Disclaimer and Copyright Notice

On-site inspections are performed with the edition of the Checklists mailed to a facility at the completion of the application or reapplication process, not necessarily those currently posted on the website. The checklists undergo regular revision and a new edition may be published after the inspection materials are sent.

For questions about the use of the Checklists or Checklist interpretation, email accredit@cap.org or call 800-323-4040 or 847-832-7000 (international customers, use country code 001).

The Checklists used for inspection by the College of American Pathologists' Accreditation Programs have been created by the CAP and are copyrighted works of the CAP. The CAP has authorized copying and use of the checklists by CAP inspectors in conducting laboratory inspections for the Council on Accreditation and by laboratories that are preparing for such inspections. Except as permitted by section 107 of the Copyright Act, 17 U.S.C. sec. 107, any other use of the Checklists constitutes infringement of the CAP's copyrights in the Checklists. The CAP will take appropriate legal action to protect these copyrights.

All Checklists are ©2021. College of American Pathologists. All rights reserved.
# Reproductive Laboratory Checklist

## TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUMMARY OF CHANGES</td>
<td>4</td>
</tr>
<tr>
<td>INTRODUCTION</td>
<td>6</td>
</tr>
<tr>
<td>ANDROLOGY AND EMBRYOLOGY</td>
<td>7</td>
</tr>
<tr>
<td>QUALITY MANAGEMENT</td>
<td>7</td>
</tr>
<tr>
<td>GENERAL ISSUES</td>
<td>7</td>
</tr>
<tr>
<td>REQUISITIONS, SPECIMEN RECEIPT, AND RESULTS REPORTING</td>
<td>9</td>
</tr>
<tr>
<td>GENERAL QUALITY CONTROL</td>
<td>10</td>
</tr>
<tr>
<td>REAGENTS AND SUPPLIES</td>
<td>12</td>
</tr>
<tr>
<td>INSTRUMENTS AND EQUIPMENT</td>
<td>15</td>
</tr>
<tr>
<td>RECORDS</td>
<td>19</td>
</tr>
<tr>
<td>ANDROLOGY PROCEDURES AND TESTS</td>
<td>21</td>
</tr>
<tr>
<td>SEMEN ANALYSIS GENERAL</td>
<td>21</td>
</tr>
<tr>
<td>AUTOMATED SEMEN ANALYSIS INSTRUMENTS</td>
<td>23</td>
</tr>
<tr>
<td>Calibration and Quality Control</td>
<td>23</td>
</tr>
<tr>
<td>MANUAL SEMEN ANALYSIS</td>
<td>26</td>
</tr>
<tr>
<td>Sperm Concentration</td>
<td>26</td>
</tr>
<tr>
<td>Sperm Motility</td>
<td>27</td>
</tr>
<tr>
<td>Semen Stained Smear - Sperm Differential</td>
<td>28</td>
</tr>
<tr>
<td>Biochemical Tests</td>
<td>30</td>
</tr>
<tr>
<td>ANTI-SPERM ANTIBODY (ASA) TESTS</td>
<td>30</td>
</tr>
<tr>
<td>SPERM PROCESSING FOR THERAPEUTIC INSEMINATION</td>
<td>31</td>
</tr>
<tr>
<td>EMBRYOLOGY</td>
<td>32</td>
</tr>
<tr>
<td>OOCYTE AND EMBRYO HANDLING</td>
<td>32</td>
</tr>
<tr>
<td>CULTURE OF SPERM, OOCYTES, AND EMBRYOS</td>
<td>32</td>
</tr>
<tr>
<td>EMBRYO TRANSFER PROCEDURES</td>
<td>34</td>
</tr>
<tr>
<td>EMBRYOLOGY PERSONNEL</td>
<td>35</td>
</tr>
<tr>
<td>EMBRYOLOGY LABORATORY DIRECTOR</td>
<td>36</td>
</tr>
<tr>
<td>CRYOPRESERVATION OF SPERM, OOCYTES, AND EMBRYOS</td>
<td>40</td>
</tr>
<tr>
<td>DONOR REPRODUCTIVE CELLS/TISSUES</td>
<td>43</td>
</tr>
</tbody>
</table>
ON-LINE CHECKLIST AVAILABILITY AND RESOURCES

Participants of the CAP accreditation programs may download the checklists from the CAP website (cap.org) by logging into e-LAB Solutions Suite. They are available in different checklist types and formatting options, including:

- Master — contains ALL of the requirements and instructions available in PDF, Word/XML or Excel formats
- Custom — customized based on the laboratory’s activity (test) menu; available in PDF, Word/XML or Excel formats
- Changes Only — contains only those requirements with significant changes since the previous checklist edition in a track changes format to show the differences; in PDF version only. Requirements that have been moved or merged appear in a table at the end of the file.

