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REPRODUCTIVE LABORATORY - SECTION 90

PROPOSED CHECKLIST

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DECEMBER 1998 OUTLINE

ANDROLOGY AND EMBRYOLOGY

EXTENT OF SERVICES PROVIDED
PROFICIENCY TESTING
QUALITY CONTROL AND QUALITY IMPROVEMENT
- SUPERVISION
- PROCEDURE MANUAL
- GENERAL QUALITY CONTROL
- REQUISITIONS, SPECIMEN RECEIPT AND RESULTS REPORTING
- REAGENTS AND CULTURE MEDIA

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- Sperm Processing for Therapeutic Insemination

ANDROLOGY PERSONNEL

EMBRYOLOGY

OOCYTE AND EMBRYO HANDLING
- CULTURE OF SPERM, OOCYTES AND EMBRYOS
- MICROMANIPULATION OF EMBRYOS
- EMBRYO TRANSFER PROCEDURES

RECORDS
INSTRUMENTS AND EQUIPMENT
EMBRYOLOGY PERSONNEL
- EMBRYOLOGY LABORATORY DIRECTOR

CRYOPRESERVATION OF SPERM, OOCYTES AND EMBRYOS

LABORATORY SAFETY

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ANDROLOGY AND EMBRYOLOGY

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EXTENT OF SERVICES PROVIDED

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NOTE: The listing of services provided by the laboratory is now in the Application Questionnaire, and no longer part of this Checklist.

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PROFICIENCY TESTING

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QUESTION: 90:AAAA PHASE: II NEW

Is the laboratory enrolled in appropriate available graded proficiency testing program for the patient testing performed?

PROFICIENCY TESTING:

THE LABORATORY MUST PARTICIPATE IN GRADED INTERLABORATORY COMPARISON TESTING APPROPRIATE TO THE SCOPE OF THE LABORATORY, IF AVAILABLE. THIS MUST INCLUDE ENROLLMENT IN SURVEYS WITH ANALYTES MATCHING THOSE FOR WHICH THE LABORATORY PERFORMS PATIENT TESTING. LABORATORIES WILL NOT BE PENALIZED IF THEY ARE UNABLE TO PARTICIPATE IN AN OVERSUBSCRIBED SURVEY.

REFERENCES: 1) DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION. CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988; FINAL RULE. FEDERAL REGISTER. 1992(FEB 28):7146 [42 CFR 493.801]; 2) THOLEN DW. REFERENCE VALUES AND PARTICIPANT MEANS AS TARGETS IN PROFICIENCY TESTING. ARCH PATHOL LAB MED. 1993;117:885-889; 3) COLLEGE OF AMERICAN PATHOLOGISTS, COMMISSION ON LABORATORY ACCREDITATION. STANDARDS FOR LABORATORY ACCREDITATION; STANDARD III. NORTHFIELD, IL: CAP, 1996; 4) WESTGARD JO, ET AL. LABORATORY PRECISION

PERFORMANCE. STATE OF THE ART VERSUS OPERATING SPECIFICATIONS THAT ASSURE THE ANALYTICAL QUALITY REQUIRED BY CLINICAL LABORATORY IMPROVEMENT AMENDMENTS PROFICIENCY TESTING. ARCH PATHOL LAB MED. 1996;120:621-625; 5) NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS. CONTINUOUS QUALITY IMPROVEMENT: ESSENTIAL MANAGEMENT APPROACHES AND THEIR USE IN PROFICIENCY TESTING; PROPOSED GUIDELINE GP22-P. WAYNE, PA: NCCLS, 1997.

COMMENTARY: 90:AAAA PHASE: II

THE LABORATORY MUST BE ENROLLED IN A PROFICIENCY TESTING PROGRAM APPROPRIATE FOR THE PATIENT TESTING PERFORMED.

QUESTION: 90:AAAC PHASE: II NEW

Does the laboratory integrate the external Surveys samples within the routine laboratory workload, and are those samples analyzed by personnel who routinely test patient samples, using the same primary method systems as for patient samples?

NOTE: Replicate analysis of Surveys samples is acceptable only if patient specimens are routinely analyzed in the same manner. If the laboratory uses multiple methods for an analyte, Surveys samples should be analyzed by the primary method. There must not be any interlaboratory communication on proficiency testing data before results reporting.

COMMENTARY: 90:AAAC PHASE: II

EXTERNAL PROFICIENCY TESTING SAMPLES MUST BE INTEGRATED WITHIN THE ROUTINE LABORATORY WORKLOAD, AND ANALYZED BY PERSONNEL WHO ROUTINELY TEST PATIENT SAMPLES, USING PRIMARY METHOD SYSTEMS. ONE OR MORE OF THESE REQUIREMENTS ARE NOT BEING MET BY THE LABORATORY, AND MUST BE CORRECTED. THERE MUST NOT BE ANY INTERLABORATORY COMMUNICATION ON PROFICIENCY TESTING DATA BEFORE RESULTS REPORTING. THE EDUCATIONAL PURPOSES AND DOCUMENTATION OF PROFICIENCY ARE BEST SERVED BY A ROTATION THAT ALLOWS ALL TECHNOLOGISTS TO BE INVOLVED IN THE PROFICIENCY TESTING PROGRAM. RECORDS OF THESE STUDIES MUST BE KEPT AND CAN BE AN IMPORTANT PART OF THE PERSONNEL AND CONTINUING EDUCATION FILES OF THE INDIVIDUALS.

REFERENCE: DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION. CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988; FINAL RULE. FEDERAL REGISTER. 1992(FEB 28):7146 [42 CFR 493.801(b)].

QUESTION: 90:AAAE PHASE: II NEW

Is there documented evidence of active review by the laboratory director or designated supervisor(s) of the Surveys results?

COMMENTARY: 90:AAAE PHASE: II

THERE IS INSUFFICIENT DOCUMENTED EVIDENCE OF ACTIVE REVIEW BY THE LABORATORY DIRECTOR OR SUPERVISOR OF PROFICIENCY SURVEYS RESULTS.

REFERENCES: 1) DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION. CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988; FINAL RULE. FEDERAL REGISTER. 1992(FEB 28):7173 [42 CFR 493.1407(e)(4)(iii)]; 2) NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS. USING PROFICIENCY TESTING (PT) TO IMPROVE THE CLINICAL LABORATORY; APPROVED GUIDELINE GP27-A. WAYNE, PA: NCCLS, 1998.

QUESTION: 90:AAAF PHASE: II NEW

Is there evidence of evaluation and, if indicated, prompt corrective action in response to "unacceptable" results on the Surveys report?

COMMENTARY: 90:AAAF PHASE: II

THERE IS INSUFFICIENT EVIDENCE OF EVALUATION AND, IF INDICATED, CORRECTIVE ACTION IN RESPONSE TO EACH "UNACCEPTABLE" RESULT ON THE PROFICIENCY SURVEYS REPORT. THE EVALUATION MUST DOCUMENT THE SPECIFIC REASON(S) FOR THE "UNACCEPTABLE" RESULTS AND ACTIONS TAKEN TO REDUCE THE LIKELIHOOD OF RECURRENCE. THIS MUST BE DONE WITHIN ONE MONTH AFTER THE LABORATORY RECEIVES ITS SURVEYS EVALUATION.

REFERENCES: 1) DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION. CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988; FINAL RULE. FEDERAL REGISTER. 1992(FEB 28):7173 [42 CFR 493.1407(e)(4)(iv)]; 2) NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS. USING PROFICIENCY TESTING (PT) TO IMPROVE THE CLINICAL LABORATORY; APPROVED GUIDELINE GP27-A. WAYNE, PA: NCCLS, 1998.

QUESTION: 90:AAAG PHASE: II NEW

For analytes where graded proficiency testing is not available, are other procedures used to validate performance at least semi-annually?

NOTE: Other appropriate procedures include: participation in ungraded proficiency survey programs, split sample analysis with reference or other laboratories, split samples with an established in-house method, assayed material, regional pools, clinical validation by chart review, or other suitable and documented means. It is the responsibility of the laboratory director to define such procedures, as applicable, in accordance with good clinical and scientific laboratory practice.

COMMENTARY: 90:AAAG PHASE: II

FOR ANALYTES WHERE GRADED PROFICIENCY TESTING IS NOT AVAILABLE, PERFORMANCE MUST BE CHECKED AT LEAST SEMI-ANNUALLY WITH APPROPRIATE PROCEDURES SUCH AS: PARTICIPATION IN UNGRADED PROFICIENCY SURVEYS, SPLIT SAMPLE ANALYSIS WITH REFERENCE OR OTHER LABORATORIES, SPLIT SAMPLES WITH AN ESTABLISHED IN-HOUSE METHOD, ASSAYED MATERIAL, REGIONAL POOLS, CLINICAL VALIDATION BY CHART REVIEW, OR OTHER SUITABLE AND DOCUMENTED MEANS. IT IS THE RESPONSIBILITY OF THE LABORATORY DIRECTOR TO DEFINE SUCH PROCEDURES, AS APPLICABLE, IN ACCORDANCE WITH GOOD CLINICAL AND SCIENTIFIC LABORATORY PRACTICE.

REFERENCES: 1) DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION. CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988; FINAL RULE. FEDERAL REGISTER. 1992(FEB 28):7184 [42 CFR 493.1709]; 2) JORGENSEN N, ET AL. SEMEN ANALYSIS PERFORMED BY DIFFERENT LABORATORY TEAMS: AN INTERVARIATION STUDY. INT J ANDROL. 1997;20:201-218; 3) SHAHANGIAN S, ET AL. A SYSTEM TO MONITOR A PORTION OF THE TOTAL TESTING PROCESS IN MEDICAL CLINICS AND LABORATORIES. FEASIBILITY OF A SPLIT-SPECIMEN DESIGN. ARCH PATHOL LAB MED. 1998;122:503-511.

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QUALITY CONTROL AND QUALITY IMPROVEMENT

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A detailed quality control program specific for the techniques in use is essential for semen analysis, special sperm tests, the identification of oocytes, and the maintenance of the developmental capacity of these oocytes during the procedures of fertilization, embryo culture, and embryo transfer.

The quality control program should be clearly defined and documented, including general policies and delegation of responsibilities.

SUPERVISION

The quality control program must be under active surveillance by the supervisor, with documented review at least weekly. Secondary review should occur at least monthly by the laboratory director or a designee not performing the weekly review (i.e., the same person cannot perform both weekly and monthly reviews).

QUESTION: 90:0440 PHASE: II

Is there a document for the design and evaluation of the laboratory quality control (QC) and quality improvement (QI) programs??

NOTE: The QC/QI program must provide the system design and evaluation of proper patient identification and preparation; specimen collection, identification, preservation, transportation, and processing; and accurate result reporting. This system must ensure optimum patient specimen and result integrity throughout the pre-analytical, analytical, and post-analytical processes. Opportunities for system improvement are identified and, based on such evaluations, corrective plans are developed and implemented.

QUALITY CONTROL AND QUALITY IMPROVEMENT:

THE QUALITY CONTROL/QUALITY IMPROVEMENT (QC/QI) PROGRAM IN THE REPRODUCTIVE LABORATORY SHOULD BE CLEARLY DEFINED AND WELL-ORGANIZED. QC RESULTS MUST BE UNDER ACTIVE SURVEILLANCE BY THE SUPERVISOR, WITH DOCUMENTED REVIEW AT LEAST WEEKLY. THE LABORATORY DIRECTOR OR DESIGNEE OTHER THAN THE WEEKLY REVIEWER SHOULD PERFORM SECONDARY QC REVIEW AT LEAST MONTHLY. THE QI PROGRAM MUST PROVIDE THE SYSTEM DESIGN AND EVALUATION OF PROPER PATIENT IDENTIFICATION AND PREPARATION; SPECIMEN COLLECTION, IDENTIFICATION, PRESERVATION, TRANSPORTATION, AND PROCESSING; AND ACCURATE RESULT REPORTING. THIS SYSTEM MUST ENSURE OPTIMUM PATIENT SPECIMEN AND RESULT INTEGRITY THROUGHOUT THE PREANALYTICAL, ANALYTICAL, AND POST-ANALYTIC PROCESSES. OPPORTUNITIES FOR SYSTEM IMPROVEMENT ARE IDENTIFIED AND, BASED ON SUCH EVALUATIONS, CORRECTIVE PLANS ARE DEVELOPED AND IMPLEMENTED.

COMMENTARY: 90:0440 PHASE: II

THE LABORATORY MUST HAVE A COMPREHENSIVE PROGRAM FOR QUALITY CONTROL AND QUALITY IMPROVEMENT.

REFERENCES: 1) BERWICK DM. CONTINUOUS IMPROVEMENT AS AN IDEAL IN HEALTH CARE. N ENGL J MED. 1989;320:53-56; 2) BYRD W. QUALITY ASSURANCE IN THE REPRODUCTIVE BIOLOGY LABORATORY. ARCH PATHOL LAB MED. 1992;116:418-422; 3) MICHELMANN HW. QUALITY MANAGEMENT IN THE ANDROLOGY LABORATORY. INT J ANDROL. 1997;20(SUPPL 3):50-54; 4) SOUTER VL, ET AL. LABORATORY TECHNIQUES FOR SEMEN ANALYSIS: A SCOTTISH SURVEY. HEALTH BULL (EDINB) 1997;55:140-149.

QUESTION: 90:AAAM PHASE: II NEW

Is there a documented procedure describing methods for patient identification, patient preparation, specimen collection and labeling, specimen preservation, and conditions for transportation, and storage before testing, consistent with good laboratory practice?

COMMENTARY: 90:AAAM PHASE: II

THE LABORATORY LACKS OR HAS AN INCOMPLETELY DOCUMENTED PROCEDURE DESCRIBING METHODS FOR PATIENT IDENTIFICATION, PATIENT PREPARATION, SPECIMEN COLLECTION AND LABELLING, SPECIMEN PRESERVATION, CONDITIONS FOR TRANSPORTATION, AND STORAGE BEFORE TESTING. SUCH PROTOCOLS MUST BE CONSISTENT WITH GOOD LABORATORY PRACTICE.

REFERENCE: BYRD W. QUALITY ASSURANCE IN THE REPRODUCTIVE BIOLOGY LABORATORY. ARCH PATHOL LAB MED. 1992;116:418-422.

QUESTION: 90:AAAN PHASE: II NEW

Is there evidence of active review of results of controls, instrument maintenance and function, temperature, *etc.* for routine procedures on all shifts?

COMMENTARY: 90:AAAN PHASE: II

THERE IS INSUFFICIENT EVIDENCE OF ACTIVE REVIEW OF RECORDS OF CONTROLS, INSTRUMENT FUNCTION AND MAINTENANCE, TEMPERATURES, *etc.*, ON ALL SHIFTS.

REFERENCE: BYRD W. QUALITY ASSURANCE IN THE REPRODUCTIVE BIOLOGY LABORATORY. ARCH PATHOL LAB MED. 1992;116:418-422.

QUESTION: 90:AAAP PHASE: II NEW

Is there a documented system in operation to detect and correct significant clerical and analytical errors, and unusual laboratory results?

COMMENTARY: 90:AAAP PHASE: II

THE LABORATORY MUST HAVE A DOCUMENTED SYSTEM IN OPERATION TO DETECT AND CORRECT SIGNIFICANT CLERICAL AND ANALYTICAL ERRORS, AND UNUSUAL LABORATORY RESULTS. ONE COMMON METHOD IS REVIEW OF RESULTS BY A QUALIFIED PERSON (TECHNOLOGIST, SUPERVISOR, PATHOLOGIST) BEFORE RELEASE FROM THE LABORATORY, BUT THERE IS NO REQUIREMENT FOR SUPERVISORY REVIEW OF ALL REPORTED DATA. THE SELECTIVE USE OF DELTA CHECKS ALSO MAY BE USEFUL IN DETECTING CLERICAL ERRORS IN CONSECUTIVE SAMPLES FROM THE SAME PATIENT. IN COMPUTERIZED LABORATORIES, THERE SHOULD BE AUTOMATIC "TRAPS" FOR IMPROBABLE RESULTS.

REFERENCES: 1) LAESSIG RH, ET AL. QUALITY CONTROL AND QUALITY ASSURANCE. CLINICS LAB MED. 1986;6:317-327; 2) BACHER P. QUALITY ASSURANCE: AN ACCREDITATION PERSPECTIVE. LAB MED. 1989;20:159-162; 3) DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION. CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988; FEDERAL REGISTER. 1996 (NOV 1):905 [42 CFR 493.1703].

QUESTION: 90:AAAQ PHASE: II NEW

Does the system provide for the timely correction of errors?

COMMENTARY: 90:AAAQ PHASE: II

THE SYSTEM FOR DETECTING CLERICAL ERRORS, SIGNIFICANT ANALYTICAL ERRORS, AND UNUSUAL LABORATORY RESULTS MUST PROVIDE FOR TIMELY CORRECTION OF ERRORS, *i.e.*, BEFORE RESULTS BECOME AVAILABLE FOR CLINICAL DECISION MAKING. FOR SUSPECTED ERRORS DETECTED BY THE END USER AFTER REPORTING, CORRECTIONS MUST BE PROMPTLY MADE IF SUCH ERRORS ARE CONFIRMED BY THE LABORATORY.

REFERENCES: 1) KILSHAW D. QUALITY ASSURANCE. I. PHILOSOPHY AND BASIC PRINCIPLES. MED LAB SCIENCES. 1986;43:377-381; 2) BYRD W. QUALITY ASSURANCE IN THE REPRODUCTIVE BIOLOGY LABORATORY. ARCH PATHOL LAB MED. 1992;116:418-422.

