# Inspecting Andrology and Embryology

REPRODUCTIVE LABORATORY CHECKLIST VERSION 08.17.2016

# The Reproductive Laboratory Checklist

- This checklist is used in conjunction with the All Common and Laboratory General Checklists to inspect a reproductive laboratory
- The Andrology Laboratory is under the purview of the Centers for Medicare and Medicaid Services (CMS) and subject to rules applying to CLIA. The Clinical Laboratory Improvement Amendments (CLIA) of 1988 are United States federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States, except clinical trials and basic research.
- The Embryology Laboratory is not subject to CLIA, therefore some of the checklist questions differ in interpretation for the two laboratories, however the intent is the same – providing quality care in a safe environment.

# How does your laboratory monitor embryology clinical outcomes?

- RLM.01000 Unusual Laboratory Events Phase I
  - There is a written policy for reporting unusual or abnormal events to the supervisor, laboratory director, or physician.
- RLM.01200 Monthly QC Review Phase II
  - Quality control data are reviewed and assessed at least monthly by the laboratory director or designee.
- RLM.01250 Clinical Outcome Review Phase II
  - The laboratory at least annually reviews embryology clinical outcome in relation to all data collected.
  - Evidence of Compliance:
    - ✓ Records of statistical data AND
    - ✓ Records of data review by the laboratory director, designee or QM committee

# Requisitions, Specimen Receipt, And Results Reporting

- RLM.01800 Specimen Collection/Handling Phase I
- There are written patient instructions for collection and prompt delivery of a semen sample to the laboratory.
  - NOTE: 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 2-7 days before collection of the specimen, avoidance of lubricants and other contamination, completeness of collection, use of the supplied container, maintenance of sample temperature, and prompt delivery.
  - Instructions must be posted in the collection room.
  - Collection instructions should be distributed to off-site physician offices that refer specimens.

# Requisitions, Specimen Receipt, And Results Reporting

- RLM.02000 Specimen Collection/Handling Phase I
- Semen specimens are accompanied by the following collection information, and records are maintained on the following.
- 1. Method of collection
- 2. Type of specimen container
- 3. Days of abstinence
- 4. Collection or transport problems (e.g. incomplete specimen, exposure to temperature extremes)
- 5. Time of specimen receipt and analysis
- 6. Identity of patient was confirmed and by whom

# Requisitions, Specimen Receipt, And Results Reporting

- RLM.02100 Liquefaction Phase I
  - All semen specimens are given sufficient time for liquefaction before testing.
    - Evidence of Compliance: ✓Written policy defining criteria for liquefaction
- RLM.02200 Specimen Handling - Pre-analytic Phase I
  - Semen specimens are mixed thoroughly before testing.

# Requisitions, Specimen Receipt, And Results Reporting

- RLM.02300 Specimen Characteristics - Analytic Phase I
  - All characteristics of the semen specimens are noted and reported (e.g. gelatinous clumps, viscosity, contaminants, erythrocytes, abnormalities of liquefaction).
    - NOTE: Macroscopic and microscopic characteristics of the semen specimens must be noted and reported, in accordance with the WHO laboratory manual for the examination and processing of human semen (i.e. fourth or fifth edition).
    - Evidence of Compliance:
      - ✓ Written policy defining characteristics to be included in the report

# Requisitions, Specimen Receipt, And Results Reporting

- RLM.02400 Reporting Phase II
  - Patient results are reported in a legible, easy-to-interpret format that clearly delineates the clinical significance of the results.

# General Quality Control

- Review a sampling of quality control policies and procedures
- Review a sampling of QC records over the previous two years
- Ask "How do you determine when quality control is unacceptable and when corrective actions are needed"?
- Select several occurrences in which QC is out of range and follow records to determine if the steps taken follow the laboratory procedure for corrective action

# General Quality Control

- RLM.02800 QC Phase II
  - For qualitative tests, a positive and negative control is included with each run of patient specimens. (ex. ASA)
    - Evidence of Compliance:
      - ✓QC records showing positive and negative control results

- RLM.02900 QC Handling Phase II
  - Control specimens are tested in the same manner and by the same personnel as patient samples.
    - Evidence of Compliance:
      - ✓ Records reflecting that QC is run by the same personnel performing patient testing

# General Quality Control

- **NEW** 08/17/2016
- RLM.02950 Alternative Control Procedures Phase II
- If the laboratory performs test procedures for which control materials are not commercially available, there are written procedures for an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be recorded.
  - NOTE: "Performance" includes elements of accuracy, precision, and clinical discriminating power. Examples of alternative procedures may include split sample testing with another method or with another laboratory, the testing of previously tested patient specimens in duplicate, testing of patient specimens in duplicate, or other defined processes approved by the laboratory director.
  - Evidence of Compliance:
    - ✓ Written procedures for alternative quality control AND
    - ✓ Records of alternative control procedures