A repository of questions and answers and other resources is also available in e-LAB Solutions Suite under Accreditation Resources, Checklist Requirement Q & A.

SUMMARY OF CHECKLIST EDITION CHANGES
Reproductive Laboratory Checklist
09/22/2021 Edition

The information below includes a listing of checklist requirements with significant changes in the current edition and previous edition of this checklist. The list is separated into three categories:

1. New
2. Revised:
   - Modifications that may require a change in policy, procedure, or process for continued compliance; or
   - A change to the Phase
3. Deleted/Moved/Merged:
   - Deleted
   - Moved — Relocation of a requirement into a different checklist (requirements that have been resequenced within the same checklist are not listed)
   - Merged — The combining of similar requirements

NOTE: The requirements listed below are from the Master version of the checklist. The customized checklist version created for on-site inspections and self-evaluations may not list all of these requirements.

NEW Checklist Requirements

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>RLM.00950</td>
<td>06/04/2020</td>
</tr>
<tr>
<td>RLM.03952</td>
<td>09/22/2021</td>
</tr>
<tr>
<td>RLM.03953</td>
<td>09/22/2021</td>
</tr>
</tbody>
</table>

REVISED Checklist Requirements

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>RLM.03915</td>
<td>06/04/2020</td>
</tr>
<tr>
<td>RLM.03935</td>
<td>09/22/2021</td>
</tr>
<tr>
<td>RLM.03940</td>
<td>09/22/2021</td>
</tr>
<tr>
<td>RLM.03944</td>
<td>09/22/2021</td>
</tr>
<tr>
<td>RLM.03950</td>
<td>09/22/2021</td>
</tr>
<tr>
<td>RLM.08700</td>
<td>06/04/2020</td>
</tr>
<tr>
<td>RLM.10254</td>
<td>09/22/2021</td>
</tr>
<tr>
<td>Requirement</td>
<td>Effective Date</td>
</tr>
<tr>
<td>-------------</td>
<td>----------------</td>
</tr>
<tr>
<td>RLM.10255</td>
<td>09/22/2021</td>
</tr>
<tr>
<td>RLM.10832</td>
<td>09/22/2021</td>
</tr>
</tbody>
</table>

**DELETED/MOVED/MERGED Checklist Requirements**

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>RLM.06450</td>
<td>06/03/2020</td>
</tr>
</tbody>
</table>
INTRODUCTION

This checklist is used in conjunction with the All Common and Laboratory General Checklists to inspect a reproductive laboratory.

Laboratories not subject to US regulations: Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist. When the phrase "FDA-cleared/approved test (or assay)" is used within the checklist, it also applies to tests approved by an internationally recognized regulatory authority (eg, CE-marking).

Checklist requirements for laboratory director, supervisory personnel, and testing personnel vary depending on the type of testing or services performed. The following table includes information to identify appropriate requirements for inspecting personnel qualifications.

<table>
<thead>
<tr>
<th>Position</th>
<th>Checklist Requirement</th>
<th>Type of Testing/Services</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Andrology and other CLIA-related Testing</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laboratory Director</td>
<td>DRA.10100</td>
<td>All Andrology and CLIA-related Testing</td>
</tr>
<tr>
<td>Section Director/Technical Supervisor</td>
<td>GEN.53400</td>
<td>High Complexity Testing</td>
</tr>
<tr>
<td>General Supervisor</td>
<td>GEN.53600</td>
<td>High Complexity Testing</td>
</tr>
<tr>
<td>Technical Consultant</td>
<td>GEN.53625</td>
<td>Moderate Complexity Testing</td>
</tr>
<tr>
<td>Clinical Consultant</td>
<td>GEN.53650</td>
<td>Moderate &amp; High Complexity Testing</td>
</tr>
<tr>
<td>Testing Personnel</td>
<td>GEN.54750</td>
<td>Moderate &amp; High Complexity Testing</td>
</tr>
<tr>
<td><strong>Embryology</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Embryology Laboratory Director</td>
<td>RLM.10166</td>
<td>Assisted Reproductive Technology Procedures</td>
</tr>
<tr>
<td>Embryology Supervisor</td>
<td>RLM.10265</td>
<td>Assisted Reproductive Technology Procedures</td>
</tr>
<tr>
<td>Embryology Laboratory Personnel</td>
<td>RLM.10250</td>
<td>Assisted Reproductive Technology Procedures</td>
</tr>
</tbody>
</table>
**ANDROLOGY AND EMBRYOLOGY**