QUESTION: 90:AAAR PHASE: II NEW

In the absence of on-site supervisors, are the results of tests performed by personnel reviewed by the laboratory director or person in charge of the reproductive laboratory on the next routine working shift?

COMMENTARY: 90:AAAR PHASE: II

IN THE ABSENCE OF ON-SITE SUPERVISORS, THE RESULTS OF TESTS PERFORMED BY PERSONNEL MUST BE REVIEWED BY THE LABORATORY DIRECTOR, OR PERSON IN CHARGE OF THE LABORATORY ON THE NEXT ROUTINE WORKING SHIFT.

REFERENCE: DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION. CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988; FINAL RULE. FEDERAL REGISTER. 1992(FEB 28):7172 [42 CFR 493.1463(a)].

Is there evidence of active review by the director or designee of the following:

QUESTION: 90:SXAB PHASE: II

Quality control of routine procedures?

THERE MUST BE EVIDENCE OF ACTIVE REVIEW BY THE DIRECTOR OR DESIGNEE OF THE FOLLOWING:

COMMENTARY: 90:SXAB PHASE: II

QUALITY CONTROL OF ROUTINE PROCEDURES.

REFERENCE: GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58 (SUPPL 1): SECTION VI, A, 2 and 10.

QUESTION: 90:SXAD PHASE: II

Documentation of the type of reagents that are used and their source?

COMMENTARY: 90:SXAD PHASE: II

DOCUMENTATION OF THE TYPE OF REAGENTS THAT ARE USED AND THEIR SOURCE.

REFERENCE: GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58 (SUPPL 1): SECTION VI, A, 2 and 10.

QUESTION: 90:SXAE PHASE: II

Instrument function checks, including temperature checks, adequate gas flow and concentration in the incubators?

COMMENTARY: 90:SXAE PHASE: II

INSTRUMENT FUNCTION CHECKS MUST BE DOCUMENTED TO DETECT TRENDS OR MALFUNCTIONS.

REFERENCES: 1) GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58 (SUPPL 1): SECTION VI, A, 2 and 10; 2) DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION. CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988; FINAL RULE. FEDERAL REGISTER. 1992(FEB 28):7166 [42 CFR 493.1215]; 3) MORTIMER D. PRACTICAL LABORATORY ANDROLOGY. NEW YORK: OXFORD UNIVERSITY PRESS. 1992.

PROCEDURE MANUAL

The complete procedure manual should be written in substantial compliance and meet the intent of the National Committee for Clinical Laboratory Standards (NCCLS) GP2-A3 (1996) without having to precisely copy it. The procedure manual should be available to, and used by, personnel at the workbench and must include: principle, clinical significance, specimen type, required reagents, calibration, quality control, procedural steps, calculations, reference ranges, and interpretation.

The inspection team should review the procedure manual in detail to understand the laboratory's standard operating procedures, ensure that all significant information and instructions are included, and that actual practice matches the contents of the procedure manuals. Deficiencies detected in the procedure manual should be listed in the Inspector's Summation Report.

QUESTION: 90:AAAT PHASE: II

Is a complete procedure manual available at the workbench or in the work area?

NOTE 1: The use of inserts provided by a manufacturer is not acceptable in place of a procedure manual. However, such inserts may be used as part of a procedure description, if the insert accurately and precisely describes the procedure as performed in the laboratory. Any variation from this printed or electronic procedure must be detailed in the procedure manual. In all cases, appropriate reviews must occur.

NOTE 2: A manufacturer's procedure manual for an instrument/ reagent system may be acceptable as a component of the overall departmental procedures. Any modification to or deviation from the procedure manual must be clearly documented.

NOTE 3: Card files or similar systems that summarize key information are acceptable for use as quick reference at the workbench provided that:

A. A complete manual is available for reference.
B. The card file or similar system corresponds to the complete manual.

NOTE 4: Electronic (computerized) manuals are fully acceptable; there is no requirement for paper copies, so long as the electronic versions are readily available to all personnel.

PROCEDURE MANUAL:

THERE MUST BE A COMPLETE PROCEDURE MANUAL AVAILABLE TO, AND USED BY, PERSONNEL AT THE WORKBENCH. THE ELEMENTS SHOULD INCLUDE: PRINCIPLE, CLINICAL SIGNIFICANCE, SPECIMEN TYPE (INCLUDING CONTAINER AND PRESERVATIVES AND/OR ANTICOAGULANTS), REQUIRED REAGENTS, CALIBRATION, QUALITY CONTROL, PROCEDURAL STEPS, CALCULATIONS, REFERENCE RANGES, AND INTERPRETATION.

COMMENTARY: 90:AAAT PHASE: II

A WRITTEN PROCEDURE MANUAL MUST BE DEVELOPED FOR THE REPRODUCTIVE LABORATORY.

NOTE 1: THE USE OF INSERTS PROVIDED BY A MANUFACTURER IS NOT ACCEPTABLE IN PLACE OF A PROCEDURE MANUAL. HOWEVER, SUCH INSERTS MAY BE USED AS PART OF A PROCEDURE DESCRIPTION, IF THE INSERT ACCURATELY AND COMPLETELY DESCRIBES THE PROCEDURE AS PERFORMED IN THE LABORATORY. ANY VARIATION FROM THIS PRINTED PROCEDURE MUST BE DETAILED IN THE PROCEDURE MANUAL. IN ALL CASES, APPROPRIATE REVIEWS MUST OCCUR.

NOTE 2: A MANUFACTURER'S PROCEDURE MANUAL FOR AN INSTRUMENT/REAGENT SYSTEM MAY BE ACCEPTABLE AS A COMPONENT

OF THE OVERALL DEPARTMENTAL PROCEDURES. ANY MODIFICATION TO OR DEVIATION FROM THE PROCEDURE MANUAL MUST BE CLEARLY DOCUMENTED.

NOTE 3: CARD FILES OR SIMILAR SYSTEMS THAT SUMMARIZE KEY INFORMATION ARE ACCEPTABLE FOR USE AS QUICK REFERENCE AT THE WORKBENCH PROVIDED THAT:

A. A COMPLETE MANUAL IS AVAILABLE FOR REFERENCE.
B. THE CARD FILE OR SIMILAR SYSTEM CORRESPONDS TO THE COMPLETE MANUAL.

NOTE 4: ELECTRONIC (COMPUTERIZED) PROCEDURE MANUALS ARE FULLY ACCEPTABLE; THERE IS NO REQUIREMENT FOR PAPER COPIES, SO LONG AS THE ELECTRONIC VERSIONS ARE READILY AVAILABLE TO ALL PERSONNEL.

REFERENCES: 1) DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION. CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988; FINAL RULE. FEDERAL REGISTER. 1992(FEB 28):7164 [42 CFR 493.1211]; 2) NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS. CLINICAL LABORATORY TECHNICAL PROCEDURE MANUALS - THIRD EDITION; APPROVED GUIDELINE GP2-A3. WAYNE, PA: NCCLS, 1996.

QUESTION: 90:AAAY PHASE: II

Is there documentation of at least annual review of all policies and procedures in the laboratory by the current laboratory director or designee?

NOTE: The director must ensure that the collection of policies and technical protocols is complete, current, and has been thoroughly reviewed by a knowledgeable person. Technical approaches must be scientifically valid and clinically relevant. To minimize the burden on the laboratory and reviewer(s), it is suggested that a schedule be developed whereby roughly 1/12 of all procedures are reviewed monthly. While each procedure should have evidence of annual review, signature or initials on each page of a procedure is not required. A single Title Page or Index of all procedures with only one signature is not sufficient documentation that each procedure has been carefully reviewed.

COMMENTARY: 90:AAAY PHASE: II

THERE MUST BE DOCUMENTATION OF AT LEAST ANNUAL REVIEW OF ALL POLICIES AND PROCEDURES IN THE LABORATORY BY THE CURRENT LABORATORY DIRECTOR OR DESIGNEE. THE DIRECTOR IS RESPONSIBLE FOR ENSURING THAT THE COLLECTION OF TECHNICAL PROTOCOLS IS COMPLETE,

CURRENT, AND HAS BEEN THOROUGHLY REVIEWED BY A KNOWLEDGEABLE PERSON. TECHNICAL APPROACHES MUST BE SCIENTIFICALLY VALID AND CLINICALLY RELEVANT. TO MINIMIZE THE BURDEN ON THE LABORATORY AND REVIEWER(S), IT IS SUGGESTED THAT A SCHEDULE BE DEVELOPED WHEREBY ROUGHLY 1/12 OF ALL PROCEDURES ARE REVIEWED MONTHLY. WHILE EACH PROCEDURE SHOULD HAVE EVIDENCE OF ANNUAL REVIEW, SIGNATURE OR INITIALS ON EACH PAGE OF A PROCEDURE IS NOT REQUIRED. A SINGLE TITLE PAGE OR INDEX OF ALL PROCEDURES WITH ONLY ONE SIGNATURE IS NOT SUFFICIENT DOCUMENTATION THAT EACH PROCEDURE HAS BEEN CAREFULLY REVIEWED.

REFERENCES: 1) DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION. CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988; FINAL RULE. FEDERAL REGISTER. 1992(FEB 28):7173 [42 CFR 493.1407(e)(13)]; 2) NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS. CLINICAL LABORATORY TECHNICAL PROCEDURE MANUALS - THIRD EDITION; APPROVED GUIDELINE GP2-A3. WAYNE, PA: NCCLS, 1996.

QUESTION: 90:ABAA PHASE: II

Does the laboratory have a system documenting that all personnel are knowledgeable about the contents of procedure manuals (including changes) relevant to the scope of their testing activities?

COMMENTARY: 90:ABAA PHASE: II

THE LABORATORY MUST HAVE A SYSTEM DOCUMENTING THAT ALL PERSONNEL ARE KNOWLEDGEABLE ABOUT THE CONTENTS OF PROCEDURE MANUALS (INCLUDING CHANGES) RELEVANT TO THE SCOPE OF THEIR TESTING ACTIVITIES. THE FORM OF THIS SYSTEM IS AT THE DISCRETION OF THE LABORATORY DIRECTOR.

QUESTION: 90:ABAB PHASE: II

If there is a change in directorship, does the new director ensure (over a reasonable period of time) that laboratory procedures are well-documented and undergo at least annual review?

COMMENTARY: 90:ABAB PHASE: II

IF THERE IS A CHANGE IN DIRECTORSHIP OF THE LABORATORY, THE NEW DIRECTOR MUST ENSURE (OVER A REASONABLE PERIOD OF TIME) THAT ALL

CHEMISTRY LABORATORY PROCEDURES ARE WELL-DOCUMENTED AND UNDERGO AT LEAST ANNUAL REVIEW.

REFERENCE: DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION. CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988; FINAL RULE. FEDERAL REGISTER. 1992(FEB 28):7164 [42 CFR 493.12119(e)].

QUESTION: 90:ABAC PHASE: II

When a procedure is discontinued, is a copy maintained for at least two years, recording initial date of use and retirement date?

COMMENTARY: 90:ABAC PHASE: II

A COPY OF A DISCONTINUED PROCEDURE MUST BE MAINTAINED FOR AT LEAST TWO YEARS, RECORDING INITIAL DATE OF USE AND RETIREMENT DATE.

REFERENCE: DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION. CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988; FINAL RULE. FEDERAL REGISTER. 1922(FEB 28):7164 [42 CFR 493.12119(g)].

GENERAL QUALITY CONTROL

QUESTION: 90:AAAK PHASE: II NEW

Is there a schedule or system AVAILABLE AT THE INSTRUMENT for the regular checking of the critical operating characteristics for all instruments in use?

NOTE: This must include, but is not limited to electronic, mechanical, and operational checks. The procedure and schedule must be as thorough and as frequent as specified by the manufacturer.

GENERAL QUALITY CONTROL:

COMMENTARY: 90:AAAK PHASE: II

THERE MUST BE A ROUTINE PLAN OR SCHEDULE AVAILABLE AT THE INSTRUMENT FOR THE REGULAR CHECKING OF THE CRITICAL OPERATING CHARACTERISTICS OF ALL THE INSTRUMENTS IN USE. THE LABORATORY SHOULD HAVE AN ORGANIZED SYSTEM FOR MONITORING AND MAINTAINING ALL INSTRUMENTS. THIS MUST INCLUDE, BUT IS NOT LIMITED TO ELECTRONIC, MECHANICAL, AND OPERATIONAL CHECKS. THE PROCEDURE AND SCHEDULE MUST BE AS THOROUGH AND AS FREQUENT AS SPECIFIED BY THE MANUFACTURER. FUNCTION CHECKS SHOULD BE DESIGNED TO CHECK THE CRITICAL OPERATING CHARACTERISTICS TO DETECT DRIFT, INSTABILITY OR MALFUNCTION, BEFORE THE PROBLEM IS ALLOWED TO AFFECT TEST RESULTS. ALL SERVICING AND REPAIRS SHOULD BE DOCUMENTED. THE INSPECTOR SHOULD HAVE IDENTIFIED THE SPECIFIC INSTRUMENTS INVOLVED AT THE SUMMATION CONFERENCE.

QUESTION: 90:0490 PHASE: II

Has a statistically valid target range been established for each lot of control material by repetitive analysis in runs that include previously tested control materials (quantitative tests)?

COMMENTARY: 90:0490 PHASE: II

THE LABORATORY MUST ESTABLISH A STATISTICALLY VALID TARGET RANGE FOR EACH LOT BY REPETITIVE ANALYSIS IN RUNS THAT INCLUDE PREVIOUSLY TESTED CONTROL MATERIALS (QUANTITATIVE TESTS).

REFERENCE: LAESSIG RH, ET AL. QUALITY CONTROL AND QUALITY ASSURANCE. CLINICS LAB MED. 1986;6:317-327.

QUESTION: 90:0510 PHASE: II

Are control specimens tested in the same manner as patient samples?

COMMENTARY: 90:0510 PHASE: II

IT IS IMPLICIT IN QUALITY CONTROL THAT CONTROL SPECIMENS ARE TESTED IN THE SAME MANNER AS PATIENT SPECIMENS. MOREOVER, QC SPECIMENS MUST BE ANALYZED BY PERSONNEL WHO ROUTINELY PERFORM PATIENT TESTING - THIS DOES NOT IMPLY THAT EACH OPERATOR MUST PERFORM QC DAILY, SO LONG AS EACH INSTRUMENT AND/OR TEST SYSTEM HAS QC PERFORMED AT REQUIRED FREQUENCIES. TO THE EXTENT POSSIBLE, ALL STEPS OF THE TESTING PROCESS MUST BE CONTROLLED, RECOGNIZING THAT PRE-ANALYTIC AND

POST-ANALYTIC VARIABLES MAY DIFFER FROM THOSE ENCOUNTERED WITH PATIENTS.

REFERENCE: DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION. CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988; FINAL RULE. FEDERAL REGISTER. 1992(FEB 28):7166 [42 CFR 493.1218(f)(1)].

QUESTION: 90:0520 PHASE: II

Are the results of controls verified for acceptability before reporting results?

COMMENTARY: 90:0520 PHASE: II

CONTROLS MUST BE REVIEWED BEFORE REPORTING PATIENT RESULTS. IT IS IMPLICIT IN QUALITY CONTROL THAT PATIENT TEST RESULTS WILL NOT BE REPORTED WHEN CONTROLS DO NOT YIELD ACCEPTABLE RESULTS.

REFERENCE: DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION. CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988; FINAL RULE. FEDERAL REGISTER. 1992(FEB 28):7166 [42 CFR 493.1218(e)].

REQUISITIONS, SPECIMEN RECEIPT, AND RESULTS REPORTING

QUESTION: 90:SEAB PHASE: II NEW

Are there specific patient instructions for collection and prompt delivery of a semen sample to the laboratory?

NOTE: This should be written in simple terms in a language readily understood by the patient. Elements should include the need to abstain from ejaculation for 2-5 days before masturbation, avoidance of lubricants and other contamination, completeness of collection, use of the supplied container, maintenance of sample temperature, and prompt delivery.

REQUISITIONS, SPECIMEN RECEIPT, AND RESULTS REPORTING:

COMMENTARY: 90:SEAB PHASE: II

PATIENTS MUST BE PROVIDED WITH SPECIFIC INSTRUCTIONS FOR COLLECTION AND PROMPT DELIVERY OF A SEMEN SAMPLE TO THE LABORATORY. THIS SHOULD BE WRITTEN IN SIMPLE TERMS IN A LANGUAGE READILY UNDERSTOOD BY THE PATIENT. ELEMENTS SHOULD INCLUDE THE NEED TO ABSTAIN FROM EJACULATION FOR 2-5 DAYS BEFORE MASTURBATION, AVOIDANCE OF LUBRICANTS AND OTHER CONTAMINATION, COMPLETENESS OF COLLECTION, USE OF THE SUPPLIED CONTAINER, MAINTENANCE OF SAMPLE TEMPERATURE, AND PROMPT DELIVERY.

QUESTION: 90:0880 PHASE: II

Are there documented criteria for the rejection of unacceptable specimens or the special handling of sub-optimal specimens?

NOTE: This question is not intended to imply that all "unacceptable" specimens be discarded or not analyzed. For example, if an unacceptable specimen is received, there must be a mechanism to notify the requesting physician, and to note the condition of the sample on the report. Many semen samples are sub-optimal; all samples should be evaluated and unusual properties noted. The laboratory may wish to record that a dialogue was held with the requesting physician.