# General Quality Control

- RLM.03000 QC Confirmation of Acceptability Phase II
- The results of controls are reviewed for acceptability before reporting results.
  - NOTE: It is implicit in quality control that patient test results will not be reported when controls do not yield acceptable results.
  - Evidence of Compliance:
    - ✓ Written policy stating that controls are reviewed and acceptable prior to reporting patient results AND
    - ✓ Evidence of corrective action taken when QC results are not acceptable

- RLM.03125 QC Corrective Action Phase II
- There is a record of corrective action when control results exceed defined acceptability limits.

# General Quality Control

- RLM.03100 QC Data Phase II
- Quality control data are organized and presented so they can be evaluated daily by the technical staff to detect problems, trends, etc.

# Culture Media

- Review test procedures for reagent handling (including media preparation/ modification
- Review in-house culture media QC records and manufacturer's QC records
- Raid the 'Fridge:  look at culture media (expiration date, condition, contamination)
- Ask how the laboratory evaluates the quality of contact material?
- Ask what happens if culture media does not meet QC requirements?

- Follow a shipment of new culture media from receipt, examination and QC (if applicable). Determine if practice follows laboratory procedure.

# Culture Media

- RLM.03500 Media Preparation/Modification Phase II
  - There are written procedures for media preparation and modification.
    - NOTE: All media preparation/modification must be performed with sterile technique, in a location and environment appropriate for media preparation. The laboratory has a responsibility for ensuring that any media purchased, prepared or modified is sterile and capable of supporting culture of gametes and embryos.

- RLM.03600 Media Handling Phase II
- There are written criteria for media storage conditions and expiration.

- RLM.03700 Media QC Phase II
- The laboratory has a written procedure for quality control of media.

  -this is applicable even if the media is purchases user-ready.

# Culture Media

- RLM.03800 Contact Material QC Phase II
- The laboratory tests and records the quality of contact materials using a bioassay.
  - NOTE: Materials pretested by the manufacturer with an appropriate bioassay system would not require further in-house testing. Records of testing performed by the manufacturer must be retained.
  - Evidence of Compliance:
    - ✓ Written procedure for the testing of contact materials, including the acceptability criteria

- RLM.03900 Media QC Corrective Action Phase II
- Records indicate corrective action when components do not meet quality control requirements after preparation or modification.

# Instruments And Equipment

- Review records for liquid nitrogen monitoring
- Review alarm monitoring records
- Review incubator monitoring records for gas concentration
- What is the course of action when equipment failure occurs?
- Ask about back-up options in an electrical power outage
- How does your laboratory monitor sterilizing devices?
- Ask how the alarm system is monitored
  - Auto-dialer to nowhere?

# Instruments And Equipment

- RLM.03910 Gas Mixtures Phase II
- There are written criteria for use of gas mixtures.

- RLM.03915 Incubator Daily QC Phase II
- Checks of incubator function are recorded each day of use using an independent measuring device for gas concentrations in incubators.
  - NOTE: In lieu of measuring daily gas concentrations, the laboratory may verify acceptable incubator culture conditions by monitoring and recording daily checks for pH. Alternatively, laboratories using premixed gas may retain the manufacturer's certificate of analysis as evidence of acceptable QC.

# Instruments And Equipment

- RLM.03910 Gas Mixtures Phase II
  - There are written criteria for use of gas mixtures.
- RLM.03920 Incubator Acceptable Limits Phase II
  - Acceptable limits of humidity, gas content, and/or pH are defined for incubators.
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# Instruments And Equipment

- RLM.03930 Incubator Gas Failure Phase II
- The laboratory has written procedures to detect and prevent incubator gas failure. Evidence of Compliance:
- ✓ Written procedure for detecting and preventing gas failure (e.g. alarms or automated monitoring systems)

- RLM.03935 Emergency Power Back-up Phase II
- The laboratory's incubator for embryos and gametes has emergency backup power, and it is tested at least quarterly.
- Evidence of Compliance:
- ✓ Record of generator testing

# Instruments And Equipment

- RLM.03940 Liquid Nitrogen Levels Phase II
- The laboratory has a written procedure to monitor and maintain adequate liquid nitrogen (LN2) levels.
- Evidence of Compliance:
- ✓ Written procedure for monitoring LN2 levels AND
- ✓ Records of monitoring of LN2 levels at defined frequency

# Instruments And Equipment

- RLM.03950 Alarm Monitoring Phase II
- The alarms are monitored 24 hours/day (either remote or in the laboratory).