**QUALITY MANAGEMENT**

**GENERAL ISSUES**

**Inspector Instructions:**

- Records for the monitoring of the misidentification risk for gametes and embryos
- Processes used to reduce the risk of misidentification of gametes and embryos
- How does your laboratory monitor embryology clinical outcomes?
- Describe the processes your laboratory uses to reduce the risk of gamete and embryo misidentification.

**NEW** 06/04/2020

RLM.00950 Misidentification Risk

The facility has a system to reduce the risk of misidentification of gametes and embryos during all critical procedural steps and monitors the effectiveness of the system implemented.

**NOTE:** Misidentification can occur at the time of collection, receipt, processing, insemination, storage, thawing, and transfer of gametes and embryos.

The laboratory is expected to have implemented a plan to reduce these risks using a risk-reduction system. Laboratories may consider the following options to mitigate risk:

- Use of a second person verification step or an electronic identification verification system to confirm proper identification at all critical stages in the process
- Other approaches (e.g., color coding systems) defined by the laboratory capable of reducing the risk of misidentification

The laboratory may also consider improvements in procedures and/or educational efforts as part of its program to reduce the risk of misidentification.

**REFERENCES**


**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.

**REFERENCES**


**RLM.01200 Monthly QC Review**

**Phase II**

Quality control data are reviewed and assessed at least monthly by the laboratory director or designee.

**NOTE:** The review of quality control data must be recorded and include follow-up for outliers, trends, or omissions that were not previously addressed.

The QC data for tests performed less frequently than once per month should be reviewed when the tests are performed.

**Evidence of Compliance:**

✓ Records of QC review with follow-up for outliers, trends, or omissions

**REFERENCES**


**RLM.01250 Clinical Outcome Review**

**Phase II**

The laboratory at least annually reviews embryology clinical outcome in relation to all data collected.

**NOTE:** The laboratory must keep statistical records and review the clinical outcome in relation to this data. The frequency of these reviews should be appropriate to the size of the laboratory and the number of patient cycles, but must be recorded at least annually.

**Evidence of Compliance:**

✓ Records of statistical data AND
✓ Records of data review by the laboratory director, designee or QM committee

**REFERENCES**

REQUISITIONS, SPECIMEN RECEIPT, AND RESULTS REPORTING

Inspector Instructions:

- Sampling of specimen collection and handling policies and procedures
- Sampling of patient records for all necessary collection information
- Patient instructions
- Sampling of patient reports

- Posted collection instructions

- What is your course of action when you receive unacceptable specimens?

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.

RLM.02000  Specimen Collection/Handling  Phase I

Semen specimens are accompanied by the following collection information, and records are retained on the following.

1. Method of collection
2. Type of specimen container
3. Days of abstinence
4. Collection or transport problems (eg, incomplete specimen, exposure to temperature extremes)
5. Time of specimen receipt and analysis
6. Identity of patient was confirmed and by whom

REFERENCES


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

REFERENCES

RLM.02200 Specimen Handling - Pre-analytic  Phase I

Semen specimens are mixed thoroughly before testing.

REFERENCES

RLM.02300 Specimen Characteristics - Analytic  Phase I

All characteristics of the semen specimens are noted and reported (eg, 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 (ie, fourth or fifth edition).

Evidence of Compliance:
✓ Written policy defining characteristics to be included in the report

REFERENCES

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

Inspector Instructions:

- Sampling of quality control policies and procedures
- Sampling of QC records

- How do you determine when quality control is unacceptable and when corrective actions are needed?
• Review a sampling of QC data over the previous two-year period. 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.

RLM.02800 QC
Phase II

For qualitative tests, a positive and negative control is included with each run of patient specimens.

Evidence of Compliance:
✓ QC records showing positive and negative control results

REFERENCES

RLM.02900 QC Handling
Phase II

Control specimens are tested in the same manner and by the same personnel as patient samples.

