Special article: Quality management issues in the ART laboratory

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Abstrak

In the United States, the Clinical Laboratory Improvement Act (CLIA) of 1988 describes requirements and guidelines for implementing a quality control/quality assurance (QC/QA) program for moderate and high complexity laboratories. These requirements and guidelines apply to Assisted Reproductive Technology (ART) laboratories as well. The general topic of QC and QA as it pertains to in vitro fertilization (IVF) and embryo transfer (ET) is extensively reviewed. This review summarizes many of the QC and QA events that contribute to the advancement of knowledge in this biotechnological field. These events include control of the culture environment inside and outside of the incubator, as well as factors that affect culture media. This review also discusses, in considerable detail, the QC and the QA that pertain to equipment used within the laboratory and how to control for potential contaminants, which reside within the laboratory. This review provides evidence to indicate the need for laboratory personnel to monitor quality improvement issues on a continuous basis. Personnel must be willing to change as improvements in technology occur in order to meet the ever-evolving demands of a more difficult patient population. Suggestions for meeting these demands are offered.