- NOTE: Alarm systems, if used, must be checked at least annually. Audible alarms are only effective if someone is able to respond and is trained to follow written procedures to correct the problem or take alternative measures.
- Evidence of Compliance:
- ✓ Written procedure for monitoring alarms AND
- ✓ Records of response to the alarm

# Instruments And Equipment

- RLM.03955 Equipment Back-up Phase II
- The laboratory has a written procedure for implementing back-up capability (refrigerators, freezers, incubators, etc.).

- NOTE: 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 backup units with adequate storage capacity to allow complete transfer of contents. The backup units must be tested at least annually to ensure their functionality if needed.
- Procedures for use of backup equipment, location, and contact personnel must be part of the procedure manual. If the backup plan involves using equipment at another laboratory or transferring specimens to another laboratory, there must be a written agreement between the laboratories.

# Records

- RLM.03965 Result Recording Phase II
- Laboratory records are generated for each individual patient's treatment cycle and a copy is retained in the laboratory to include the following as applicable.
- 1. Results of oocyte retrieval
- 2. Semen analysis before and after processing
- 3. Outcome of insemination (e.g. fertilization)
- 4. Outcome of any culture (e.g. cleavage)
- 5. Relative timing of protocol events (incubation hours, etc.)

# Records

- RLM.03970 Specimen Handling and Disposition Phase II
- Laboratory records identify the person performing each step in the collection, processing and administration of gametes and/or embryos.
  - Evidence of Compliance:
    - ✓ Patient records or worksheet identifying the person performing each step of the process

- RLM.03975 Specimen Handling and Disposition Phase II
- Records allow for the tracking of the disposition for gametes or embryos handled or stored.

# Records

- RLM.03980 Reagent Records Phase II
- Records of all critical reagents, supplies and equipment used in collection and processing of gametes and embryos, including lot numbers and expiration dates, are maintained and traceable for each product.

# Semen Analysis General

- Review a sampling of semen analysis policies and procedures
- Review a sampling of patient records or worksheets
- Review a sampling of patient reports
- Follow a semen analysis from requisition, collection information, testing, reporting and recording of result. Determine if practice follows laboratory procedure.

# Semen Analysis General

- RLM.03982 Report Disclaimer Phase I
- If cell clumps or debris are observed during semen analysis, the laboratory indicates on the report that results may be inaccurate.

- RLM.03984 Azoospermic Specimen Result Reporting Phase I
- For azoospermic and post-vasectomy seminal fluid specimens, the laboratory clearly communicates the findings of the assay and either employs a concentrating technique on seminal fluid or includes a comment in the patient report indicating that a concentrating technique was not performed.

# Semen Analysis General

- NOTE: Without a concentration technique, the presence of both motile and non-motile sperm may not be detected. The method for detection of motile and non-motile sperm and the laboratory findings must be clearly communicated on the patient report so that the clinician can interpret the results in context to the method performed. The decision on the method used and extent of testing to be performed should be made in consultation with the medical staff served.
- The American Urological Association (AUA) Vasectomy Guideline recommends a careful evaluation of an uncentrifuged specimen and does not recommend centrifugation of the specimen for further assessment. The AUA Guideline also recommends reporting both the presence and absence of sperm and presence or absence of sperm motility on the patient report. If no sperm are seen in the uncentrifuged specimen, the guideline recommends reporting that the presence of sperm is below the limit of detection.

# Semen Analysis General

- RLM.03986 Motility/Progression Evaluation Phase II
- Sperm motility percent and progression are routinely evaluated within one hour of collection.

- NOTE: Exceptions must be noted on the final report.
- Evidence of Compliance:
- ✓ Written procedure with requirement for motility evaluation AND
- ✓ Records indicating time of collection and evaluation AND
- ✓ Patient reports noting exceptions, when appropriate

# Semen Analysis General

- RLM.03988 Viability Testing Criteria Phase I
- The laboratory performs viability testing on specimens with low percent motility (e.g. less than 30%), or includes a comment that the decreased motility may be the result of non- viable or non-motile sperm.

- NOTE: Non-motile sperm may represent forms that were originally non-viable in the ejaculate, or previously motile forms that have subsequently lost motility. Thus, viability assessment is useful in making the distinction, and is commonly performed with a dye-exclusion method such as eosin-nigrosin.
- Evidence of Compliance:
- ✓ Written procedure for viability testing AND
- ✓ Patient records or worksheet with results of viability testing OR patient report with cautionary verbiage

# Semen Analysis General

- RLM.03990 Standard Temperature Range Phase II
- The laboratory has established a standard temperature range for semen analysis assessment, and deviations from this temperature are noted on the report.