NOTE: QC specimens must be analyzed by personnel who routinely perform patient/client 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, and all analysts participate in QC on a regular basis. To the extent possible, all steps of the testing process must be controlled.

Evidence of Compliance:
✓ Records reflecting that QC is run by the same personnel performing patient testing

REFERENCES

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

REFERENCES

RLM.03000 QC Confirmation of Acceptability
Phase II

The results of controls are reviewed for acceptability before reporting results.
Evidence of Compliance:
✓ Written policy stating that controls are reviewed and acceptable prior to reporting patient results AND
✓ Records of control result approval

REFERENCES

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.

REFERENCES

RLM.03125  QC Corrective Action  Phase II

There is a record of corrective action when control results exceed defined acceptability limits.

NOTE: Patient test results obtained in an analytically unacceptable test run or since the last acceptable test run must be re-evaluated to determine if there is a significant clinical difference in patient/client results. Re-evaluation may or may not include re-testing samples, depending on the circumstances.

REFERENCES

REAGENTS AND SUPPLIES

Additional requirements are found in the REAGENTS section of the All Common Checklist.
### Inspector Instructions:

<table>
<thead>
<tr>
<th>READ</th>
<th>OBSERVE</th>
<th>ASK</th>
<th>DISCOVER</th>
</tr>
</thead>
</table>
| ● Sampling of test procedures for reagent and supply handling (including media and supplement preparation/modification)  
● Sampling of in-house media and supplement QC records and manufacturer’s QC records |
| ● Sampling of media and supplements (expiration date, condition, contamination)  
● Appropriate environment for media preparation |
| ● How does your laboratory evaluate the quality of contact material?  
● What is your course of action when media does not meet QC requirements? |
| ● Follow a shipment of new media from receipt, examination and QC (if applicable). Determine if practice follows laboratory procedure. |

### RLM.03480  FDA-Cleared/Approved Reagents and Supplies  Phase II

**Whenever available, reagents and supplies used in the collection, processing and cryopreservation of gametes and/or embryos 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

**REFERENCES**

1) U.S Department of Health and Human Services, Food and Drug Administration [https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products](https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products)

### RLM.03500  Media and Supplement Preparation/Modification  Phase II

**There are written procedures for media and supplement preparation and modification.**

**NOTE:** Preparation and 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.

**REFERENCES**

RLM.03600  Media and Supplement Storage  Phase II

There are written criteria for media and supplement storage conditions and expiration.

REFERENCES

RLM.03700  Media and Supplement QC  Phase II

The laboratory has a written procedure for quality control of media and supplements, with records of quality control testing for each lot and shipment.

NOTE: Media and supplements must be sterile and able to support the viability of gametes and/or the growth of embryos. They must be evaluated using a bioassay system such as the one or two cell mouse embryo culture assay or a sperm motility assay and be used within the expiration date.

The laboratory must have records of on-site quality control testing for media and supplements prepared by the laboratory.

For purchased media and supplements, laboratories may retain records of quality control testing using an appropriate bioassay system provided by the manufacturer in lieu of on-site testing. The quality control procedure must include a process to evaluate the acceptability of the media upon receipt in the laboratory (eg, temperature, visual inspection).

The combining of two pre-tested ingredients does not require additional quality control testing by the laboratory, as long as the materials are being used as defined by the manufacturer.

REFERENCES

RLM.03800  Contact Material QC  Phase II

The laboratory has a written procedure for quality control of contact materials using a bioassay, with records of the quality control testing for each type of contact material prior to use by the laboratory.

NOTE: Contact material that is not tested by the manufacturer must be initially tested and then re-tested:
1. When the manufacturer makes a change in the product or its manufacturing process and
2. Annually if there have been no known changes.

Laboratories may retain records of quality control testing with an appropriate bioassay system provided by the manufacturer in lieu of on-site testing.

REFERENCES

RLM.03900  Reagent and Supply QC Corrective Action  Phase II

There is evidence of corrective action when quality control of reagents and supplies do not meet defined criteria for acceptability.

REFERENCES
INSTRUMENTS AND EQUIPMENT

The checklist requirements in this section must be used in conjunction with the requirements in the All Common Checklist relating to instruments and equipment.

