laboratory may be directed by a bachelors or masters-prepared scientist provided he/she has been certified as an Embryology Laboratory Director (ELD) by the American Board of Bioanalysis.) The director must have expertise in biochemistry, biology, and the physiology of reproduction. The director must be qualified to assume professional, scientific, consultative, organizational, administrative, and educational responsibilities for the services provided. The director is responsible for maintaining the Standards, implementing the requirements of the Accreditation Checklists, and documenting compliance. The director must have the authority to fulfill these
responsibilities effectively. The laboratory shall be staffed with a sufficient number of personnel to perform quality laboratory testing. The laboratory shall be organized to ensure that the laboratory director’s responsibilities are fulfilled, lines of authority within the laboratory are defined, and individuals who work within the laboratory fulfill their responsibilities and interact effectively with one another.

Standard II – Physical Resources
There shall be sufficient resources to support the activities of the laboratory. Such resources include, but are not limited to, physical space, testing instruments, reagents, information processing and communication systems, ventilation, public utilities, and storage and disposal facilities. Patients, laboratory personnel and visitors shall be protected from hazardous conditions. Reasonable accommodation shall be made for disabled persons.

Standard III – Quality Management
The laboratory shall have policies and procedures to ensure quality laboratory testing and patient safety. These requirements include, but are not limited to, validation of test systems, analytic quality control, quality management of pre- and postanalytic processes, proficiency testing (or periodic alternative assessments of laboratory test performance), human resource management, information management, ongoing quality improvement, storage of specimens, and appropriate communication with clinicians and patients.

Standard IV – Administrative Requirements
Laboratories accredited by the CAP Laboratory Accreditation Program must comply with the requirements specified in the CAP Accreditation Checklists and Terms of Accreditation. These requirements include, but are not limited to, periodic on-site inspections, interim inspections, interim self-assessment, maintenance of appropriate records and documentation, cooperation with the RLAP, and adherence to its policies.

Revision history
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