- NOTE: Specimen motility is temperature-dependent. Temperature ranges must be defined.
- Evidence of Compliance:
- ✓ Written procedure with acceptable temperature range defined AND
- ✓ Records showing monitoring of temperatures

# Semen Analysis General

- RLM.05100 Counting Chamber Quality Phase I
- The lines in the counting or motility chambers are bright, and the chambers are clean and free of scratches.

- **REVISED** 08/17/2016
- RLM.05150 Cell Count Controls Phase II
- At least one cell count control specimen is analyzed, or a procedural control used, for each eight hours of patient testing.
  - NOTE: This requirement can be met with assayed liquid control material, a previously assayed patient sample, or a procedural control. (An example of a procedural control is correlation of the cell count with the cellularity of a stained slide prepared by a standard, validated method.) Liquid controls performed in a hemocytometer must be run in duplicate.
  - Evidence of Compliance:
    - ✓ Written procedure for quality control of manual sperm counts AND
    - ✓ Records of cell count or procedural controls at defined frequency

# Semen Analysis General

- RLM.05200 Semen Analysis Procedure Phase II
- For samples counted using a standard hemocytometer, each sperm sample is counted in duplicate.

- NOTE: Defined limits of agreement between replicate counts must be established.
  - Evidence of Compliance:
    - ✓ Written procedure requiring duplicate counts to include limits of agreement AND
    - ✓ Records or worksheets reflecting duplicate counts and corrective action when limits of agreement are exceeded

# Semen Analysis General

- RLM.05900 Motility Microscopic Examination Phase II
- The laboratory has written instructions for evaluating a sufficient number of separate and randomly chosen microscopic fields and sperm cells.

- RLM.06000 Motility Quantification Phase II
- Manual measures of percent sperm motility are quantified in a standardized manner.
  - NOTE: The laboratory must have a written method for determining and reporting sperm motility in its procedure manual that describes how sperm are assessed and counted (percent motility) and is based on a reference method, such as the World Health Organization (WHO) Standards (i.e. fourth or fifth edition).

# Semen Analysis General

- RLM.06100 Forward Progression Phase II
- Forward progression of sperm is evaluated.
  - Evidence of Compliance:
    - ✓ Written procedure for evaluation of forward progression AND
    - ✓ Patient reports or worksheets with results of forward progression

- RLM.06200 Motility Method Verification Phase II
- The sperm motility method is verified at least every six months (e.g. video tapes/digital images of specimens with known percent motility and/or specific motion quality).
  - Evidence of Compliance:
    - ✓ Records of method verification

# Semen Analysis General

- RLM.06300 Stain Usage Phase II
- Stains are used to facilitate morphologic classification of cell types in semen (as opposed to performing differentials of unstained preparations).
  - Evidence of Compliance:
    - ✓ Written procedure for the use of stains for cell classification

- RLM.06350 White Cell Confirmation Techniques Phase I
- There is 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).
  - NOTE: This requirement only applies to laboratories that differentiate leukocytes from other round cells on the patient report,
    - Evidence of Compliance:
      - ✓ Written procedure for confirmation for cell differentiation

# Semen Analysis General

- RLM.06700 Morphology Classification Phase I
- The sperm morphology classification method used is indicated on the report.

  - NOTE: Different classification systems have different reference intervals for normality. To improve the consistency and usefulness of reporting, CAP recommends the use of the WHO Standards (i.e. fourth or fifth edition) and the Kruger classification system, and discontinuing the use of older classification systems.

# Semen Analysis General

- RLM.06800 Slide Retention Phase II
- The slides are retained for at least seven days for future reference.

- RLM.06900 Morphologic Observation Assessment Phase II
- The laboratory at least annually assesses morphologic observations among personnel performing microscopic morphologic classification of sperm and other cells, to ensure consistency.
  - NOTE: Suggested methods to accomplish this include:
    - 1. Circulation of stained semen smears with defined specific qualitative abnormalities of sperm
    - 2. Multi-headed microscopy
    - 3. Use of published references
    - 4. Digital images (e.g. from CD-ROM)

# Semen Analysis General

- RLM.07000 Sperm Morphology Reference Phase I
- There is a file of unusual slides or current atlas of sperm morphology available for training and reference.