Inspector Instructions:

- Sampling of written procedures for monitoring liquid nitrogen storage and responding to alarms
- Sampling of records for liquid nitrogen monitoring
- Sampling of alarm monitoring records
- Sampling of incubator monitoring records for gas concentration
- Records of staff training on alarm response

- Liquid nitrogen storage unit visual inspection (condensation, frost, cracks, rusting, damage to the outer layer) and process to monitor LN2 level
- Functionality of active alarm system(s) for all storage units
- LN2 supply tanks stored securely
- Incubator for system to protect from gas failure

- What is your laboratory's course of action when equipment failure occurs?
- What back-up options are available in the event of an electrical power outage?
- How does your laboratory monitor sterilizing devices?
- How is the alarm system monitored when the laboratory is closed?

RLM.03910  Gas Mixtures  Phase II

There are written criteria for use of gas mixtures.

REFERENCES

**REVISED** 06/04/2020

RLM.03915  Incubator Gas Concentrations  Phase II

Incubator gas concentrations are checked and recorded using one of the following processes as defined in the written procedure:

- Measurement of gas concentrations each day of use
- Monitoring and recording pH checks each day of use
- Retention of the manufacturer's certificate of analysis for laboratories purchasing premixed gas.

NOTE: It is acceptable to monitor and record gas concentrations from digital readouts; however, the laboratory must verify that the readout is accurate initially, at least monthly, and as recommended by the manufacturer. Laboratories using media with phenol may also wish to monitor media for changes in color as an additional process to confirm continued accuracy of the digital readout.

For monitoring of gas concentrations each day of use, gas concentrations may be recorded either manually or using a recording device or system by: 1) recording the numerical value, or
2) placing a mark on a graph that corresponds to a numerical value. If gas concentrations are recorded manually, the identity of the individual recording the value must be recorded (initials of the individual are adequate).

If an automated (including remote) gas concentration monitoring system is used instead of manual monitoring, laboratory personnel must have ongoing immediate access to the monitoring data so that appropriate corrective action can be taken if gas concentrations are outside of the acceptable range. System records must demonstrate daily functionality of the system.

REFERENCES

RLM.03920 Incubator Acceptable Limits

Acceptable limits of humidity, gas content, and/or pH are defined for incubators.

REFERENCES

RLM.03930 Incubator Gas Failure

The laboratory has written procedures to detect and prevent incubator gas failure.

Evidence of Compliance:
✓ Written procedure for detecting and preventing gas failure (eg, alarms or automated monitoring systems)

REFERENCES

**REVISED** 09/22/2021

RLM.03935 Emergency Power Back-up

The laboratory's incubator for embryos and gametes has emergency backup power sufficient to stabilize specimens, and it is tested at least quarterly.

Evidence of Compliance:
✓ Record of generator or other backup power supply testing

REFERENCES

**REVISED** 09/22/2021

RLM.03940 Liquid Nitrogen Levels

The laboratory monitors and maintains adequate liquid nitrogen (LN2) levels and temperatures for all critical storage containers as defined in written procedure.

NOTE: The monitoring process must ensure that the level of LN2 is never below the laboratory's established minimum level. If temperature alarms are used instead of level or weight-based alarms, minimum monitoring must include recording of the following at least three times per week:
● Visual inspection of storage tanks (condensation or water pooling, frost or ice, cracks about the neck and welded seams, rusting, damage to the outer layer of the tank) AND
● Measurement of the level of liquid nitrogen
Autofill devices are not acceptable as the sole mechanism to ensure that the tank is full. If used, the written procedure must define how they are monitored.

Evidence of Compliance:
✓ Written procedure for monitoring LN2 levels AND
✓ Records of visual inspection and measurement of LN2 levels at defined frequency OR
✓ Records of continuous monitoring of liquid nitrogen levels or weight

REFERENCES

**REVISED** 09/22/2021
RLM.03944 Liquid Nitrogen Supplies Phase II

Adequate liquid nitrogen (LN2) supplies are maintained securely onsite.

NOTE: The laboratory must have sufficient LN2 supply to fill a spare storage vessel and/or to allow for freezing of specimens in an emergency.

Access to supply tanks stored outside of the laboratory must be limited to trained personnel and authorized individuals (e.g., vendors).

Evidence of Compliance:
✓ LN2 supply storage within the restricted area of the laboratory OR locked supply storage area outside of the laboratory with limited key access

REFERENCES

**REVISED** 09/22/2021
RLM.03950 Alarm System Continuous Monitoring Phase II

All incubators and liquid nitrogen storage tanks in use for storage of reproductive cells and tissues are monitored continuously (24 hours/day) using an alarm system (either remote or in the laboratory).