COMMENTARY: 90:0880 PHASE: II

DOCUMENTED CRITERIA MUST BE DEVELOPED FOR ACCEPTABILITY OR REJECTION OF SPECIMENS. IF COMPROMISED SPECIMENS ARE ACCEPTED, THE FINAL REPORT MUST HAVE A NOTE INDICATING THE NATURE OF THE PROBLEM AND, IF APPLICABLE, CAUTION IN INTERPRETING THE RESULT. THE LABORATORY MAY WISH TO RECORD THAT A DIALOGUE WAS HELD WITH THE REQUESTING PHYSICIAN.

Are semen specimens accompanied by the following collection information, and are records maintained on the following:

QUESTION: 90:0930 PHASE: II

Method of collection?

SEMEN SPECIMENS SHOULD BE ACCOMPANIED BY THE FOLLOWING COLLECTION INFORMATION AND RECORDS SHOULD BE MAINTAINED ON THE FOLLOWING:

COMMENTARY: 90:0930 PHASE: II

METHOD OF COLLECTION.

REFERENCES: 1) WORLD HEALTH ORGANIZATION LABORATORY MANUAL FOR THE EXAMINATION OF HUMAN SEMEN AND SPERM-CERVICAL MUCUS INTERACTION, THIRD EDITION. NEW YORK: CAMBRIDGE UNIVERSITY PRESS, 1992; 2) MORTIMER D. PRACTICAL LABORATORY ANDROLOGY. NEW YORK: OXFORD UNIVERSITY PRESS. 1994.

QUESTION: 90:0940 PHASE: II

Type of specimen container?

COMMENTARY: 90:0940 PHASE: II

TYPE OF SPECIMEN CONTAINER.

REFERENCES: 1) WORLD HEALTH ORGANIZATION LABORATORY MANUAL FOR THE EXAMINATION OF HUMAN SEMEN AND SPERM-CERVICAL MUCUS INTERACTION, THIRD EDITION. NEW YORK: CAMBRIDGE UNIVERSITY PRESS, 1992; 2) MORTIMER D. PRACTICAL LABORATORY ANDROLOGY. NEW YORK: OXFORD UNIVERSITY PRESS. 1994.

QUESTION: 90:0950 PHASE: II

Days of abstinence?

COMMENTARY: 90:0950 PHASE: II

DAYS OF ABSTINENCE.

REFERENCES: 1) WORLD HEALTH ORGANIZATION LABORATORY MANUAL FOR THE EXAMINATION OF HUMAN SEMEN AND SPERM-CERVICAL MUCUS INTERACTION, THIRD EDITION. NEW YORK: CAMBRIDGE UNIVERSITY PRESS, 1992; 2) MORTIMER D. PRACTICAL LABORATORY ANDROLOGY. NEW YORK: OXFORD UNIVERSITY PRESS. 1994.

QUESTION: 90:0960 PHASE: II

Collection or transport problems (*e.g.*, incomplete specimen, exposure to temperature extremes)?

COMMENTARY: 90:0960 PHASE: II

COLLECTION OR TRANSPORT PROBLEM (*e.g.*, INCOMPLETE SPECIMEN, EXPOSURE TO TEMPERATURE EXTREMES).

REFERENCE: WORLD HEALTH ORGANIZATION LABORATORY MANUAL FOR THE EXAMINATION OF HUMAN SEMEN AND SPERM-CERVICAL MUCUS INTERACTION, THIRD EDITION. NEW YORK: CAMBRIDGE UNIVERSITY PRESS, 1992.

QUESTION: 90:0980 PHASE: II

Abnormalities of liquefaction?

COMMENTARY: 90:0980 PHASE: II

ABNORMALITIES OF LIQUEFACTION.

REFERENCES: 1) WORLD HEALTH ORGANIZATION LABORATORY MANUAL FOR THE EXAMINATION OF HUMAN SEMEN AND SPERM-CERVICAL MUCUS INTERACTION, THIRD EDITION. NEW YORK: CAMBRIDGE UNIVERSITY PRESS, 1992; 2) MORTIMER D. PRACTICAL LABORATORY ANDROLOGY. NEW YORK: OXFORD UNIVERSITY PRESS. 1994.

QUESTION: 90:0990 PHASE: II

Time of specimen receipt and analysis?

COMMENTARY: 90:0990 PHASE: II

TIME OF SPECIMEN RECEIPT AND ANALYSIS.

REFERENCES: 1) WORLD HEALTH ORGANIZATION LABORATORY MANUAL FOR THE EXAMINATION OF HUMAN SEMEN AND SPERM-CERVICAL MUCUS INTERACTION, THIRD EDITION. NEW YORK: CAMBRIDGE UNIVERSITY PRESS, 1992; 2) MORTIMER D. PRACTICAL LABORATORY ANDROLOGY. NEW YORK: OXFORD UNIVERSITY PRESS. 1994.

QUESTION: 90:1000 PHASE: II

Is sperm motility percent and progression routinely evaluated within one hour of receipt?

COMMENTARY: 90:1000 PHASE: II

SPERM MOTILITY PERCENT AND PROGRESSION MUST BE EVALUATED WITHIN ONE HOUR OF RECEIPT.

REFERENCES: 1) WORLD HEALTH ORGANIZATION LABORATORY MANUAL FOR THE EXAMINATION OF HUMAN SEMEN AND SPERM-CERVICAL MUCUS INTERACTION, THIRD EDITION. NEW YORK: CAMBRIDGE UNIVERSITY PRESS, 1992; 2) MORTIMER D. PRACTICAL LABORATORY ANDROLOGY. NEW YORK: OXFORD UNIVERSITY PRESS. 1994.

QUESTION: 90:1010 PHASE: II

Are all semen specimens given sufficient time for liquefaction before testing?

COMMENTARY: 90:1010 PHASE: II

ALL SEMEN SPECIMENS MUST BE GIVEN SUFFICIENT TIME FOR LIQUEFACTION BEFORE TESTING.

REFERENCE: WORLD HEALTH ORGANIZATION LABORATORY MANUAL FOR THE EXAMINATION OF HUMAN SEMEN AND SPERM-CERVICAL MUCUS INTERACTION, THIRD EDITION. NEW YORK: CAMBRIDGE UNIVERSITY PRESS, 1992.

QUESTION: 90:1020 PHASE: II

Are semen specimens mixed thoroughly before testing?

COMMENTARY: 90:1020 PHASE: II

SEMEN SPECIMENS MUST BE MIXED THOROUGHLY BEFORE TESTING.

REFERENCES: 1) WORLD HEALTH ORGANIZATION LABORATORY MANUAL FOR THE EXAMINATION OF HUMAN SEMEN AND SPERM-CERVICAL MUCUS INTERACTION, THIRD EDITION. NEW YORK: CAMBRIDGE UNIVERSITY PRESS, 1992; 2) MORTIMER D. PRACTICAL LABORATORY ANDROLOGY. NEW YORK: OXFORD UNIVERSITY PRESS. 1994.

QUESTION: 90:1030 PHASE: II

Are all characteristics of the semen specimens noted and reported (*e.g.*, gelatinous clumps, viscosity, contaminants, erythrocytes, *etc.*)?

COMMENTARY: 90:1030 PHASE: II

ALL CHARACTERISTICS OF THE SEMEN SPECIMENS MUST BE NOTED AND REPORTED.

REFERENCES: 1) WORLD HEALTH ORGANIZATION LABORATORY MANUAL FOR THE EXAMINATION OF HUMAN SEMEN AND SPERM-CERVICAL MUCUS INTERACTION, THIRD EDITION. NEW YORK: CAMBRIDGE UNIVERSITY PRESS, 1992; 2) MORTIMER D. PRACTICAL LABORATORY ANDROLOGY. NEW YORK: OXFORD UNIVERSITY PRESS. 1994.

QUESTION: 90:FFAF PHASE: II NEW

Are patient results reported in a legible, easy-to-interpret format that clearly delineates the clinical significance of the results?

COMMENTARY: 90:FFAF PHASE: II

PATIENT RESULTS MUST BE REPORTED IN A LEGIBLE, EASY TO INTERPRET FORMAT THAT CLEARLY INDICATES THE CLINICAL IMPLICATION OF THE RESULT. DATA MUST BE LEGIBLE, ACCURATE, REPORTED IN CLEARLY DESIGNATED UNITS OF MEASUREMENT, AND REPORTED TO PERSONS AUTHORIZED TO RECEIVE AND USE INFORMATION.

QUESTION: 90:FFAG PHASE: II NEW

Where possible, are all patient results reported with accompanying reference (normal) intervals or interpretations?

COMMENTARY: 90:FFAG PHASE: II

THE LABORATORY MUST REPORT REFERENCE (NORMAL) INTERVALS OR INTERPRETATIONS WITH PATIENT RESULTS, WHERE SUCH EXIST. THIS IS IMPORTANT TO ALLOW PROPER INTERPRETATION OF PATIENT DATA. ALSO, THE USE OF HIGH AND LOW FLAGS (GENERALLY AVAILABLE WITH A COMPUTERIZED LABORATORY INFORMATION SYSTEM) IS RECOMMENDED.

REFERENCES: 1) DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION. CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988; FINAL RULE. FEDERAL REGISTER. 1992(FEB 28):7162 [42 CFR 493.(d)]; 2) MORTIMER D. PRACTICAL LABORATORY ANDROLOGY. NEW YORK: OXFORD UNIVERSITY PRESS. 1994.

QUESTION: 90:1150 PHASE: I

Are results routinely available within a time compatible with clinical needs?

COMMENTARY: 90:1150 PHASE: I

ALL RESULTS, WHETHER "ROUTINE" OR "STAT," MUST BE AVAILABLE WITHIN A TIME COMPATIBLE WITH CLINICAL NEEDS. THERE SHOULD BE SUFFICIENT PERSONNEL TO PROMPTLY PROVIDE ALL NECESSARY SERVICES AS REQUIRED. MECHANISMS SHOULD BE IN PLACE TO PROVIDE BACK-UP FOR LABORATORY PERSONNEL AS REQUIRED.

REAGENTS AND CULTURE MEDIA

QUESTION: 90:PAAA PHASE: II

Are all reagents labeled with content and expiration date, and are records available to document receipt/date of preparations or date when placed in use?

REAGENTS AND CULTURE MEDIA:

REAGENT PERFORMANCE AND ADEQUACY MUST BE VERIFIED BEFORE PLACING THE MATERIAL IN SERVICE. VARIOUS METHODS, SUCH AS DIRECT ANALYSIS, USE OF REFERENCE MATERIALS, OR PARALLEL TESTING OF OLD VERSUS NEW REAGENTS, ARE ACCEPTABLE. THE RESULTS OF VERIFICATION CHECKS MUST BE RECORDED.

COMMENTARY: 90:PAAA PHASE: II

ALL REAGENTS MUST BE LABELED AS TO CONTENT AND EXPIRATION DATE, AND THERE MUST BE RECORDS AVAILABLE TO DOCUMENT RECEIPT/DATE OF PREPARATIONS OR DATE WHEN PLACED IN USE.

REFERENCE: JONES HW, JONES GS, HODGEN GD, ROSENWAKS S. IN VITRO FERTILIZATION. BALTIMORE, MD: WILLIAMS AND WILKINS, 1986:178.

QUESTION: 90:PAAC PHASE: II

Are results of reagent checks recorded?

COMMENTARY: 90:PAAC PHASE: II

RESULTS OF REAGENTS CHECKS MUST BE DOCUMENTED.

QUESTION: 90:PAAD PHASE: II

Does the laboratory use only components of reagent kits within the kit lot unless otherwise specified by the manufacturer?

COMMENTARY: 90:PAAD PHASE: II

THE LABORATORY MUST USE COMPONENTS OF REAGENT KITS ONLY WITH OTHER KITS THAT ARE IN THE SAME LOT NUMBER, UNLESS OTHERWISE SPECIFIED BY THE MANUFACTURER.

REFERENCE: DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION. CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988; FINAL RULE. FEDERAL REGISTER. 1992(FEB 28):7164 [42 CFR 493.1205(e)].

QUESTION: 90:PAAE PHASE: II

Are all reagents used within their indicated expiration date?

COMMENTARY: 90:PAAE PHASE: II

REAGENTS MUST NOT BE USED BEYOND THEIR STATED OR ASSIGNED EXPIRATION DATE.

REFERENCES: 1) DIAMOND I. QUALITY CONTROL REVISTED. PATHOLOGIST. 1980;34:333-336; 2) BYRD W. QUALITY ASSURANCE IN THE REPRODUCTIVE BIOLOGY LABORATORY. ARCH PATHOL MED. 1992;116:418-422.

QUESTION: 90:PAAF PHASE: II

Is the water used in preparing culture media type I water or special purpose water which has been defined and documented as being suitable for use with human in vitro fertilization culture media?

COMMENTARY: 90:PAAF PHASE: II

TYPE I WATER OR SPECIAL PURPOSE WATER WHICH HAS BEEN DEFINED AND DOCUMENTED AS SUITABLE FOR USE WITH HUMAN IN VITRO FERTILIZATION MUST BE USED IN PREPARING CULTURE MEDIA. WATER IS ONE OF THE MOST IMPORTANT AGENTS USED IN THE MEDIA PREPARATION SINCE CONTAMINANTS IN WATER ARE QUITE FREQUENTLY ENCOUNTERED THAT CAN HAVE A SUBSTANTIALLY DETRIMENTAL EFFECT ON OOCYTE AND EMBRYO GROWTH.

REFERENCE: NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS. PREPARATION AND TESTING OF REAGENT WATER IN THE CLINICAL LABORATORY, THIRD EDITION; APPROVED GUIDELINE C3-A3. WAYNE, PA: NCCLS, 1997.

QUESTION: 90:PAAG PHASE: II

Are explicit procedures for media preparation documented?

NOTE: Mark this question "N/A" if no media are prepared by the laboratory.

COMMENTARY: 90:PAAG PHASE: II

EXPLICIT PROCEDURES FOR MEDIA PREPARATION MUST BE DOCUMENTED. PROCEDURES FOR MEDIA PREPARATION SHOULD BE CLEARLY DOCUMENTED AND READILY AVAILABLE TO LABORATORY PERSONNEL. IF THERE IS NO DE NOVO PREPARATION OF MEDIA IN THE LABORATORY, PROCEDURES FOR PREPARATION OF PURCHASED MEDIA FOR USE NEED NOT BE WRITTEN. ALL MEDIA PREPARATION MUST BE PERFORMED WITH STERILE TECHNIQUE, INCLUDING LOCATION AND ENVIRONMENT APPROPRIATE FOR MEDIA PREPARATION. THE LABORATORY HAS A RESPONSIBILITY FOR ENSURING THAT ANY MEDIA PURCHASED OR PREPARED IS STERILE AND CAPABLE OF SUPPORTING CULTURE OF GAMETES AND EMBRYOS.

REFERENCE: JONES HW, ET AL. IN VITRO FERTILIZATION. BALTIMORE, MD: WILLIAMS AND WILKINS, 1986;178.

QUESTION: 90:PAAH PHASE: II

Are all media and reagents labeled as to content?

COMMENTARY: 90:PAAH PHASE: II

ALL MEDIA AND REAGENTS MUST BE LABELED AS TO CONTENT. ALL MEDIA OR REAGENTS MUST BE LABELED TO AVOID POSSIBLE MISTAKES OR USE OF AN INAPPROPRIATE REAGENT.

REFERENCE: JONES HW, ET AL. IN VITRO FERTILIZATION. BALTIMORE, MD: WILLIAMS AND WILKINS, 1986;178.

QUESTION: 90:PAAJ PHASE: II

Are media storage and expiration requirements documented?

COMMENTARY: 90:PAAJ PHASE: II

MEDIA STORAGE AND EXPIRATION REQUIREMENTS MUST BE DOCUMENTED AT ALL TIMES IN ORDER TO ENSURE ACTIVE REAGENTS IN ALL MEDIA.

REFERENCE: JONES HW, ET AL. IN VITRO FERTILIZATION. BALTIMORE, MD: WILLIAMS AND WILKINS, 1986;178.

QUESTION: 90:PAAK PHASE: II

Does the laboratory have a method for quality control of media and is it documented?

COMMENTARY: 90:PAAK PHASE: II

THE LABORATORY MUST HAVE A DOCUMENTED METHOD FOR QUALITY CONTROL OF THE MEDIA AND ALL MEDIA SUPPLEMENTS. CULTURE MEDIA MUST BE ABLE TO SUPPORT THE VIABILITY OF GAMETES AND/OR AND THE GROWTH OF EMBRYOS. MEDIA MUST BE EVALUATED USING A BIOASSAY SYSTEM SUCH AS THE ONE OR TWO CELL MOUSE EMBRYO CULTURE ASSAY OR A SPERM MOTILITY ASSAY. IF CULTURE MEDIA OR PROTEIN SUPPLEMENT IS PURCHASED, THERE MUST BE DOCUMENTATION THAT IT HAS BEEN TESTED BY THE SUPPLIER. IT IS HIGHLY RECOMMENDED THAT NEW MEDIA BE TESTED ON SITE. QUALITY CONTROL TESTING IS HIGHLY RECOMMENDED WHEN COMMERCIAL MEDIA IS PURCHASED AND USED WITHIN ITS LABELED EXPIRATION PERIOD, SINCE PRETESTING BY THE MANUFACTURER MAY NOT REFLECT MEDIA SUITABILITY WHEN IN ACTUAL USE IN THE LABORATORY. DOCUMENTATION OF QUALITY CONTROL TESTING USING AN APPROPRIATE BIOASSAY SYSTEM MUST ALWAYS BE SUPPLIED BY THE MANUFACTURER

REFERENCE: AMERICAN FERTILITY SOCIETY GUIDELINES FOR HUMAN EMBRYOLOGY LABORATORIES. AUGUST 1990, SECTION IV, C, 1c.