- RLM.07100 Stain Quality Phase II
- The stains used (Wright's, Papanicolaou, eosin-nigrosin, peroxidase, etc.) and slide preparations are of sufficient quality to demonstrate the cellular characteristics for which they are designed.
  - NOTE: The stains used for semen analysis must be defined in the laboratory's procedure manual.
    - Evidence of Compliance:
      - ✓ Examples of each type of stained slide available for microscopic review by inspector, as applicable

# Biochemical Tests

- **REVISED** 07/28/2015
- RLM.07400 Biochemical Tests - Daily QC Phase II
- For biochemical tests such as fructose, positive and negative controls are run with each assay, with results recorded and reviewed for acceptability.
  - Evidence of Compliance:
    - ✓ Written procedure for QC AND
    - ✓ QC records

# Anti-sperm Antibody (ASA) Tests

- **REVISED** 07/28/2015
- RLM.07500 Heat Inactivation Phase II
- Serum and follicular fluid specimens used for indirect ASA testing are heat-inactivated before use.
  - NOTE: Serum and follicular fluid specimens used for indirect ASA testing must be treated to inactivate complement.
    - Evidence of Compliance:
      - ✓ Written procedure for pre-analytic treatment of specimens
- RLM.07600 Motility Testing Phase I
- If the testing for ASA requires motile sperm, specimens are assayed with minimal delay and the motility assessed and recorded.
  - Evidence of Compliance:
    - ✓ Patient records and worksheets showing time of collection and evaluation of motility

# Anti-sperm Antibody (ASA) Tests

- RLM.07700 ASA Controls Phase II
- For indirect antibody testing, positive and negative controls are run with each assay, with results recorded and reviewed for acceptability.
  - Evidence of Compliance:
    - ✓ Written procedure for QC AND
    - ✓ QC records

# Sperm Processing For Therapeutic Insemination

- RLM.07800 Specimen Handling - Therapeutic Insemination Phase II
- Special handling requirements for insemination specimens are defined and followed (e.g. aseptic technique, processing with minimum delay), as necessary.

- RLM.07900 Sperm Preparation Phase II
- There are written procedures for preparing sperm for insemination (e.g. gradient, swim-up techniques).

# Sperm Processing For Therapeutic Insemination

- RLM.08000 Specimen Handling Phase II
- There is a system to verify and maintain the identity of the specimen throughout receipt, storage, processing, and disposition.
  - NOTE: All specimens must be labeled with a minimum of two identifiers.
    - Evidence of Compliance:
    - ✓ Written procedure for maintaining specimen identity

# Culture Of Sperm, Oocytes, And Embryos

- NOTE: If a sperm count and/or motility are performed as part of the sperm processing procedure, the laboratory must comply with the pertinent checklist items for sperm count, motility, and proficiency testing listed in the other sections of this checklist.

Very few embryology labs do not need to comply with the andrology checklist!

# Culture Of Sperm, Oocytes, And Embryos

- RLM.08290 Time-Out Phase II
- A "time-out" is called and the following information recorded prior to initiation of each egg retrieval or embryo transfer procedure.
- 1. Patient's two identifiers
- 2. Planned procedure (e.g. egg retrieval or embryo transfer)
- 3. Written physician's order
- 4. Number of embryos to be transferred

# Culture Of Sperm, Oocytes, And Embryos

- NOTE: The "time out," or immediate preoperative pause, must occur in the location where the procedure is to be done with active participation of the appropriate members of the team. The time-out is an opportunity to confirm agreement of all team members present and to resolve any discrepancies prior to initiation of the procedure.
- The procedures for egg retrieval and embryo transfer must explain the laboratory's role, the elements to be confirmed, and the method used for recording the time-out. The record of the time-out must demonstrate that all required elements have been verified.
- 
- Evidence of Compliance:
- ✓ Written procedure with steps to verify information AND
- ✓ Records of time-out verification for each procedure

# Culture Of Sperm, Oocytes, And Embryos

- RLM.08300 Sterile Techniques Phase II
- Sterile techniques are employed in the handling, assessment, culturing, and transfer of human sperm, oocytes and embryos.
- Evidence of Compliance:
- ✓ Written procedure detailing use of appropriate sterile techniques at each step

# Culture Of Sperm, Oocytes, And Embryos

- RLM.08400 Oocyte Maturity/Embryo Quality Phase II
- There are written criteria for evaluation/assessment of oocyte maturity and embryo quality prior to insemination and embryo transfer respectively.

  - NOTE: Procedures should include description of oocyte and embryo quality and maturity. The stage of embryo development at transfer must be recorded.

# Culture Of Sperm, Oocytes, And Embryos

- RLM.08450 Embryo Quality Assessment Verification Phase II
- The procedure of embryo transfer includes verification of the laboratory's proficiency to assess the quality of embryos (e.g. participation in a commercial proficiency testing or inter-laboratory comparison program).