QUESTION: 90:PAAL PHASE: I

Does the laboratory test and document the quality of the contact material using a bioassay?

COMMENTARY: 90:PAAL PHASE: I

CONTACT MATERIALS SHOULD BE EVALUATED ROUTINELY BY A BIOASSAY.

REFERENCE: GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58 (SUPPL 1): SECTION IV, C, 1a AND VI, A, 5.

QUESTION: 90:PAAM PHASE: II

Do the records indicate that, when components are prepared that do not meet the quality control requirements, immediate corrective action was taken and documented?

COMMENTARY: 90:PAAM PHASE: II

THE RECORDS MUST INDICATE THAT WHEN COMPONENTS ARE PREPARED THAT DO NOT MEET THE QUALITY CONTROL REQUIREMENTS, IMMEDIATE CORRECTIVE ACTION IS TAKEN AND DOCUMENTED.

REFERENCE: GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58 (SUPPL 1): SECTION IV, A, 2.

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ANDROLOGY PROCEDURES AND TESTS

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COMPUTER-ASSISTED SEMEN ANALYSIS (CASA) AUTOMATED INSTRUMENTS

A variety of systems are in use and some questions may not apply to every system. The questions are intended to check factors common to all automated systems. Inspectors should use individual judgment in applying the questions to the particular type of system being used.

QUESTION: 90:1180 PHASE: 0 LAB

Is an automated sperm morphology or morphometry assessment (flow-through or stained smear pattern recognition type) used for sperm differential counts?

(If "NO," mark all questions in this subsection "N/A" and continue with the MANUAL SEMEN ANALYSIS section.)

QUESTION: 90:1190 PHASE: I

Where applicable, are the optical and imaging components used those recommended by the manufacturer or a validated substitution?

COMPUTER ASSISTED SEMEN ANALYSIS (CASA) AUTOMATED INSTRUMENTS:

COMMENTARY: 90:1190 PHASE: I

WHERE APPLICABLE, THE OPTICAL AND IMAGING COMPONENTS USED SHOULD BE THOSE RECOMMENDED BY THE MANUFACTURER OR THE SUBSTITUTION SHOULD BE VALIDATED BY THE LABORATORY.

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Calibration and Quality Control

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Several different methods may be used for calibration and quality control in the automated analysis of semen characteristics. "Calibration" techniques include:

A. the use of multiple analyzed sperm specimens,
B. the use of stabilized preparations of sperm cells (e.g., fixed or preserved),
C. sperm surrogates (e.g., latex particles),
D. videotaped sperm specimens.

NOTE: If stabilized control materials are used, they should represent different analytic levels (e.g., normal and high). Similarly, retained patient specimens should be of differing counts and/or motility, as applicable.

QUESTION: 90:1200 PHASE: II

Is calibration verified with materials appropriate to the reportable range of the instrument, and is verification documented?

CALIBRATION AND QUALITY CONTROL:

COMMENTARY: 90:1200 PHASE: II

THE QUALITY CONTROL PROCEDURE FOR THE AUTOMATED INSTRUMENT MUST INCLUDE CALIBRATION AND EVALUATION USING DEFINED LIMITS OF AGREEMENT WITH MANUALLY COUNTED SEMEN SMEARS OR STORED DIGITAL IMAGES, AS APPROPRIATE FOR THE PARTICULAR SYSTEM. COMPUTER-ASSISTED SEMEN ANALYSIS LABORATORIES MUST PERIODICALLY ESTABLISH THAT THEIR

COMPUTER ASSISTED SEMEN ANALYSIS EQUIPMENT IS FUNCTIONING CORRECTLY AND THERE IS A PROTOCOL TO DETERMINE IF THE ANALYSIS IS IN CONTROL.

REFERENCE: GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58 (SUPPL 1): SECTION I, B, 6.

QUESTION: 90:1210 PHASE: II

Does the laboratory perform and document calibration and quality control methods for the analyzer during each day of use, using an appropriate number of controls with varying ranges of values?

COMMENTARY: 90:1210 PHASE: II

THE LABORATORY MUST PERFORM AND DOCUMENT CALIBRATION AND QUALITY CONTROL METHODS FOR THE ANALYZER DURING EACH DAY OF USE, USING AN APPROPRIATE NUMBER OF CONTROLS WITH VARYING RANGES OF RELEVANT VALUES.

REFERENCE: GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58 (SUPPL 1): SECTION I, B, 6.

QUESTION: 90:1220 PHASE: II

Does the laboratory have a procedure for recalibration of CASA instrument parameter(s) when problems are encountered?

COMMENTARY: 90:1220 PHASE: II

THE LABORATORY MUST HAVE A PROCEDURE FOR RECALIBRATION OF CASA INSTRUMENT PARAMETER(S) WHEN PROBLEMS ARE ENCOUNTERED.

REFERENCE: WORLD HEALTH ORGANIZATION LABORATORY MANUAL FOR THE EXAMINATION OF HUMAN SEMEN AND SPERM-CERVICAL MUCUS INTERACTION, THIRD EDITION. NEW YORK: CAMBRIDGE UNIVERSITY PRESS, 1992.

QUESTION: 90:1230 PHASE: II

Has the material used for calibration been validated using primary reference procedures (*e.g.*, manual counts)?

COMMENTARY: 90:1230 PHASE: II

THE MATERIAL USED FOR CALIBRATION MUST HAVE BEEN VALIDATED USING PRIMARY REFERENCE PROCEDURES.

REFERENCES: 1) WORLD HEALTH ORGANIZATION LABORATORY MANUAL FOR THE EXAMINATION OF HUMAN SEMEN AND SPERM-CERVICAL MUCUS INTERACTION, THIRD EDITION. NEW YORK: CAMBRIDGE UNIVERSITY PRESS, 1992; 2) KRAUSE W. [VALUE OF COMPUTER-ASSISTED SPERM ANALYSIS (CASA). REPRODUCIBILITY--ONLINE DOCUMENTATION--PROGNOSTIC VALUE]. [Article in German]. FORTSCHR MED. 1996;114:470-473.

QUESTION: 90:1240 PHASE: II

If a manual method is used as the system control for automated or semi-automated sperm counts, is its accuracy verified and documented at intervals appropriate for laboratory volume?

COMMENTARY: 90:1240 PHASE: II

WHEN A MANUAL METHOD IS USED AS THE SYSTEM CONTROL FOR AUTOMATED OR SEMI-AUTOMATED SPERM COUNTS, ITS ACCURACY MUST BE VERIFIED AND DOCUMENTED PERIODICALLY.

REFERENCES: 1) MORTIMER D. PRACTICAL LABORATORY ANDROLOGY. NEW YORK: OXFORD UNIVERSITY PRESS. 1994; 2) LENZI A. COMPUTER-AIDED SEMEN ANALYSIS (CASA) 10 YEARS LATER: A TEST-BED FOR THE EUROPEAN SCIENTIFIC ANDROLOGICAL COMMUNITY. IN J ANDROL. 1997;20:1-2; 3) MAHMOUD AM, ET AL. PERFORMANCE OF THE SPERM QUALITY ANALYSER IN PREDICTING THE OUTCOME OF ASSISTED REPRODUCTION. INT J ANDROL. 1998;21:41-46.

QUESTION: 90:1250 PHASE: II

Are tolerance limits established for the value of each quality control sample?

COMMENTARY: 90:1250 PHASE: II

TOLERANCE LIMITS MUST BE ESTABLISHED FOR THE VALUE OF EACH SAMPLE USED IN QUALITY CONTROL.

REFERENCE: NATIONAL COMMITTEE FOR CLINICAL LABORATORY STANDARDS. ASSESSMENT OF CLINICAL SENSITIVITY AND SPECIFICITY OF LABORATORY TESTS; PROPOSED GUIDELINE GP10-P. WAYNE, PA: NCCLS, 1987.

QUESTION: 90:1260 PHASE: II

If sperm motility and/or count are assessed by CASA, is a procedure established to determine that the concentration of the specimen is within the range appropriate for automated counting?

COMMENTARY: 90:1260 PHASE: II

IF SPERM MOTILITY AND/OR COUNT ARE ASSESSED BY CASA, A PROCEDURE MUST BE ESTABLISHED TO DETERMINE THAT THE CONCENTRATION OF THE SPECIMEN IS WITHIN THE RANGE APPROPRIATE FOR AUTOMATED COUNTING.

REFERENCES: 1) VANTMAN D, ET AL. COMPUTER-ASSISTED SEMEN ANALYSIS: EVALUATION OF METHOD AND ASSESSMENT OF THE INFLUENCE OF SPERM CONCENTRATION ON LINEAR VELOCITY DETERMINATION. FERTIL STERIL. 1988;49:510-515; 2) YEUNG CH, ET AL. A TECHNIQUE FOR STANDARDIZATION AND QUALITY CONTROL OF SUBJECTIVE SPERM MOTILITY ASSESSMENTS IN SEMEN ANALYSIS. FERTIL STERIL. 1997;67:1156-1158; 3) SIDHU RS, ET AL. ACCURACY OF COMPUTER-ASSISTED SEMEN ANALYSIS IN PREFREEZE AND POST-THAW SPECIMENS WITH HIGH AND LOW SPERM COUNTS AND MOTILITY. UROLOGY. 1998;51:306-312.

QUESTION: 90:1270 PHASE: II

Are upper and lower limits of all reportable parameters on CASA instruments defined so that results which fall outside these limits are verified before reporting?

COMMENTARY: 90:1270 PHASE: II

THE LABORATORY MUST VERIFY THE LINEARITY RANGE FOR EACH REPORTABLE PARAMETER OF ITS INSTRUMENTS. RESULTS WHICH FALL OUTSIDE OF THESE LIMITS MAY BE VERIFIED BY REPEATING THE TEST, USING AN ALTERNATIVE METHOD OR DILUTING/CONCENTRATING THE SPECIMEN, AS APPROPRIATE.

REFERENCE: MORTIMER D. PRACTICAL LABORATORY ANDROLOGY. NEW YORK: OXFORD UNIVERSITY PRESS. 1994.

QUESTION: 90:1275 PHASE: II

Are criteria established for method calibration verification?

NOTE: Criteria must be established for method calibration verification. Criteria for determining the need for calibration verification typically include:

1. *at complete changes of reagents, unless the laboratory can demonstrate that changing reagent lots does not affect either the range used to report patient test results or the control values,*
2. *when indicated by quality control data,*
3. *after major maintenance or service,*
4. *when recommended by the manufacturer,*
5. *at least every six months.*

COMMENTARY: 90:1275 PHASE: II

CRITERIA MUST BE ESTABLISHED FOR METHOD CALIBRATION VERIFICATION. CRITERIA FOR DETERMINING THE NEED FOR CALIBRATION VERIFICATION TYPICALLY INCLUDE:

1. AT COMPLETE CHANGES OF REAGENTS,
2. WHEN INDICATED BY QUALITY CONTROL DATA,
3. AFTER MAJOR MAINTENANCE OR SERVICE,
4. WHEN RECOMMENDED BY THE MANUFACTURER,
5. AT LEAST EVERY SIX MONTHS.

WHEN CALIBRATION VERIFICATION CRITERIA ARE EXCEEDED, THE LABORATORY MUST RECALIBRATE.

REFERENCE: DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION. CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988; FINAL RULE. FEDERAL REGISTER. 1992(FEB 28):7165 [42 CFR 493.1217].

MANUAL SEMEN ANALYSIS

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Sperm Concentration

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QUESTION: 90:1280 PHASE: 0 LAB

Does the laboratory perform manual sperm counts?

(If "NO," mark all questions in this subsection "N/A" and continue with the SPERM MOTILITY section.)

What type of counting chamber is used?

QUESTION: 90:1290 PHASE: 0 LAB

a) Makler chamber

QUESTION: 90:1300 PHASE: 0 LAB

b) Hemocytometer

QUESTION: 90:1310 PHASE: 0 LAB

c) Disposable sperm counting chamber

QUESTION: 90:1320 PHASE: I

Are the lines in the counting or motility chambers bright, and are the chambers clean and free of scratches?

NOTE: The inspector should examine several chambers.

MANUAL DETERMINATION OF SPERM CONCENTRATION:

COMMENTARY: 90:1320 PHASE: I

ALL LINES ON THE COUNTING AND MOTILITY CHAMBERS SHOULD BE BRIGHT. AND THE CHAMBERS SHOULD BE CLEAN AND FREE OF SCRATCHES.

QUESTION: 90:1330 PHASE: II

Is a system defined and documented for assuring that dilution fluids are free of contaminants that may spuriously change the true sperm counts?

COMMENTARY: 90:1330 PHASE: II

A PROCEDURE MUST BE DEFINED AND DOCUMENTED FOR ASSURING THAT DILUTION FLUIDS ARE FREE OF CONTAMINANTS THAT MAY SPURIOUSLY CHANGE THE TRUE SPERM COUNTS.

QUESTION: 90:1340 PHASE: II

If sperm counts are performed after pipette dilution, is each sample diluted in duplicate and each dilution counted?

COMMENTARY: 90:1340 PHASE: II

IF SPERM COUNTS ARE PERFORMED MANUALLY BY PIPETTE DILUTION AND CHAMBER COUNT, EACH SAMPLE MUST BE DILUTED IN DUPLICATE AND EACH DILUTION COUNTED. COUNTING FROM TWO SEPARATE DILUTIONS (AS OPPOSED TO TWO COUNTS FROM THE SAME DILUTION) PERMITS COMPARISON OF DILUTION AND COUNTING PRECISION. DEFINED LIMITS OF VARIATION MUST BE ESTABLISHED. IF CASA IS USED, A SINGLE DILUTION IS ACCEPTABLE IF COMPARED TO AN ESTIMATE OF COUNT FROM THE UNDILUTED CASA IMAGE.

QUESTION: 90:1350 PHASE: II

Does the laboratory indicate on the report that results may be inaccurate because cell clumps or debris are present in the counting chamber?

COMMENTARY: 90:1350 PHASE: II

THE LABORATORY MUST INDICATE ON THE REPORT THAT RESULTS MAY BE INACCURATE BECAUSE CELL CLUMPS OR DEBRIS ARE PRESENT IN THE COUNTING CHAMBER.

QUESTION: 90:1360 PHASE: I

Is there an additional procedure beyond unstained bright-field microscopy to ensure the accurate distinction of leukocytes from other round cells (*e.g.*, Wright's or PAP stain, leukocyte alkaline phosphatase, myeloperoxidase)?

COMMENTARY: 90:1360 PHASE: I

THERE MUST BE AN ADDITIONAL PROCEDURE BEYOND UNSTAINED BRIGHT-FIELD MICROSCOPY TO ENSURE THE ACCURATE DISTINCTION OF LEUKOCYTES FROM OTHER ROUND CELLS (*e.g.*, WRIGHT'S OR PAP STAIN, LEUKOCYTE ALKALINE PHOSPHATASE, MYELOPEROXIDASE).

REFERENCES: 1) WORLD HEALTH ORGANIZATION LABORATORY MANUAL FOR THE EXAMINATION OF HUMAN SEMEN AND SPERM-CERVICAL MUCUS INTERACTION, THIRD EDITION. NEW YORK: CAMBRIDGE UNIVERSITY PRESS, 1992; 2) FISHEL TJ, ET AL. INCREASED POLYMORPHONUCLEAR GRANULOCYTES IN SEMINAL PLASMA IN RELATION TO SPERM MORPHOLOGY. HUM REPROD. 1997;12:2418-2421; 3) ZIMMERMANN BS, ET AL. RELATIONSHIP OF BACTERIOLOGICAL CHARACTERISTICS TO SEMEN INDICES AND ITS INFLUENCE ON FERTILIZATION AND PREGNANCY RATES AFTER IVF. ACTA OBSTET GYNECOL SCAND. 1997;76:964-968; 4) TRUM JW, ET AL. VALUE OF DETECTING LEUKOCYTOSPERMIA IN THE DIAGNOSIS OF GENITAL TRACT INFECTION IN SUBFERTILE MED. FERTIL STERIL. 1998;70:315-319.

QUESTION: 90:ALIG PHASE: II NEW

For azoospermic specimens, as well as post-vasectomy checks for sterility, is a concentrating technique employed?

COMMENTARY: 90:ALIG PHASE: II

FOR AZOOSPERMIC SPECIMENS, AS WELL AS POST-VASECTOMY CHECKS FOR STERILITY, A CONCENTRATING TECHNIQUE MUST BE EMPLOYED. WITHOUT SUCH AN APPROACH, THE PRESENCE OF BOTH MOTILE AND NON-MOTILE SPERM MAY NOT BE DETECTED.

REFERENCES: 1) JONES CD, CORNBLEET PJ. WRIGHT-GIEMSA CYTOLOGY OF BODY FLUIDS. TECHNIQUES FOR OPTIMAL CYTOCENTRIFUGE SLIDE PREPARATION. LAB MED. 1997;28:713-716; 2) JAFFE TM, ET AL. SPERM PELLET ANALYSIS: A TECHNIQUE TO DETECT THE PRESENCE OF SPERM IN MEN CONSIDERED TO HAVE AZOOSPERMIA BY ROUTINE SEMEN ANALYSIS. J UROL. 1998;159:1548-1550.

QUESTION: 90:1370 PHASE: I

Is qualitative fructose measured in azoospermic specimens?

COMMENTARY: 90:1370 PHASE: I

QUALITATIVE FRUCTOSE SHOULD BE MEASURED ON AZOOSPERMIC SPECIMENS.

REFERENCES: 1) WORLD HEALTH ORGANIZATION LABORATORY MANUAL FOR THE EXAMINATION OF HUMAN SEMEN AND SPERM-CERVICAL MUCUS INTERACTION: THIRD EDITION. NEW YORK: CAMBRIDGE UNIVERSITY PRESS, 1992; 2) GONZALES GF, VILLENA A. INFLUENCE OF LOW CORRECTED SEMINAL

FRUCTOSE LEVELS ON SPERM CHROMATIN STABILITY IN SEMEN FROM MEN ATTENDING AN INFERTILITY SERVICE. FERTIL STERIL. 1997;67:763-768.

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Sperm Motility

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QUESTION: 90:1380 PHASE: 0 LAB

Does the laboratory assess percentage and/or quality of motile sperm?

(If "NO," mark all questions in this subsection "N/A" and continue with the Stained Smear - Sperm Differential section.)

QUESTION: 90:1390 PHASE: II

Has the laboratory established a standard specimen temperature range for semen analysis assessment, and are deviations from this temperature noted on the report?

SPERM MOTILITY:

COMMENTARY: 90:1390 PHASE: II

THE LABORATORY MUST ESTABLISH A STANDARD SPECIMEN TEMPERATURE RANGE FOR SEMEN EVALUATION ASSESSMENT, AND DEVIATIONS FROM THIS TEMPERATURE MUST BE NOTED ON THE REPORT, SINCE SPECIMEN MOTILITY IS TEMPERATURE DEPENDENT.

REFERENCE: WORLD HEALTH ORGANIZATION LABORATORY MANUAL FOR THE EXAMINATION OF HUMAN SEMEN AND SPERM-CERVICAL MUCUS INTERACTION, THIRD EDITION. NEW YORK: CAMBRIDGE UNIVERSITY PRESS, 1992.

QUESTION: 90:1400 PHASE: II

Does the laboratory have an appropriate procedure for evaluating a sufficient number of separate and randomly chosen microscopic fields and sperm cells?

COMMENTARY: 90:1400 PHASE: II

THE LABORATORY MUST DETERMINE AN APPROPRIATE PROCEDURE FOR EVALUATING A SUFFICIENT NUMBER OF SEPARATE AND RANDOMLY CHOSEN MICROSCOPIC FIELDS AND NUMBER OF MOTILE SPERM CELLS.

REFERENCE: WORLD HEALTH ORGANIZATION LABORATORY MANUAL FOR THE EXAMINATION OF HUMAN SEMEN AND SPERM-CERVICAL MUCUS INTERACTION, THIRD EDITION. NEW YORK: CAMBRIDGE UNIVERSITY PRESS, 1992.

QUESTION: 90:1410 PHASE: I

Does the laboratory use a chamber specifically designed for determining sperm motility?

COMMENTARY: 90:1410 PHASE: I

THE LABORATORY SHOULD USE A CHAMBER SPECIFICALLY DESIGNED FOR DETERMINING SPERM MOTILITY.

QUESTION: 90:1420 PHASE: I

Has the laboratory defined when viability measurements should be performed on specimens with abnormally low percent motility (*e.g.*, less than 30%)?

COMMENTARY: 90:1420 PHASE: I

THE LABORATORY SHOULD DEFINE WHEN VIABILITY MEASUREMENTS SHOULD BE PERFORMED ON SPECIMENS WITH ABNORMALLY LOW PERCENT MOTILITY (*e.g.*, LESS THAN 30%).

REFERENCE: WORLD HEALTH ORGANIZATION LABORATORY MANUAL FOR THE EXAMINATION OF HUMAN SEMEN AND SPERM-CERVICAL MUCUS INTERACTION: THIRD EDITION. NEW YORK: CAMBRIDGE UNIVERSITY PRESS, 1992.

QUESTION: 90:1430 PHASE: II

Are manual measures of percent sperm motility quantified objectively?

COMMENTARY: 90:1430 PHASE: II

MANUAL MEASURES OF SPERM MOTILITY MUST BE QUANTIFIED OBJECTIVELY.

REFERENCES: 1) WORLD HEALTH ORGANIZATION LABORATORY MANUAL FOR THE EXAMINATION OF HUMAN SEMEN AND SPERM-CERVICAL MUCUS INTERACTION: THIRD EDITION. NEW YORK: CAMBRIDGE UNIVERSITY PRESS,

1992; 2) YEUNG CH, ET AL. A TECHNIQUE FOR STANDARDIZATION AND QUALITY CONTROL OF SUBJECTIVE SPERM MOTILITY ASSESSMENTS IN SEMEN ANALYSIS. FERTIL STERIL. 1997;67:1156-1158.

QUESTION: 90:1440 PHASE: II

Is forward progression of sperm evaluated?

COMMENTARY: 90:1440 PHASE: II

THE FORWARD PROGRESSION OF SPERM MUST BE EVALUATED.

REFERENCES: 1) WORLD HEALTH ORGANIZATION LABORATORY MANUAL FOR THE EXAMINATION OF HUMAN SEMEN AND SPERM-CERVICAL MUCUS INTERACTION: THIRD EDITION. NEW YORK: CAMBRIDGE UNIVERSITY PRESS, 1992; 2) VULCANO GJ, ET AL. A LINEAL EQUATION FOR THE CLASSIFICATION OF PROGRESSIVE AND HYPERACTIVE SPERMATOZOA. MATH BIOSCI. 1998;149:77-93.

QUESTION: 90:1450 PHASE: II

Are specimens analyzed at concentrations appropriate for the method of motility analysis used?

COMMENTARY: 90:1450 PHASE: II

SPECIMENS MUST BE ANALYZED AT CONCENTRATIONS APPROPRIATE FOR THE SYSTEM USED.

REFERENCE: VANTMAN D, ET AL. THE USE OF AMNIOTIC FLUID AND SERUM WITH PROPANEDIOL IN FREEZING OF MURINE 2-CELL EMBRYOS. FERTIL STERIL. 1988;49:510-515.

QUESTION: 90:1460 PHASE: II

Does a procedure exist to verify the sperm motility method used (*e.g.*, video tapes of specimens with known percent motility and/or specific motion quality)?

COMMENTARY: 90:1460 PHASE: II

A PROCEDURE MUST EXIST TO MEASURE AND VERIFY THE SPERM MOTILITY METHOD USED (*e.g.*, VIDEO TAPES OF SPECIMENS WITH KNOWN MOTILITY).

REFERENCES: 1) MORTIMER D. PRACTICAL LABORATORY ANDROLOGY. NEW YORK: OXFORD UNIVERSITY PRESS. 1994; 2) YEUNG CH, ET AL. A TECHNIQUE FOR STANDARDIZATION AND QUALITY CONTROL OF SUBJECTIVE SPERM MOTILITY ASSESSMENTS IN SEMEN ANALYSIS. FERTIL STERIL. 1997;67:1156-1158.

QUESTION: 90:1470 PHASE: I

Has the laboratory established reference ranges (normal values) for the motion variables measured?

COMMENTARY: 90:1470 PHASE: I

THE LABORATORY SHOULD ESTABLISH REFERENCE RANGES FOR THE MOTION VARIABLES MEASURED DURING SPERM MOTILITY ASSESSMENT.

REFERENCE: SCHIEFERSTEIN G, ET AL. SPERM MOTILITY INDEX. ARCH ANDROL. 1998;40:43-48.

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Semen Stained Smear - Sperm Differential

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QUESTION: 90:1480 PHASE: 0 LAB

Are differential counts performed on cell types in semen smears (*e.g.*, immature sperm, head and tail morphology, leukocytes, *etc.*?

(If "NO," mark all questions in this subsection "N/A" and continue with the Biochemical Tests section.)

QUESTION: 90:1490 PHASE: I

Are stains used to facilitate classification of cell types (as opposed to performing differentials of unstained preparations)?

SEMEN STAINED SMEAR (SPERM DIFFERENTIAL):

COMMENTARY: 90:1490 PHASE: I

STAINS SHOULD ALWAYS BE USED TO FACILITATE CLASSIFICATION OF CELL TYPES, AS OPPOSED TO PERFORMING DIFFERENTIALS ON UNSTAINED PREPARATIONS.

REFERENCE: COETZEE K, ET AL. PREDICTIVE VALUE OF NORMAL SPERM MORPHOLOGY: A STRUCTURED LITERATURE REVIEW. HUM REPROD UPDATE. 1998;4:73-82.

QUESTION: 90:1500 PHASE: II

Are all stains checked for intended reactivity each day of use?

COMMENTARY: 90:1500 PHASE: II

STAINS MUST BE CHECKED EACH DAY OF USE FOR INTENDED REACTIVITY TO ENSURE PREDICTABLE STAINING CHARACTERISTICS.

REFERENCE: DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION. CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988; FINAL RULE. FEDERAL REGISTER. 1992(FEB 28):7166 [42 CFR 493.1218(f)(2)].

QUESTION: 90:1510 PHASE: I

Examine a smear. Is the quality satisfactory (uniform cell distribution, properly stained, ready recognition of cell types that are reported)?

COMMENTARY: 90:1510 PHASE: I

THE QUALITY OF THE SMEAR SHOULD BE SATISFACTORY (UNIFORM CELL DISTRIBUTION, PROPERLY STAINED, READY RECOGNITION OF CELL TYPES THAT ARE REPORTED).

REFERENCE: MORTIMER D. PRACTICAL LABORATORY ANDROLOGY. NEW YORK: OXFORD UNIVERSITY PRESS. 1994.

QUESTION: 90:1520 PHASE: II

Are slides adequately identified?

COMMENTARY: 90:1520 PHASE: II

SLIDES MUST BE ADEQUATELY IDENTIFIED. SLIDE IDENTIFICATION MUST INCLUDE A UNIQUE SPECIMEN OR ACCESSION NUMBER, PATIENT NAME AND/OR NUMBER, DATE.

REFERENCE: GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58 (SUPPL 1): SECTION IV, D.

QUESTION: 90:1530 PHASE: II

Is the classification method used indicated on the report?

COMMENTARY: 90:1530 PHASE: II

THE CLASSIFICATION METHOD MUST BE INDICATED ON THE REPORT, SINCE MANY DIFFERENT CLASSIFICATION SYSTEMS ARE IN USE.

QUESTION: 90:1540 PHASE: I

Are the slides retained for at least 30 days for future reference?

COMMENTARY: 90:1540 PHASE: I

SLIDES SHOULD BE RETAINED FOR AT LEAST 30 DAYS FOR FUTURE REFERENCE.

QUESTION: 90:1550 PHASE: I

Does the laboratory have a defined, documented system to ensure consistency of morphologic observations among all personnel performing microscopic morphologic classification of sperm and other cells?

COMMENTARY: 90:1550 PHASE: I

THE LABORATORY MUST HAVE A DOCUMENTED SYSTEM THAT ENSURES THAT ALL PERSONNEL REPORT MICROSCOPIC MORPHOLOGIC DATA ON PATIENT SAMPLES IN A SIMILAR FASHION. FOR INITIAL ACCURACY AS WELL AS CONSISTENCY IN SERIAL SAMPLES FROM THE SAME PATIENT, THE LABORATORY MUST BE ABLE TO DOCUMENT THAT ALL OF ITS STAFF ARE CONSISTENT WITH RESPECT TO MORPHOLOGIC CLASSIFICATION. SUGGESTED METHODS TO ACCOMPLISH THIS INCLUDE:

1. CIRCULATION OF STAINED SEMEN SMEARS WITH DEFINED SPECIFIC QUALITATIVE ABNORMALITIES OF SPERM, AND/OR

2. MULTI-HEADED MICROSCOPY, AND/OR

3. USE OF RELIABLE PUBLISHED ATLASES.

REFERENCES: 1) FREUND M. STANDARDS FOR THE RATING OF HUMAN SPERM MORPHOLOGY: A COOPERATIVE STUDY. INT J FERTIL. 1966;11(SUPPL):1-9; 2) CALAMERA JC, VILAR O. COMPARATIVE STUDY OF SPERM MORPHOLOGY WITH THREE DIFFERENT STAINING PROCEDURES. ANDROLOGIA. 1979;11:255-258; 3) KOSS LG. DIAGNOSTIC CYTOLOGY AND ITS HISTOPATHOLOGIC BASES. PHILADELPHIA: JB LIPPINCOTT, 1979:1211-1230; 4) URRY R. SEMINAL FLUID. IN: KJELDSBERG CR, KNIGHT JA. BODY FLUIDS. LABORATORY EXAMINATION OF AMNIOTIC, CEREBROSPINAL, SEMINAL, SEROUS, & SYNOVIAL FLUIDS: A TEXTBOOK ATLAS. 2ND ED. CHICAGO: AMERICAN SOCIETY OF CLINICAL PATHOLOGISTS PRESS, 1986:117-127; 5) ADELMAN MM, CAHILL EM. ATLAS OF SPERM MORPHOLOGY. CHICAGO: AMERICAN SOCIETY OF CLINICAL PATHOLOGISTS PRESS, 1989; 6) WORLD HEALTH ORGANIZATION. WHO LABORATORY MANUAL FOR THE EXAMINATION OF HUMAN SEMEN AND SEMEN-CERVICAL MUCUS INTERACTION. NEW YORK: CAMBRIDGE UNIVERSITY PRESS, 1992; 7) MORTIMER D. PRACTICAL LABORATORY ANDROLOGY. NEW YORK: OXFORD UNIVERSITY PRESS. 1994.

QUESTION: 90:1560 PHASE: II

Is an individual with expertise in sperm morphology (the pathologist, lab director, supervisor, or other technologist) available for consultation, when needed?

COMMENTARY: 90:1560 PHASE: II

AN INDIVIDUAL WITH EXPERTISE IN SPERM CELL MORPHOLOGY MUST BE AVAILABLE FOR CONSULTATION WHEN NEEDED. THERE MUST BE SUFFICIENT PERSONNEL TO PROVIDE ALL NECESSARY SERVICES AS REQUIRED IN A TIMELY FASHION WITH MECHANISMS IN PLACE TO PROVIDE BACK-UP FOR LABORATORY PERSONNEL AS REQUIRED.

REFERENCE: GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL 1992;58 (SUPPL 1): SECTION II, A.

QUESTION: 90:1570 PHASE: I

Is there a file of unusual slides?

COMMENTARY: 90:1570 PHASE: I

THERE SHOULD BE A FILE OF UNUSUAL SLIDES THAT ARE RETAINED FOR TRAINING AND DEMONSTRATION.

The selection of types of stains is at the discretion of the Director. Of those used, are the following of sufficient quality to demonstrate the cellular characteristics for which they are designed:

QUESTION: 90:1580 PHASE: II

Papanicolaou?

THE STAINS LISTED BELOW SHOULD BE OF SUFFICIENT QUALITY TO DEMONSTRATE THE CELLULAR CHARACTERISTICS FOR WHICH THEY ARE DESIGNED.

COMMENTARY: 90:1580 PHASE: II

PAPANICOLAOU.

QUESTION: 90:1590 PHASE: II

Eosin/nigrosin?

COMMENTARY: 90:1590 PHASE: II

EOSIN/NIGROSIN.

QUESTION: 90:1600 PHASE: II

Wright's or other Giemsa stain?

COMMENTARY: 90:1600 PHASE: II

WRIGHT'S OR OTHER GIEMSA STAIN.

QUESTION: 90:1610 PHASE: II

Nuclear fast red and picroindigocarmine?

COMMENTARY: 90:1610 PHASE: II

NUCLEAR FAST RED AND PICROINDIGOCARMINE.

QUESTION: 90:1620 PHASE: II

Myeloperoxidase?

COMMENTARY: 90:1620 PHASE: II

MYELOPEROXIDASE.

QUESTION: 90:1640 PHASE: II

Are controls (where available and when appropriate) routinely run on all special stains?

NOTE: There must be an assessment to distinguish leukocytes from immature sperm using both the semen smear and an evaluation of the staining of normal cells on the blood film. The expected staining of normal cells on the semen smear may be absent for technical reasons. Failure to evaluate the expected reaction of normal cells may cause diagnostic errors.

COMMENTARY: 90:1640 PHASE: II

CONTROLS (WHERE AVAILABLE AND WHEN APPROPRIATE) MUST BE ROUTINELY RUN ON ALL SPECIAL STAINS. THERE MUST BE AN ASSESSMENT TO DISTINGUISH LEUKOCYTES FROM IMMATURE SPERM USING BOTH THE SEMEN SMEAR AND AN EVALUATION OF THE STAINING OF NORMAL CELLS ON THE BLOOD FILM. THE EXPECTED STAINING OF NORMAL CELLS ON THE SEMEN SMEAR MAY BE ABSENT FOR TECHNICAL REASONS. FAILURE TO EVALUATE THE EXPECTED REACTION OF NORMAL CELLS MAY CAUSE DIAGNOSTIC ERRORS.

REFERENCE: GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL 1992;58 (SUPPL 1): SECTION VII, A, 1.

QUESTION: 90:1650 PHASE: II

Are stains examined for contamination and replaced, as appropriate?

COMMENTARY: 90:1650 PHASE: II

STAINS MUST BE EXAMINED PERIODICALLY FOR CONTAMINATION AND REPLACED, AS APPROPRIATE.