- RLM.08500 Insemination - Oocyte Maturity Phase II
- There are written criteria for insemination relative to oocyte maturity.
  - NOTE: Procedures must be defined for instances of immature and/or atretic oocytes.

# Culture Of Sperm, Oocytes, And Embryos

- **REVISED** 07/28/2015
- RLM.08600 Sperm Number/Volume Phase II
- There are defined criteria for volume and number of sperm used for insemination of each egg.
  - NOTE: There are written procedures 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.

# Culture Of Sperm, Oocytes, And Embryos

- RLM.08700 Disposition of Oocytes Phase II
- There is a written procedure for the immediate disposition of oocytes with an abnormal number of pronuclei.
  - NOTE: Embryos with abnormal numbers of pronuclei should not be transferred.

# Culture Of Sperm, Oocytes, And Embryos

- RLM.08800 Oocyte Examination Phase II
- There is a defined period for examination of oocytes for fertilization.

- RLM.08900 Re-Insemination Criteria Phase II
- The laboratory has written procedures for re-insemination, using either in vitro fertilization or intracytoplasmic sperm injection.
  - NOTE: Procedures for re-insemination of oocyte and/or micromanipulation 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.

# Culture Of Sperm, Oocytes, And Embryos

- RLM.09100 Micromanipulation Phase II
- The laboratory has a program to ensure that micromanipulation procedures are performed at an acceptable level.
  - NOTE: This would include fertilization of oocytes, survival following zona hatching and pregnancy rates using micromanipulated embryos.
    - Evidence of Compliance:
      - ✓ Written procedure to assess ongoing performance, including criteria defining the acceptable levels of performance AND
      - ✓ Records of evaluation of individuals performance OR evaluation of fertilization rate statistics for each embryologist OR records of another documented method approved by the laboratory director AND
      - ✓ Records of corrective action when acceptable level of performance are not achieved

# Culture Of Sperm, Oocytes, And Embryos

- **REVISED** 08/17/2016
- RLM.09150 Embryo Biopsy/Specimen Preparation Training Phase II
- There is a written program to train personnel and evaluate competence in the performance of embryo biopsy and specimen preparation.
  - NOTE: This training must include the process for identifying and labeling individual biopsy specimens to ensure that records of genetic testing performed on each biopsy specimen can be correlated to the native embryo.
  - Evidence of Compliance:
    - ✓ Records of training and competency

# Embryo Transfer Procedures

- RLM.09200 Embryo Culture Timeline Phase II
- There are written procedures for the length of time that embryos are cultured before transfer.

- RLM.09300 Embryo Quality/Status Phase II
- The laboratory records the status and quality of embryos before transfer.
  - NOTE: It is suggested that, whenever possible, photographic records be retained.

# Embryo Transfer Procedures

- RLM.09400 Chain-of-Custody Phase II
- The identity of the patient specimen (sperm or embryos) is checked against the identity of the patient prior to transfer or insemination and this identification is recorded.
  - NOTE: There must be an established chain-of-custody for all reproductive gametes or embryos that are transferred back to a patient. This includes records 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 check should be performed and recorded by a nurse, physician, or other health care provider before transfer.
  - Evidence of Compliance:
    - ✓ Written procedure defining chain-of-custody for patient and patient specimen ID prior to transfer or insemination

# Embryo Transfer Procedures

- RLM.09500 Catheter Check Phase II
- The laboratory records a check of the catheter for any embryos left after transfer.

# Cryopreservation Of Sperm, Oocytes, And Embryos

- Review cryopreservation policies and procedures (includes labeling and tracking of specimens)
- Review current inventory records
- Review specimen storage, retention, retrieval and disposition policies and procedures
- Review record storage and retention policies
- Follow the records of randomly selected cryopreserved sperm and embryos from receipt, preparation, storage and use. Determine if inventory procedures are functioning correctly and procedures
- Ask staff what is done if a sample can't be located; review the policy to see if it conforms.

# Cryopreservation Of Sperm, Oocytes, And Embryos

- RLM.11500 Cryopreservation Phase II
- The laboratory has a written procedure(s) for cryopreservation of sperm, oocytes, and/or embryos

- RLM.11525 Specimen Handling Phase II
- Procedures are adequate to verify specimen identity and integrity throughout the entire cryopreservation process.
  - NOTE: All specimens must be labeled with a minimum of two identifiers.
  - Evidence of Compliance:
    - ✓ Written procedure for maintenance of specimen integrity/identity throughout the process

# Cryopreservation Of Sperm, Oocytes, And Embryos

- RLM.11600 Specimen Labeling/Tracking Phase II
- The laboratory has a reliable method for labeling and tracking of cryopreserved specimens.
  - Evidence of Compliance:
    - ✓ Written procedure for specimen labeling and tracking requirements

- RLM.11700 Record Retention Phase II
- Records of all patient specimens, donor specimens, and patient/donor matches are retained and easily accessible.
  - Evidence of Compliance:
    - ✓ Written record retention policy

# Cryopreservation Of Sperm, Oocytes, And Embryos

- RLM.11800 Duplicate Record Storage Phase II
- Duplicate records are maintained in a separate area from the originals, and there is evidence that all copies of the records are reconciled at least annually.