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Biochemical Tests

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Does the laboratory perform any of the following semen quantitative biochemical tests:

(If "NO," mark all questions in this section "N/A" and continue with the CERVICAL MUCUS PENETRATION TEST section.)

QUESTION: 90:1660 PHASE: 0 LAB

Fructose?

QUESTION: 90:1670 PHASE: 0 LAB

Zinc?

QUESTION: 90:1730 PHASE: II

Are positive and negative controls run with each assay?

SEMEN BIOCHEMICAL TESTS:

COMMENTARY: 90:1730 PHASE: II

POSITIVE AND NEGATIVE CONTROLS MUST BE RUN WITH EACH BIOCHEMICAL TEST.

REFERENCE: MORTIMER D. PRACTICAL LABORATORY ANDROLOGY. NEW YORK: OXFORD UNIVERSITY PRESS. 1992.

CERVICAL MUCUS PENETRATION TEST

QUESTION: 90:1740 PHASE: 0 LAB

Does the laboratory perform cervical mucus penetration testing?

(If "NO," mark all questions in this subsection "N/A" and continue with the ANTI-SPERM ANTIBODY (ASA) TESTING section.)

QUESTION: 90:1750 PHASE: I

Are semen specimens tested in duplicate?

CERVICAL MUCUS PENETRATION TEST:

COMMENTARY: 90:1750 PHASE: I

SEMEN SPECIMENS SHOULD BE TESTED IN DUPLICATE.

REFERENCE: WORLD HEALTH ORGANIZATION LABORATORY MANUAL FOR THE EXAMINATION OF HUMAN SEMEN AND SPERM-CERVICAL MUCUS INTERACTION: THIRD EDITION. NEW YORK: CAMBRIDGE UNIVERSITY PRESS, 1992.

ANTI-SPERM ANTIBODY (ASA) TESTS

QUESTION: 90:1760 PHASE: 0 LAB

Does the laboratory measure ASA in/on any of the following?

(If "NO," mark all questions in this subsection "N/A" and continue with the SPERM-EGG INTERACTION TESTS section.)

QUESTION: 90:1770 PHASE: 0 LAB

Serum?

QUESTION: 90:1780 PHASE: 0 LAB

Seminal plasma?

QUESTION: 90:1790 PHASE: 0 LAB

Spermatozoa?

QUESTION: 90:1800 PHASE: 0 LAB

Cervical mucus?

QUESTION: 90:1810 PHASE: II

Are serum and follicular fluid specimens used for indirect ASA testing heat-inactivated before use?

ANTI-SPERM ANTIBODY (ASA) TESTS:

COMMENTARY: 90:1810 PHASE: II

ALL SERUM AND FOLLICULAR FLUID SPECIMENS USED FOR INDIRECT ASA TESTING MUST BE TREATED TO INACTIVATE COMPLEMENT.

REFERENCE: KEEL BA, WEBSTER BW. CRC HANDBOOK OF THE LABORATORY DIAGNOSIS AND TREATMENT OF INFERTILITY. BOCA RATON, FL: CRC PRESS, 1990:185.

QUESTION: 90:1820 PHASE: II

If the method uses donor sperm, were the sperm tested for ASA binding before use?

COMMENTARY: 90:1820 PHASE: II

CONTROL SPERM USED MUST BE TESTED FOR ASA BEFORE TO USE.

REFERENCES: 1) MORTIMER D. PRACTICAL LABORATORY ANDROLOGY. NEW YORK: OXFORD UNIVERSITY PRESS. 1992; 2) KAMADA M, ET AL. SEMEN ANALYSIS AND ANTISPERM ANTIBODY. ARCH ANDROL. 1998;40:117-128.

QUESTION: 90:1830 PHASE: I

If the testing for ASA requires motile sperm, are specimens assayed with minimal delay and is the motility assessed and recorded?

COMMENTARY: 90:1830 PHASE: I

WHEN ASA TESTING REQUIRES MOTILE SPERM, SPECIMENS SHOULD BE ASSAYED WITH MINIMAL DELAY, AND THE MOTILITY SHOULD BE ASSESSED AND RECORDED.

REFERENCE: MORTIMER D. PRACTICAL LABORATORY ANDROLOGY. NEW YORK: OXFORD UNIVERSITY PRESS. 1994.

QUESTION: 90:1840 PHASE: II

For indirect antibody testing, are positive and negative controls run with each assay?

COMMENTARY: 90:1840 PHASE: II

POSITIVE AND NEGATIVE CONTROLS MUST BE RUN WITH EACH ASSAY.

REFERENCES: 1) KEEL BA, WEBSTER BW. CRC HANDBOOK OF LABORATORY DIAGNOSIS AND TREATMENT OF INFERTILITY. BOCA RATON, FL: CRC PRESS, 1990:185; 2) DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION. CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988; FINAL RULE. FEDERAL REGISTER. 1992(FEB 28):7166 [42 CFR 493.1241(a)]; 3) EVANS ML, ET AL. A CONVENIENT MIXED IMMUNOBEADS SCREEN FOR ANTISPERM ANTIBODIES DURING ROUTINE SEMEN ANALYSIS. FERTIL STERIL. 1998;70:344-349.

SPERM-EGG INTERACTION TESTS

QUESTION: 90:1850 PHASE: 0 LAB

Does the laboratory perform tests of sperm-egg interaction (*e.g.*, hamster egg penetration assay, hemizona bioassay)?

(If "NO," mark all questions in this subsection "N/A" and continue with the SPERM PROCESSING FOR THERAPEUTIC INSEMINATION section.)

QUESTION: 90:1860 PHASE: II

Has the laboratory validated sperm-egg interaction assays inter- and intra-assay coefficients of variation?

SPERM-EGG INTERACTION TESTS:

COMMENTARY: 90:1860 PHASE: II

THE INTRA-ASSAY COEFFICIENT OF VARIATION MUST NOT EXCEED 15%, AND THE INTER-ASSAY COEFFICIENT OF VARIATION MUST NOT EXCEED 25% AS DETERMINED USING WHO METHODS.

REFERENCE: WORLD HEALTH ORGANIZATION LABORATORY MANUAL FOR THE EXAMINATION OF HUMAN SEMEN AND SPERM-CERVICAL MUCUS INTERACTION: THIRD EDITION. NEW YORK: CAMBRIDGE UNIVERSITY PRESS, 1992.

QUESTION: 90:1880 PHASE: II

Is a positive control semen specimen run with each assay?

COMMENTARY: 90:1880 PHASE: II

A POSITIVE CONTROL SEMEN SPECIMEN MUST BE RUN WITH EACH ASSAY.

REFERENCE: WORLD HEALTH ORGANIZATION LABORATORY MANUAL FOR THE EXAMINATION OF HUMAN SEMEN AND SPERM-CERVICAL MUCUS INTERACTION, THIRD EDITION. CAMBRIDGE UNIVERSITY PRESS, 1992.

SPERM PROCESSING FOR THERAPEUTIC INSEMINATION

QUESTION: 90:1890 PHASE: 0 LAB

Does the laboratory process sperm for therapeutic insemination?

(If "NO," mark all questions in this subsection "N/A" and continue with the EMBRYOLOGY section.)

QUESTION: 90:1900 PHASE: I

Has the laboratory identified appropriately non-toxic plasticware for semen collection and processing that does not impair sperm motility or viability and are new lots tested before introduction?

SPERM PROCESSING FOR THERAPEUTIC INSEMINATION:

COMMENTARY: 90:1900 PHASE: I

ALL LABORATORY CONTAINERS USED FOR SEMEN COLLECTION OR PROCESSING SHOULD BE TESTED FOR TOXICITY TO ENSURE THAT SPERM MOTILITY AND VIABILITY ARE NOT IMPAIRED.

REFERENCE: WORLD HEALTH ORGANIZATION LABORATORY MANUAL FOR THE EXAMINATION OF HUMAN SEMEN AND SPERM-CERVICAL MUCUS INTERACTION, THIRD EDITION. LONDON: CAMBRIDGE UNIVERSITY PRESS, 1992.

QUESTION: 90:1910 PHASE: II

Does the laboratory have a systematic method for quality assessment and is it documented?

COMMENTARY: 90:1910 PHASE: II

THERE MUST BE A QUALITY ASSESSMENT PROGRAM IN USE IN THE LABORATORY THAT IS COMPLETE FOR ALL PROCEDURE PROCESSING. OUTCOMES SHOULD BE TRACKED WHENEVER POSSIBLE.

QUESTION: 90:1920 PHASE: II

Are special handling requirements for insemination specimens defined and followed (*e.g.*, aseptic technique, processing with minimum delay), as necessary?

COMMENTARY: 90:1920 PHASE: II

SPECIAL HANDLING REQUIREMENTS FOR INSEMINATION SPECIMENS MUST BE DEFINED AND FOLLOWED (*i.e.*, ASEPTIC TECHNIQUE, PROCESSING WITH MINIMUM DELAY) AS NECESSARY.

REFERENCE: GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58 (SUPPL 1): SECTION I, B, 5.

QUESTION: 90:1930 PHASE: II

Are there documented procedures for preparing sperm for insemination (*e.g.*, swim-up technique)?

COMMENTARY: 90:1930 PHASE: II

THERE MUST BE DOCUMENTED PROCEDURES FOR PREPARING SPERM FOR INSEMINATION (*e.g.*, SWIM-UP TECHNIQUE).

REFERENCE: GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58 (SUPPL 1): SECTION IV, B, 2.

QUESTION: 90:1950 PHASE: II

Is there a system in place to verify and maintain the identity of the specimen throughout receipt, storage, processing and disposition?

COMMENTARY: 90:1950 PHASE: II

PROCEDURES MUST BE IN PLACE TO ENSURE THAT INSEMINATION SPECIMENS ARE CORRECTLY IDENTIFIED FOR THE RECIPIENT.

REFERENCE: BYRD W. QUALITY ASSURANCE IN THE REPRODUCTIVE BIOLOGY LABORATORY. ARCH PATHOL LAB MED. 1992;116:418-422.

QUESTION: 90:1960 PHASE: II

Is there documentation of all individuals handling the specimen from receipt to final disposition?

COMMENTARY: 90:1960 PHASE: II

DOCUMENTATION MUST BE IN PLACE TO IDENTIFY THE INDIVIDUAL HANDLING THE SPECIMEN FOR ALL PHASES OF SPERM PROCESSING.

REFERENCE: WORLD HEALTH ORGANIZATION LABORATORY MANUAL FOR THE EXAMINATION OF HUMAN SEMEN AND SPERM-CERVICAL MUCUS INTERACTION, THIRD EDITION. LONDON: CAMBRIDGE UNIVERSITY PRESS, 1992.

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ANDROLOGY PERSONNEL

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The laboratory should have an organizational plan, personnel policies, and job descriptions that define qualifications and duties for all positions. Personnel files should contain qualifications, references, performance evaluations, health records and continuing education records for each employee. Ideally, these files should be located in the laboratory. However, they may be kept in the personnel office or health clinic if the laboratory has ready access to them (i.e., easily available to the inspector).

Andrology laboratory personnel must have the same qualifications as other "high complexity" (CLIA-88 terminology) personnel as listed in Laboratory General Checklist 1.

QUESTION: 90:PERS PHASE: II NEW

Does the Director and all other personnel in the Andrology Laboratory meet all of the requirements described in Laboratory General Checklist 1?

NOTE: The Inspector must describe any specific deficiencies in the narrative portion of the Summation Report.

ANDROLOGY PERSONNEL:

COMMENTARY: 90:PERS PHASE: II

THE LABORATORY DIRECTOR AND ALL PERSONNEL MUST MEET ALL OF THE REQUIREMENTS DESCRIBED IN LABORATORY GENERAL CHECKLIST 1.

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EMBRYOLOGY

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Embryology laboratories may have separate andrology facilities that are not accredited by the College of American Pathologists. However, if the embryology laboratory either processes sperm for therapeutic insemination, oocyte insemination, or performs any form of a semen analysis, it must complete questions in the preceding SPERM PROCESSING FOR THERAPEUTIC INSEMINATION section and/or the ANDROLOGY section.

If no embryology procedures are performed in the laboratory, mark all questions in this section "N/A" and continue with the PERSONNEL section.

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OOCYTE AND EMBRYO HANDLING

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CULTURE OF SPERM, OOCYTES AND EMBRYOS

QUESTION: 90:2057 PHASE: II

Are sterile techniques employed in the handling, assessment and culturing of human sperm, oocytes and embryos?

CULTURE OF SPERM, OOCYTES AND EMBRYOS:

COMMENTARY: 90:2057 PHASE: II

STERILE TECHNIQUES MUST BE EMPLOYED IN THE HANDLING, ASSESSMENT AND CULTURING OF HUMAN SPERM, OOCYTES AND EMBRYOS. ALL PROCEDURES RELATING TO RECOVERY OF EGGS FROM FOLLICULAR ASPIRATES MUST BE PERFORMED USING STERILE TECHNIQUE. ALL PROCEDURES RELATING TO EMBRYO TRANSFER MUST BE PERFORMED USING STERILE TECHNIQUE, AS FAR AS POSSIBLE.

QUESTION: 90:2090 PHASE: II

Are there documented criteria for evaluation/assessment of oocyte maturity and embryo quality?

CULTURE OF SPERM, OOCYTES AND EMBRYOS:

COMMENTARY: 90:2090 PHASE: II

THERE MUST BE DOCUMENTED CRITERIA FOR EVALUATION AND ASSESSMENT OF OOCYTE MATURITY AND EMBRYO QUALITY. DOCUMENTED PROTOCOLS SHOULD INCLUDE DESCRIPTION OF OOCYTE AND EMBRYO QUALITY AND MATURITY. THE STAGE OF EMBRYO DEVELOPMENT AT TRANSFER MUST BE DOCUMENTED.

REFERENCE: GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58 (SUPPL 1): SECTION VIII, B-2.

QUESTION: 90:2100 PHASE: II

Are there documented criteria for insemination relative to oocyte maturity?

COMMENTARY: 90:2100 PHASE: II

THERE MUST BE DOCUMENTED CRITERIA FOR INSEMINATION RELATIVE TO OOCYTE MATURITY. DOCUMENTED PROTOCOLS MUST INCLUDE REMEDIAL STEPS TO BE USED FOR IMMATURE AND/OR ATRETIC OOCYTES.

REFERENCE: GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58 (SUPPL 1): SECTION B-1.

QUESTION: 90:JAAA PHASE: II

Are there defined criteria for volume, numbers, and quality of sperm used for insemination of each egg?

COMMENTARY: 90:JAAA PHASE: II

THERE MUST BE DEFINED CRITERIA FOR VOLUME, NUMBERS, AND QUALITY OF SPERM USED FOR INSEMINATION OF EACH EGG. TECHNIQUES MUST BE DOCUMENTED FOR ESTIMATION OF SAMPLE PARAMETERS FOR CONCENTRATION, MOTILITY, AND MORPHOLOGY ALONG WITH TECHNIQUES FOR INSEMINATION WITH RESPECT TO COUNT AND MOTILITY FOR BOTH NORMAL AND MALE FACTOR PATIENTS.

REFERENCE: GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58 (SUPPL 1): SECTION V, 1-4.

QUESTION: 90:2110 PHASE: II

Is there a documented policy for the disposition of oocytes with an abnormal number of pronuclei?

COMMENTARY: 90:2110 PHASE: II

THERE MUST BE A DOCUMENTED POLICY FOR THE DISPOSITION OF POLY-PRONUCLEAR OOCYTES. EMBRYOS WITH THREE OR MORE PRONUCLEI SHOULD NOT BE TRANSFERRED.

REFERENCE: GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58 (SUPPL 1): SECTION VI, B-8.

QUESTION: 90:2120 PHASE: II

Is there a defined period for examination of oocytes for fertilization?

COMMENTARY: 90:2120 PHASE: II

THERE MUST BE A DEFINED PERIOD FOR EXAMINATION OF OOCYTES FOR FERTILIZATION. THE INTERVAL FROM OOCYTE INSEMINATION TO EXAMINATION SHOULD BE 14 TO 20 HOURS.

REFERENCE: GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58 (SUPPL 1): SECTION VI, B-2.

QUESTION: 90:2130 PHASE: II

Does the laboratory have documented criteria for re-insemination, using either in vitro fertilization or intracytoplasmic sperm injection?

COMMENTARY: 90:2130 PHASE: II

THE LABORATORY MUST HAVE DOCUMENTED CRITERIA FOR RE-INSEMINATION. DOCUMENTED PROCEDURES FOR RE-INSEMINATION OF OOCYTE AND/OR MICRO-MANIPULATION SHOULD INCLUDE TIME FRAME FOR RE-INSEMINATION, CRITERIA FOR USE OF INITIAL SAMPLE, TIME FRAME FOR RE-EXAMINATION OF THESE OOCYTES AND THE HIERARCHY FOR THEIR USE AT EMBRYO TRANSFER.

REFERENCE: GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58 (SUPPL 1): SECTION VI, B-7.

MICROMANIPULATION OF EMBRYOS

QUESTION: 90:TAAB PHASE: 0 LAB NEW

Does the laboratory perform micromanipulation on oocytes or embryos?

(If no, then mark all questions in this subsection "N/A" and continue with the Embryo Transfer Procedures section).

QUESTION: 90:TAAD PHASE: II NEW

Is there a documented program to train and evaluate personnel in their competency to perform micromanipulation?

MICROMANIPULATION OF EMBRYOS:

COMMENTARY: 90:TAAD PHASE: II

FOR LABORATORIES PERFORMING MICROMANIPULATION, THERE MUST BE A TRAINING PROGRAM FOR NEW PERSONNEL, USING ANIMAL MODEL SYSTEMS OR NONVIABLE HUMAN OOCYTES.

REFERENCE: GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58(SUPPL 1): SECTION VI, B, 2.

QUESTION: 90:TAAE PHASE: II NEW

Does the laboratory have a program to ensure that micromanipulation procedures are performed at an acceptable level?

COMMENTARY: 90:TAAE PHASE: II

THERE MUST BE A DOCUMENTED PROGRAM TO ENSURE THAT MICROMANIPULATION PROCEDURES ARE PROVIDING ACCEPTABLE LEVELS OF PERFORMANCE. THIS WOULD INCLUDE FERTILIZATION OF OOCYTES, SURVIVAL FOLLOWING ZONA HATCHING, AND PREGNANCY RATES USING MICROMANIPULATED EMBRYOS.

EMBRYO TRANSFER PROCEDURES

QUESTION: 90:2190 PHASE: II

Are there documented procedures for the length of time embryos are cultured before transfer?

EMBRYO TRANSFER PROCEDURES:

COMMENTARY: 90:2190 PHASE: II

THERE MUST BE DOCUMENTED PROCEDURES FOR THE LENGTH OF TIME EMBRYOS ARE CULTURED BEFORE TRANSFER.

REFERENCE: GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58(SUPPL 1): SECTION VI, B-7.

QUESTION: 90:2200 PHASE: II

Does the laboratory document the status and quality of embryos before transfer?

COMMENTARY: 90:2200 PHASE: II

THE LABORATORY MUST DOCUMENT THE STATUS AND QUALITY OF EMBRYOS BEFORE TRANSFER.

REFERENCE: GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58 (SUPPL 1).

REFERENCE: GUIDELINES FOR HUMAN EMBRYOLOGY LABORATORIES.

QUESTION: 90:2210 PHASE: II

Are techniques employed that minimize the risk of infection or contamination in the loading and transport of embryos?

COMMENTARY: 90:2210 PHASE: II

TECHNIQUES MUST BE EMPLOYED IN THE LOADING AND TRANSPORT OF EMBRYOS TO MINIMIZE INFECTION OR CONTAMINATION.

REFERENCE: GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58 (SUPPL 1): SECTION IV, C, 7c.

QUESTION: 90:ZYXW PHASE: II NEW

Is the identity of the patient specimen (sperm or embryos) checked against the identity of the patient prior to transfer or insemination and is this identification documented?

COMMENTARY 90:ZYXW PHASE: II

THERE MUST BE AN ESTABLISHED CHAIN OF CUSTODY FOR ALL REPRODUCTIVE GAMETES OR EMBRYOS THAT ARE TRANSFERRED BACK TO A PATIENT. THIS INCLUDES DOCUMENTATION OF THE PATIENT SPECIMEN IDENTIFICATION (ID), AS WELL AS THE PATIENT'S ID. WHEN IT IS NOT POSSIBLE FOR THE LABORATORY STAFF TO CHECK THE PATIENT'S ID, THEN THIS SHOULD BE DONE AND DOCUMENTED BY A NURSE, PHYSICIAN, OR OTHER HEALTH CARE PROVIDER BEFORE TRANSFER.

QUESTION: 90:2220 PHASE: II

Does the laboratory check the catheter for any embryos left after transfer?

COMMENTARY: 90:2220 PHASE: II

THE LABORATORY MUST CHECK THE CATHETER FOR ANY EMBRYOS LEFT AFTER TRANSFER. EMBRYOS CAN BE RETAINED IN THE CATHETER. THESE SHOULD BE IDENTIFIED AND THE TRANSFER MAY BE REPEATED OR THE EMBRYOS FROZEN.

REFERENCE: POINDEXTER AN, ET AL. RESIDUAL EMBRYOS IN FAILED EMBRYO TRANSFER. FERTIL STERIL. 1986;46:262-267.

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RECORDS

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QUESTION: 90:2230 PHASE: II

Are written records generated and retained for each individual patient's treatment cycle?

RECORDS:

COMMENTARY: 90:2230 PHASE: II

DOCUMENTED RECORDS MUST BE GENERATED AND RETAINED FOR EACH INDIVIDUAL PATIENT'S TREATMENT CYCLE.

REFERENCE: QUIGLEY MM. DATA MANAGEMENT IN AN IN VITRO FERTIILIZATION AND EMBRYO TRANSFER PROGRAM. IN: HUMAN IN VITRO FERTILIZATION AND EMBRYO TRANSFER. WOLF DP, QUIGLEY, MM, EDS. NEW YORK: PLENUM PRESS, 1984;383-402.

Do the records contain information concerning:

QUESTION: 90:2240 PHASE: II

a. Results of oocyte retrieval procedure?

COMMENTARY: 90:2240 PHASE: II

THE RECORDS MUST CONTAIN THE RESULTS OF OOCYTE RETRIEVAL.

REFERENCE: SHARMA V, ET AL. AN ANALYSIS OF FACTORS INFLUENCING THE ESTABLISHMENT OF A CLINICAL PROGRAM IN AN ULTRASOUND-BASED AMBULATORY IN VITRO FERTILIZATION PROGRAM. FERTIL STERIL. 1988;49:468-478.

QUESTION: 90:2250 PHASE: II

b. Semen analysis before and after processing?

COMMENTARY: 90:2250 PHASE: II

THE RECORD MUST CONTAIN INFORMATION CONCERNING THE SEMEN ANALYSIS.

REFERENCE: BYRD W, WOLF DP. OOGENESIS, FERTILIZATION AND EARLY DEVELOPMENT. IN: HUMAN IN VITRO FERTILIZATION AND EMBRYO TRANSFER. WOLF DP, QUIGLEY MM, EDS. NEW YORK: PLENUM PRESS, 1984;213-273.

QUESTION: 90:2260 PHASE: II

c. Disposition of all oocytes collected?

COMMENTARY: 90:2260 PHASE: II

THE RECORD MUST CONTAIN INFORMATION CONCERNING THE DISPOSITION OF ALL OOCYTES COLLECTED.

REFERENCES: 1) VEECK LL, ET AL. MATURATION AND FERTILIZATION OF MORPHOLOGICALLY IOMATURE HUMAN OOCYTES IN A PROGRAM OF IN VITRO FERTILIZATION. FERTIL STERIL. 1983;39:594-602; 2) GERRITY M. QUALITY CONTROL AND LABORATORY MONITORING. IN: IN VITRO FERTILIZATION AND EMBRYO TRANSFER. DP WOLF (ED). NEW YORK: PLENUM PRESS, 1988;25-45.

QUESTION: 90:2270 PHASE: II

d. Outcome of insemination (*e.g.*, fertilization)?

COMMENTARY: 90:2270 PHASE: II

THE RECORD MUST CONTAIN INFORMATION CONCERNING THE OUTCOME OF INSEMINATION (FERTILIZATION).

REFERENCES: 1) GERRITY M: DP WOLF (ED). QUALITY CONTROL AND LABORATORY MONITORING. IN: HUMAN IN VITRO FERTILIZATION AND EMBRYO TRANSFER. NEW YORK: PLENUM PRESS, 1988;25-45; 2) TARKOWSKI AK. RECENT STUDIES IN PARTHENOGENESIS IN THE MOUSE. REPROD FERT SUPPL. 1971;14:31-39.

QUESTION: 90:2280 PHASE: II

e. Outcome of any culture (*e.g.*, cleavage)?

COMMENTARY: 90:2280 PHASE: II

THE RECORD MUST CONTAIN INFORMATION CONCERNING THE OUTCOME OF ANY CULTURE (CLEAVAGE).

REFERENCE: GERRITY M. QUALITY CONTROL AND LABORATORY MONITORING. IN: HUMAN IN VITRO FERTILIZATION AND EMBRYO TRANSFER. IN: HUMAN IN VITRO FERTILIZATION AND EMBRYO TRANSFER. DP WOLF. NEW YORK: PLENUM PRESS, 1988;25-45.

QUESTION: 90:2290 PHASE: II

f. Disposition of all embryos?

COMMENTARY: 90:2290 PHASE: II

DOCUMENTED PROTOCOLS MUST BE ESTABLISHED FOR THE DISPOSAL OF ANY POLY-PRONUCLEAR OR OTHERWISE ABNORMAL EMBRYOS (MANNER OF DISCARDING OR NATURE OF EXPERIMENTATION: MICROMANIPULATION, CULTURING, MICROSCOPY, *etc.*).

REFERENCE: GERRITY M. QUALITY CONTROL AND LABORATORY MONITORING. IN: HUMAN IN VITRO FERTILIZATION AND EMBRYO TRANSFER. IN: HUMAN IN VITRO FERTILIZATION AND EMBRYO TRANSFER. DP WOLF (ED). NEW YORK: PLENUM PRESS, 1988;25-45.

QUESTION: 90:2300 PHASE: II

g. Relative timing of protocol events (incubation hours, *etc.*)?

COMMENTARY: 90:2300 PHASE: II

THE RECORD MUST CONTAIN INFORMATION CONCERNING THE RELATIVE TIMING OF PROTOCOL EVENTS (INCUBATION HOURS, *etc.*).

QUESTION: 90:2310 PHASE: II

h. Does the record identify the individual(s) performing each procedure?

COMMENTARY: 90:2310 PHASE: II

FOR QUALITY ASSURANCE OF IVF PROGRAMS, THE MINIMAL STANDARDS SUGGESTED ARE THAT ALL CERTIFIED EMBRYOLOGY LABORATORY PERSONNEL PERFORM AT LEAST 20 COMPLETE IVF PROCEDURES PER YEAR.

REFERENCE: GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58(SUPPL 1).

QUESTION: 90:2320 PHASE: II

i. Does the record identify specific media and protein solutions used in each phase of the procedure?

COMMENTARY: 90:2320 PHASE: II

TO MAINTAIN PROPER QUALITY CONTROL AND QUALITY ASSURANCE OF IVF PROCEDURES, DOCUMENTATION OF THE SOURCE AND LOT NUMBER OF EACH BATCH OF CULTURE MEDIUM AND THE SOURCE/LOT OF EVERY PROTEIN SUPPLEMENT MUST BE AVAILABLE FOR REVIEW.

REFERENCE: GERRITY M. QUALITY CONTROL AND LABORATORY MONITORING. IN: HUMAN IN VITRO FERTILIZATION AND EMBRYO TRANSFER. IN: HUMAN IN VITRO FERTILIZATION AND EMBRYO TRANSFER. DP WOLF (ED). NEW YORK: PLENUM PRESS, 1988;25-45.

QUESTION: 90:2330 PHASE: II

Is there a mechanism for reporting unusual or abnormal events to the supervisor, director, or physician?

COMMENTARY: 90:2330 PHASE: II

THERE MUST BE A MECHANISM FOR REPORTING UNUSUAL OR ABNORMAL EVENTS TO THE SUPERVISOR, DIRECTOR, OR PHYSICIAN.

QUESTION: 90:2340 PHASE: II

Is a copy of the record retained for laboratory files?

COMMENTARY: 90:2340 PHASE: II

A COPY OF THE RECORD MUST BE RETAINED IN THE LABORATORY.

REFERENCES: GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58(SUPPL 1): SECTION VI, A, 7-9.

QUESTION: 90:2350 PHASE: II

Does the laboratory periodically review clinical outcome in relation to all data collected?

COMMENTARY: 90:2350 PHASE: II

THE LABORATORY MUST PERIODICALLY REVIEW CLINICAL OUTCOME IN RELATION TO ALL DATA COLLECTED. THE LABORATORY SHOULD KEEP STATISTICAL RECORDS AND PERIODICALLY REVIEW CLINICAL OUTCOME IN RELATION TO THIS DATA.

REFERENCES: 1) GERRITY M. QUALITY CONTROL AND LABORATORY MONITORING. IN: HUMAN IN VITRO FERTILIZATION AND EMBRYO TRANSFER. IN: HUMAN IN VITRO FERTILIZATION AND EMBRYO TRANSFER. DP WOLF (ED),. NEW YORK: PLENUM PRESS, 1988;25-45; 2) GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58 (SUPPL 1):1S-16S.

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INSTRUMENTS AND EQUIPMENT

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The laboratory should have an organized system for monitoring and maintaining all instruments.

QUESTION: 90:2360 PHASE: II

Does the laboratory have a documented procedure for the preparation of glassware used in therapeutic procedures?

INSTRUMENTS AND EQUIPMENT:

COMMENTARY: 90:2360 PHASE: II

THE LABORATORY MUST HAVE A DOCUMENTED PROCEDURE FOR THE PREPARATION OF CONTACT GLASSWARE USED IN THERAPEUTIC PROCEDURES. GLASSWARE MUST BE PREPARED IN A MANNER SUCH THAT ALL TOXINS ARE REMOVED BEFORE USE. ALL CONTACT GLASSWARE USED FOR THERAPEUTIC PROCEDURES MUST BE CAREFULLY PROCESSED. GLASSWARE WASHING PROTOCOLS INCLUDING DETERGENT TYPE AND SOURCE, TYPE OF WATER USED, NUMBER OF RINSES AND EXACT PROCEDURE TO BE FOLLOWED MUST BE STRICTLY DEFINED. HEAT STERILIZATION SHOULD BE USED WHENEVER POSSIBLE.

REFERENCES: 1) VEECK LL, MALONEY M. INSEMINATION AND FERTILIZATION. IN: IN VITRO FERTILIZATION. NORFOLK HW, ET AL (EDS). BALTIMORE, MD: WILLIAMS AND WILKINS, 1986;178-200; 2) GERRITY M. QUALITY CONTROL AND LABORATORY MONITORING. IN: HUMAN IN VITRO FERTILIZATION AND EMBRYO TRANSFER. IN: HUMAN IN VITRO FERTILIZATION AND EMBRYO TRANSFER. DP WOLF (ED). NEW YORK: PLENUM PRESS, 1988;25-45; 3) GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58 (SUPPL 1):1S-16S.

QUESTION: 90:2370 PHASE: II

Are there documented criteria for use of gas mixtures?

COMMENTARY: 90:2370 PHASE: II

THERE MUST BE DOCUMENTED CRITERIA FOR GAS MIXTURES USED. THE GASEOUS ENVIRONMENT THAT THE OOCYTES AND EMBRYOS ARE MAINTAINED IN THROUGHOUT THE ENTIRE PROCEDURE MUST BE OUTLINED IN THE PROCEDURE MANUAL.

REFERENCES: 1) GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58 (SUPPL 1):1S-16S; 2) VEECK LL, MALONEY M. INSEMINATION AND FERTILIZATION. IN: IN VITRO FERTILIZATION. JONES, HW, JR, ET AL (EDS). BALTIMORE: WILLIAMS AND WILKINS, 1986:178-200.

Is there documentation of checks of instrument function each day of use using an independent measuring device for:

QUESTION: 90:2380 PHASE: II

Gas concentrations in incubators?

COMMENTARY: 90:2380 PHASE: II

DAILY RECORDINGS NEED TO BE MADE AND RECORDED TO ENABLE CORRECTIVE MEASURES TO BE TAKEN IF VALUES ARE NOT WITHIN ACCEPTABLE DOCUMENTED LIMITS.

REFERENCES: 1) GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58 (SUPPL 1):1S-16S; 2) EDWARDS RG, PURDY JM, EDS. ACADEMIC PRESS. 1982;141-156, 203-206; 3) VEECK LL, MALONEY M. INSEMINATION AND FERTILIZATION. IN: IN VITRO FERTILIZATION. BALTIMORE, MD: WILLIAMS AND WILKINS 1986;178-200; 4) GERRITY M. QUALITY CONTROL AND LABORATORY MONITORING. IN: IN VITRO FERTILIZATION AND EMBRYO TRANSFER. IN: HUMAN IN VITRO FERTILIZATION AND EMBRYO TRANSFER. DP WOLF, ET AL (EDS). PLENUM PRESS. NEW YORK 1988;24-45.

QUESTION: 90:2390 PHASE: II

Temperature of incubators?

COMMENTARY: 90:2390 PHASE: II

DAILY RECORDINGS NEED TO BE MADE AND RECORDED TO ENABLE CORRECTIVE MEASURES TO BE TAKEN IF VALUES ARE NOT WITHIN ACCEPTABLE DOCUMENTED LIMITS.

REFERENCES: 1) GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58 (SUPPL 1):1S-16S; 2) RG EDWARDS AND JM PURDY, EDS. ACADEMIC PRESS. 1982;141-156, 203-206; 3) VEECK LL, MALONEY M. INSEMINATION AND FERTILIZATION. IN: IN VITRO FERTILIZATION NORFOLK HW JONES, JR.ET AL (EDS). BALTIMORE: WILLIAMS AND WILKINS. 1986;178-200; 4) GERRITY M. QUALITY CONTROL AND LABORATORY MONITORING. IN: IN VITRO FERTILIZATION AND EMBRYO TRANSFER. DP WOLD (ED). NEW YORK: PLENUM PRESS, 1988;25-45.

QUESTION: 90:2400 PHASE: II

Are acceptable limits of temperature, gas content, and humidity defined?

COMMENTARY: 90:2400 PHASE: II

ACCEPTABLE LIMITS OF TEMPERATURE, CO2, CONTENT, AND HUMIDITY MUST BE DEFINED. ONLY IF LIMITS ARE DEFINED CAN VARIANCES BE REPORTED AND ACTION TAKEN TO CORRECT THE PROBLEM.