  - NOTE: Laboratories that use computer-based record systems must demonstrate that the records are backed up when changes are made to the inventory database. The back-up media must be stored in a location separate from the primary records. In this context, "separate" means that in case of fire or other disaster in the laboratory, the back-up records would be preserved (or readily taken to safety).

# Cryopreservation Of Sperm, Oocytes, And Embryos

- RLM.11900 Specimen Retrieval Phase II
- Procedures are adequate to ensure that cryopreserved patient specimens can be easily retrieved.

- RLM.12000 Inventory Phase II
- Records are available for the current inventory of all specimens that have been stored in its cryobanks.

- RLM.12100 Lost Inventory Phase II
- There is a procedure to investigate inventoried samples that cannot be located in the bank.

# Cryopreservation Of Sperm, Oocytes, And Embryos

- RLM.12300 Viable Recovery Rate Phase II
- The laboratory has a program to ensure that cryopreservation is capable of providing viable recovery rates.
  - Evidence of Compliance:
    - ✓ Written procedure or written quality indicator detailing process to verify viable recovery rates, including thresholds for acceptable performance AND
    - ✓ Records including data and evaluation of post-thaw recovery rates AND
    - ✓ Records of corrective action when thresholds are not achieved

# Cryopreservation Of Sperm, Oocytes, And Embryos

- RLM.12400 Specimen Storage/Long-Term Disposition Phase II
- There is a written procedure regarding the length of storage, informed consent and long- term disposition of cryopreserved gametes or embryos.

  - NOTE: Good practice dictates that the consent form for all procedures is on file and readily available to the laboratory staff.

# Cryopreservation Of Sperm, Oocytes, And Embryos

- Review reproductive tissues policies and procedures (includes labeling, tracking, quarantine, storage)
- Review applicable FDA registration
- Review tissue storage records
- Review donor eligibility determination records

- Follow the records of donor tissue identification through receipt, preparation, storage, issuing, acceptance and disposition. Determine that procedures and records ensure adequate tracking of all tissues.

# Cryopreservation Of Sperm, Oocytes, And Embryos

- RLM.12411 Tissue Program Phase II
- The authority, responsibility and accountability of the reproductive tissue program are clearly defined.
  - NOTE: This includes donor testing and reproductive medically related procedures.
    - Evidence of Compliance:
      - ✓ Written policy defining authority, responsibility and accountability for program

# Reproductive Tissues

- RLM.12411 Tissue Program Phase II
- The authority, responsibility and accountability of the reproductive tissue program are clearly defined.
  - NOTE: This includes donor testing and reproductive medically related procedures.
    - Evidence of Compliance:
    - ✓ Written policy defining authority, responsibility and accountability for program

# Reproductive Tissues

- RLM.12455 FDA Registered Phase II
- The laboratory is registered with the FDA.

- NOTE: Laboratories that recover, process, store, label, package, or distribute any reproductive tissue, or screen or test the tissue donor must register with the FDA annually and update their current product listing.

# Reproductive Tissues

- RLM.12466 Record Retention Phase II
- Donor records are maintained at least 10 years after the date of transfer or distribution, disposition or expiration, whichever is latest.
  - Evidence of Compliance:
    - ✓ Written record retention policy

# Reproductive Tissues

- RLM.12477 FDA-Cleared/Approved Reagents/Supplies Phase II
- Whenever available, reagents and supplies used in the collection, processing and cryopreservation of reproductive tissues are cleared/approved by FDA for human use.
  - NOTE: The use of reagents or supplies that are not FDA-cleared/approved must be either approved by the institution's Institutional Review Board as part of a trial, covered under an investigational new drug or device exemption, or previously validated in the scientific literature.
    - Evidence of Compliance:
    - ✓ Written procedure for the internal review and approval of non-FDA-cleared/approved reagents and supplies AND
    - ✓ Records showing FDA approval of reagents and supplies, as applicable AND
    - ✓ Records for the internal review of non-FDA-cleared/approved reagents and supplies, as applicable

# Reproductive Tissues

- RLM.12499 Donor Tissue Labeling/Tracking Phase II
- Each donor tissue is assigned a unique identification code that relates to the tissue donor and to all records pertaining to that tissue, with maintenance and tracking of this identifier throughout receipt, storage, issuing of the product, and disposition.

  - NOTE: The labeling number and information may not contain the donor's name, social security number, or medical record number, unless the donor tissue is for autologous or directed donation. An institution may choose to use a unique identification code for autologous and directed donations.

# Reproductive Tissues

- RLM.12510 Donor Tissue Labeling Requirement Phase II
- Donor tissues are labeled in accordance with intended use, i.e. 1) Use in case of urgent medical need; 2) For autologous use only; 3) Not evaluated for infectious substances; or
- 4) Directed donor.
  - NOTE: The tissue label must contain a distinct identification code, description of the type of tissue, expiration date (if any), warnings (if any); the name and address of the establishment that made the eligibility determination and makes the tissue available for distribution may either appear on the label or accompany the tissue.
  - For laboratories subject to US regulations, the warnings are those required by FDA regulation Title 21; 1271.60(d), 1271.65(b)(2) or 1271.90(b).
  - Donor tissues stored for autologous use only must be prominently labeled as such.

# Reproductive Tissues

- RLM.12521 Donor Tissue Quarantine Phase II
- Reproductive donor tissues are placed in quarantine until completion of the donor eligibility determination.
  - NOTE: Units in quarantine status must be easily distinguishable from units available for release and distribution. If units in quarantined status are shipped outside of the laboratory, the quarantined status must be clearly indicated.
    - Evidence of Compliance:
      - ✓ Written procedure for quarantine of tissues including storage, release and distribution AND
      - ✓ Records of quarantined tissues

# Reproductive Tissues

- RLM.12532 Donor Records Phase II
- Donor records contain a summary or statement to indicate that all communicable disease testing was performed, including tests performed and results, and a statement containing the name and address of the laboratory making the donor eligibility determination.

  - NOTE: If the donor was determined to be ineligible, a statement with a reason for ineligibility must be included.

# Reproductive Tissues

- RLM.12543 Release From Quarantine Phase II
- There is a written procedure to release reproductive tissues from quarantine that includes a review of records by a supervisor or other designated individual.

  - NOTE: There must be a mechanism to ensure that quarantined units, units from deferred donors and units on which testing is incomplete are not inappropriately released. The disposition of these units must be controlled and recorded. Records must allow for an audit for compliance with the release from quarantine.

# Reproductive Tissues

- RLM.12554 Reproductive Tissue - Ineligible Donors Phase II
- For reproductive tissues from donors determined to be ineligible, tissues are stored in a separate area and specifically labeled as a biohazard, and/or subject to other procedures to prevent improper release.
  - NOTE: Donor tissues may be used only under limited circumstances when results of any screening or testing performed indicate the presence of relevant communicable disease agents and/or risk factors or clinical evidence of disease agents. If these products are stored for use they must be labeled as a biohazard, and the physician must be notified of the results. Physically separate does not necessarily indicate that a separate dewar (LN2 storage tank) is needed. Storage may be maintained in a separate basket or section of the dewar.
  - Evidence of Compliance:
    - ✓ Written procedure for storage and labeling of ineligible donor tissues

# Reproductive Tissues

- RLM.12565 Reproductive Tissue Shipping Requirements Phase II
- If reproductive tissues are shipped to another laboratory or received from another laboratory outside of the facility, detailed information is provided for the following.
  - 1. Unique identifier ID code on the container, not to include the donor's name, and/or SSN or medical record number, unless the units are designated for autologous or directed donation
  - 2. Statement that donor is eligible or ineligible
  - 3. Summary of records (disease testing, name and address of lab making the eligibility determination, statement of reasons for ineligibility if determined)
  - 4. Statement on specimen quality and number of samples shipped
  - 5. Quality control data on freeze/thawing of the specimen, including detailed thawing technique to be used with each specimen

# Reproductive Tissues

- RLM.12587 Donor Infection/Adverse Events Investigation Phase II
- There are written procedures for investigating donor infections or adverse events after reproductive donor tissues are received or implanted.
  - NOTE: Possible tissue-transmitted infections and other adverse events must be investigated and reported to the reproductive tissue source facility when appropriate. If the reproductive tissue source facility notifies the user facility about a donor's infection or reactive infectious-disease test, procedures are required for quarantining tissue or notifying the tissue recipient when appropriate.
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  - Evidence of Compliance:
    - ✓ Records of investigation of tissue-transmitted infections or adverse events AND
    - ✓ Records from source facility recalls indicating action taken

# End of the RLM Checklist!