REFERENCES: 1) GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58 (SUPPL 1):1S-16S; 2) ABRAMCZYK JW, LOPATA A. INCUBATOR PERFORMANCE IN THE CLINICAL IN VITRO FERTILIZATION PROGRAM: IMPORTANCE OF TEMPERATURE CONDITIONS FOR THE FERTILIZATION AND CLEAVAGE OF HUMAN EMBRYOS. FERTIL STERIL. 1986;46:132-134.

QUESTION: 90:2410 PHASE: II

Are digital displays of incubator temperature calibrated with a certified thermometer?

COMMENTARY: 90:2410 PHASE: II

DIGITAL DISPLAYS OF INCUBATOR TEMPERATURE MUST BE CALIBRATED WITH A CERTIFIED THERMOMETER. DISPLAYS NEED TO BE CHECKED AND CALIBRATED TO A NIST TRACEABLE THERMOMETER.

QUESTION: 90:2420 PHASE: II

Does the laboratory have a method to detect and prevent incubator temperature and gas control failure?

COMMENTARY: 90:2420 PHASE: II

THE LABORATORY MUST HAVE A METHOD TO DETECT AND PREVENT INCUBATOR TEMPERATURE AND CO2 FAILURE. BOTH INCUBATOR DISPLAY AND A SEPARATE INTERNAL THERMOMETER NEED TO BE CHECKED AND RECORDED DAILY. THE CO2 NEEDS TO BE CHECKED AND RECORDED DAILY FROM THE DISPLAY AND A FYRITE TEST KIT IF THE INCUBATOR IS IN USE.

REFERENCE: GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58 (SUPPL 1): SECTION V, A, 1.

QUESTION: 90:WAAS PHASE: II

Does the laboratory's incubator for embryos have emergency back-up power, and is it tested periodically?

COMMENTARY: 90:WAAS PHASE: II

THE LABORATORY'S INCUBATOR FOR EMBRYOS MUST HAVE A BACK-UP POWER SUPPLY. THE BACK-UP POWER SUPPLY MUST BE CHECKED PERIODICALLY.

REFERENCE: REVISED MINIMUM STANDARDS FOR IN VITRO FERTILIZATION, GAMETE INTRAFALLOPIAN TRANSFER, AND RELATED PROCEDURES. FERTIL STERIL. 1998;70(SUPPL 2):1S-5S.

QUESTION: 90:2430 PHASE: II

Does the laboratory have a method to monitor and maintain adequate liquid nitrogen levels?

COMMENTARY: 90:2430 PHASE: II

THE LABORATORY MUST HAVE A METHOD TO MONITOR AND MAINTAIN ADEQUATE NITROGEN LEVELS.

REFERENCE: STANDARDS AND TECHNICAL MANUAL REPRODUCTIVE CELLS AND TISSUES. AMERICAN ASSOCIATION OF TISSUE BANKS, 1992: D.3000.

QUESTION: 90:2440 PHASE: II

Are all critical incubator, storage, refrigeration, and freezing units monitored and checked periodically?

COMMENTARY: 90:2440 PHASE: II

THERE MUST BE EVIDENCE OF MONITORING OF ALL CRITICAL INCUBATOR, STORAGE, REFRIGERATION AND FREEZING UNITS. ALARM SYSTEMS, IF USED, MUST BE CHECKED PERIODICALLY.

REFERENCE: REVISED MINIMUM STANDARDS FOR IN VITRO FERTILIZATION, GAMETE INTRAFALLOPIAN TRANSFER, AND RELATED PROCEDURES. FERTIL STERIL. 1998;70(SUPPL 2):1S-5S.

QUESTION: 90:2450 PHASE: II

Are the alarms monitored 24 hours a day (either remote or in the laboratory)?

COMMENTARY: 90:2450 PHASE: II

THE ALARMS MUST BE MONITORED 24 HOURS A DAY (EITHER REMOTE OR IN LABORATORY). AUDIBLE ALARMS ARE ONLY EFFECTIVE IF SOMEONE IS ABLE TO RESPOND TO THE DIFFICULTY AND IS TRAINED TO FOLLOW THE APPROPRIATE METHODOLOGY TO CORRECT THE PROBLEM OR TAKE ALTERNATIVE MEASURES.

REFERENCE: GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES. FERTIL STERIL. 1992;58 (SUPPL 1): SECTION IV, A, 2 and 10.

QUESTION: 90:2460 PHASE: II

Does the laboratory have a policy for implementing back-up capability (refrigerators, freezers, incubators)?

COMMENTARY: 90:2460 PHASE: II

THE LABORATORY MUST HAVE A PROCEDURE FOR USE OF BACK-UP EQUIPMENT AVAILABLE (REFRIGERATORS, FREEZERS, INCUBATORS).

NOTE 1: IF ANY UNIT BEGINS TO FAIL, A REPAIR OR REPLACEMENT WOULD PROBABLY NOT BE ABLE TO BE PURCHASED AND DELIVERED SOON ENOUGH TO AVOID LOSS OF CONTENTS. IT IS THEREFORE NECESSARY TO HAVE AN EMERGENCY PROCEDURE TO PROVIDE BACK-UP UNITS WITH ADEQUATE STORAGE CAPACITY TO ALLOW COMPLETE TRANSFER OF CONTENTS. THE BACK-UP UNITS MUST BE RUNNING AND MONITORED LIKE THE OTHER REFRIGERATORS, FREEZERS, LIQUID NITROGEN TANKS, AND INCUBATORS.

NOTE 2: DOCUMENTED PROCEDURES FOR USE OF BACK-UP EQUIPMENT, LOCATION, AND CONTACT PERSONNEL MUST BE PART OF THE PROCEDURE MANUAL.

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EMBRYOLOGY PERSONNEL

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EMBRYOLOGY LABORATORY DIRECTOR

QUESTION: 90:2470 PHASE: II

Does the director of the embryology laboratory have proper qualifications through education and experience to provide direction and administration of the laboratory?

EMBRYOLOGY LABORATORY DIRECTOR:

THE LABORATORY DIRECTOR MUST HAVE SUFFICIENT TRAINING AND EXPERIENCE IN CLINICAL MEDICINE, SCIENCES BASIC TO MEDICINE, CLINICAL LABORATORY SCIENCES, AND OPERATIONS TO ENSURE THAT THE FOLLOWING FUNCTIONS ARE PERFORMED. THE DIRECTOR OF THE EMBRYOLOGY LABORATORY SHOULD HAVE 2 YEARS OF DOCUMENTED EXPERIENCE IN A LABORATORY PERFORMING IN VITRO FERTILIZATION OR ASSISTED REPRODUCTIVE TECHNOLOGIES-RELATED PROCEDURES. DIRECTORS OF EMBRYOLOGY LABORATORIES WHO ARE NOT PHYSICIANS OR QUALIFIED DOCTORAL SCIENTISTS, BUT WHO WERE FUNCTIONING AS EMBRYOLOGY DIRECTORS ON OR BEFORE 1/1/92 ARE CONSIDERED IN COMPLIANCE WITH THIS STANDARD, SO LONG AS THEY MEET ALL OTHER REQUIREMENTS. THE DIRECTOR NEED NOT PERFORM ALL OF THESE FUNCTIONS PERSONALLY, BUT IS RESPONSIBLE FOR THE OVERALL OPERATION AND ADMINISTRATION OF THE LABORATORY TO ASSURE QUALITY PATIENT CARE SERVICES.

COMMENTARY: 90:2470 PHASE: II

THE DIRECTOR OF THE LABORATORY MUST HAVE PROPER QUALIFICATIONS THROUGH EDUCATION AND EXPERIENCE TO PROVIDE DIRECTION AND ADMINISTRATION OF THE QUALITY ASSURANCE PROGRAM. THE LABORATORY DIRECTOR SHOULD HAVE PROPER QUALIFICATIONS, MOSTLY THROUGH EXPERIENCE AND EDUCATION, TO PROVIDE ADEQUATE LEADERSHIP, DIRECTION, QUALITY ASSURANCE, RESEARCH AND OTHER ADMINISTRATIVE DUTIES.

REFERENCES: 1) UNITED STATES GENERAL ACCOUNTING OFFICE. DECEMBER 1989, p 17, 7d; 2) GUIDELINES FOR HUMAN EMBRYOLOGY AND ANDROLOGY LABORATORIES FERTIL STERIL. 1992;58 (SUPPL1): SECTION II, A, 1; 3) COLLEGE OF AMERICAN PATHOLOGISTS. STANDARDS FOR ACCREDITATION, REPRODUCTIVE LABORATORY ACCREDITATION PROGRAM. NORTHFIELD, IL: CAP.

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CRYOPRESERVATION OF SPERM, OOCYTES AND EMBRYOS

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QUESTION: 90:TTAB PHASE: II

Does the laboratory have a documented procedure(s) for cryopreservation of sperm, oocytes and/or embryos?

CRYOPRESERVATION OF SPERM, OOCYTES AND EMBRYOS:

COMMENTARY: 90:TTAB PHASE: II

THE LABORATORY MUST HAVE A DOCUMENTED PROCEDURE FOR CRYOPRESERVATION ACCORDING TO STAGE OF DEVELOPMENT OF THE EMBRYO OR THE TYPE OF GAMETE. THE SURVIVAL OF HUMAN EMBRYOS REQUIRES THE USE OF TECHNIQUES SPECIFIC TO THE STAGE OF EMBRYO DEVELOPMENT.

REFERENCES: 1) FEHILLY CB, ET AL. CRYOPRESERVATION OF CLEAVING EMBRYOS AND EXPANDED BLASTOCYSTS IN THE HUMAN. A COMPARATIVE STUDY. FERTIL STERIL. 1985;44:638-; 2) LASALLE B, TESTART J. HUMAN EMBRYO FEATURES THAT INFLUENCE THE SUCCESS OF CYROPRESERVATION WITH THE USE OF 1,2 PROPANEDIOL. FERTIL STERIL. 1985;44:645-651.

QUESTION: 90:TTAD PHASE: II

Does the laboratory have a reliable method for labeling and tracking of cryopreserved specimens?

COMMENTARY: 90:TTAD PHASE: II

THE LABORATORY MUST HAVE A RELIABLE METHOD FOR LABELING AND TRACKING CRYOPRESERVED SPECIMENS.

REFERENCE: AMERICAN ASSOCIATION OF TISSUE BANKS. STANDARDS FOR TISSUE BANKING, 1997.

QUESTION: 90:TTAE PHASE: II NEW

Are records of all patient specimens, donor specimens, and patient/donor matches retained and easily accessible?

COMMENTARY: 90:TTAE PHASE: II

THE LABORATORY MUST MAINTAIN PERMANENT RECORDS OF GAMETES AND EMBRYOS THAT ARE USED FOR INSEMINATION OR DONATED. THERE MUST BE PERMANENT RECORDS FOR EACH PERSON THAT IS INSEMINATED WITH DONOR SPERM OR RECEIVES EMBRYOS THAT RESULTED FROM DONATED OOCYTES OR EMBRYOS, AND BE ABLE TO RECOVER THE IDENTITY OF THE DONOR(S).

REFERENCE: AMERICAN ASSOCIATION OF TISSUE BANKS. STANDARDS FOR TISSUE BANKING, 1997.

QUESTION: 90:TTAF PHASE: II

Are duplicate records maintained in a separate area from the originals?

COMMENTARY: 90:TTAF PHASE: II

DUPLICATE RECORDS OF CRYOPRESERVED SPECIMENS MUST BE MAINTAINED IN A SEPARATE AREA FROM THE ORIGINALS.

REFERENCE: GUIDELINES FOR HUMAN EMBRYOLOGY LABORATORIES. 1988, SECTION VI, A, 7.

QUESTION: 90:TTAG PHASE: II NEW

Are procedures adequate to ensure that cryopreserved patient specimens can be easily retrieved?

COMMENTARY: 90:TTAG PHASE: II

THERE MUST BE A MECHANISM BY WHICH PATIENT SPECIMENS CAN EASILY BE RETRIEVED.

REFERENCE: DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION. CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988; FINAL RULE. FEDERAL REGISTER. 1992(FEB 28):7173 [42 CFR 493.1265].

QUESTION: 90:TTAH PHASE: II NEW

Is the laboratory able to document the disposition and current inventory of all specimens that have been stored in its cryobanks?

COMMENTARY: 90:TTAH PHASE: II

THE LABORATORY MUST BE ABLE TO REPORT THE DISPOSITION OF ALL SAMPLES THAT HAVE BEEN STORED IN THE BANK, AND THE CURRENT REMAINING INVENTORY OF SAMPLES IN THE BANK.

REFERENCE: AMERICAN ASSOCIATION OF TISSUE BANKS. STANDARDS FOR TISSUE BANKING, 1997.

QUESTION: 90:TTAJ PHASE: II NEW

Is there a policy to cover inventoried samples that cannot be located in the bank?

COMMENTARY: 90:TTAJ PHASE: II

THERE MUST BE A POLICY IN PLACE THAT ADDRESSES THE ISSUE OF SAMPLES THAT CANNOT BE LOCATED. THIS WILL REQUIRE A PHYSICAL INVENTORY OF THE BANK ON A PERIODIC BASIS.

QUESTION: 90:TTAK PHASE: II NEW

Are procedure adequate to verify specimen identity and integrity throughout the entire process of cryopreservation?

COMMENTARY: 90:TTAK PHASE: II

THE IDENTITY OF THE SPECIMEN MUST BE ENSURED THROUGH ALL STEPS OF THE PROCEDURE. THERE MUST BE UNIQUE IDENTIFYING NUMBERS ON ALL SPECIMENS.

REFERENCE: DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION. CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988; FINAL RULE. FEDERAL REGISTER. 1992(FEB 28):7173 [42 CFR 493.1103].

QUESTION: 90:TTAM PHASE: II

Does the laboratory have a program in place to ensure that cryopreservation is capable of providing viable recovery rates?

COMMENTARY: 90:TTAM PHASE: II

THE LABORATORY MUST HAVE A PROGRAM IN PLACE TO ENSURE THAT CRYOPRESERVATION IS CAPABLE OF PROVIDING ACCEPTABLE RECOVERY RATES OF VIABLE SPERM, OOCYTES AND/OR EMBRYOS.

REFERENCES: 1) DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH CARE FINANCING ADMINISTRATION. CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988; FINAL RULE. FEDERAL REGISTER. 1992(FEB 28):7173 [42 CFR 493.1103]; 2) AMERICAN ASSOCIATION OF TISSUE BANKS. STANDARDS FOR TISSUE BANKING, 1997.

QUESTION: 90:TTAN PHASE: II

Is there a documented procedure in place to cover length of storage, informed consent and long term disposition of cryopreserved gametes or embryos?

COMMENTARY: 90:TTAN PHASE: II

THERE MUST BE CONSENT FORMS THAT COVER THE LENGTH OF STORAGE OF GAMETES, EMBRYOS, OR REPRODUCTIVE TISSUE, AND THEIR LONG-TERM DISPOSITION. GOOD PRACTICE ALSO DICTATES THAT THE CONSENT FORM FOR ALL PROCEDURES IS ON FILE AND READILY AVAILABLE TO THE LABORATORY STAFF.

REFERENCES: 1) TROUNSON A, ET AL. ULTRARAPID FREEZING: A NEW LOS-COST AND EFFECTIVE METHOD OF EMBRYO CRYOPRESERVATION. FERTIL STERIL. 1987;48:843-850; 2) HARRISON KL, ET AL. THE OPTIMAL CONCENTRATION OF ALBUMIN AS EMBRYO CRYOPROTECTANT. J IN VITRO EMBRYO TRANSFER. 1987;4:288-291; 3) AMERICAN ASSOCIATION OF TISSUE BANKS. STANDARDS FOR TISSUE BANKING, 1997.

QUESTION: 90:TTAP PHASE: II NEW

If samples are transferred to another facility, is detailed information provided regarding sample identity, specimen quality and thawing techniques for that specimen?

COMMENTARY: 90:TTAP PHASE: II

THERE MUST BE DOCUMENTED PROCEDURES FOR THE RELEASE OF ANY SPECIMEN AND ITS TRANSPORT TO ANOTHER FACILITY. DETAILED INFORMATION MUST BE PROVIDED TO ANOTHER FACILITY WHEN SPECIMENS ARE TRANSFERRED TO THAT FACILITY. THIS INFORMATION MUST INCLUDE, BUT NOT BE LIMITED TO, THE NUMBER OF SPECIMENS, THE IDENTITY OF THE SPECIMENS, THE QUALITY OF THE SPECIMEN, ANY QUALITY CONTROL DATA ON FREEZE/THAWING OF THE SPECIMEN AND THE APPROPRIATE THAWING TECHNIQUE TO USE WITH EACH SPECIMEN.

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LABORATORY SAFETY

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NOTE TO THE INSPECTOR: Please review ALL safety questions in the Laboratory General checklist. These questions have been omitted from this checklist to avoid repetition. Deficiencies should be marked in the Laboratory General checklist. Please elaborate upon the location and the details of each deficiency in the Inspector's Summation Report.

QUESTION: 90:SDAA PHASE: I

Is the reproductive laboratory in compliance with all safety requirements as identified in the Laboratory General checklist?

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LABORATORY SAFETY:

COMMENTARY: 90:SDAA PHASE: I

ONE OR MORE SAFETY DEFICIENCIES FOR THE REPRODUCTIVE LABORATORY ARE ITEMIZED IN THE LABORATORY GENERAL CHECKLIST.