NOTE: The laboratory must be able to demonstrate how the alarm system works.

Alarm systems may electronically detect rises in temperature or a decrease in liquid nitrogen levels. If the laboratory is not staffed 24 hours/day, a remote alarm system that notifies personnel (e.g., via phone call or text) must be used to ensure timely response to the alarm.

The CAP recommends that alarm level sensors and settings be set in consideration of anticipated response time for action to be taken before contents are compromised.

Evidence of Compliance:
✓ Written procedure for monitoring alarms

REFERENCES

**NEW** 09/22/2021
RLM.03952 Alarm Systems Functionality Phase II

Alarm systems are checked for functionality initially and at least quarterly.
NOTE: Alarm systems must be able to function in case of a power failure, such as through the use of a back-up generator, uninterruptible power supply, or cloud-based system. Alarm testing must include the evaluation of the full functionality of the system.

Evidence of Compliance:
✓ Written procedure for alarm testing AND
✓ Records of alarm testing

REFERENCES

**NEW** 09/22/2021

RLM.03953 Alarm Response Plan and Records

The laboratory follows a well-defined, written plan for responding to alarms during work and non-work hours and retains records of alarm responses.

NOTE: The laboratory must be able to demonstrate that the response plan ensures timely response to both audible (in laboratory) and remote alarms.

Personal responsible for responding to alarms must be trained to follow written procedures to correct the problem or take alternative measures.

Records retained for alarm response must include:
- Name of the individual responding to the alarm
- Description of the problem encountered
- Actions taken to correct the problem
- Timing of the response and the notification.

If an alarm response involves the loss of reproductive cells or tissues due to a failure in storage conditions, the laboratory must conduct a root cause analysis (refer to GEN.20310) and implement appropriate risk-reduction strategies.

Evidence of Compliance:
✓ Written procedure for monitoring alarms AND
✓ Records of response to the alarm

REFERENCES

RLM.03955 Equipment Back-up

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.
**Reproductive Laboratory Checklist**

**RLM.03960 Sterilizing Device Monitoring Phase II**

All sterilizing devices are routinely monitored with a biologic indicator (or chemical equivalent) for effectiveness of sterility under conditions that simulate actual use with results recorded.

**NOTE:** Chemical indicators that reflect sporicidal conditions may be used. One recommended method is to wrap the Bacillus stearothermophilus spore indicator strip in packaging identical to that used for a production run, and to include the test package with an actual sterilization procedure. This must be monitored with each sterilization cycle.

**RECORDS**

**Inspector Instructions:**

- Sampling of patients’ treatment cycle records for completeness
- Sampling of tracking records from source to final disposition
- Policies and procedures for shipping reproductive cells and tissues

- Select a representative patient record and track progression through collection, processing, and administration of gametes and/or embryos. Confirm that the identity of the individual performing each step is recorded.

**RLM.03965 Cycle Records 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, as applicable
3. Outcome of insemination (e.g., fertilization)
4. Outcome of any culture (e.g., cleavage)
5. Relative timing of protocol events (incubation hours, etc.)
6. Cryopreservation
7. Genetic testing of embryos

**REFERENCES**


**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 of gametes or embryos handled or stored.**

**NOTE:** Records must allow for the tracking of tissues to their disposition to allow withdrawals/recalls to be directed appropriately and to allow problems in reproductive tissue recipients to be tracked to their source.

**REFERENCES**
2) Haimowitz MD. Practical issues in tissue banking. *Am J Clin Pathol.* 1997;107(suppl 1):S75-S81
3) U.S Department of Health and Human Services, Food and Drug Administration [https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products](https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products)

---

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 retained and traceable for each product.**

**REFERENCES**
1) U.S Department of Health and Human Services, Food and Drug Administration [https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products](https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products)

---

RLM.03981 Reproductive Cells/Tissue Shipping  
**Phase II**

If reproductive cells/tissues are shipped to another laboratory, detailed information is provided for the following:

- Statement on the total number of specimens shipped, the number of specimens in each storage device (straw, vial, etc.), and the quality of each specimen
- Freezing/vitrification protocol originally used in the cryopreservation procedure and the thawing/warming technique recommended for each specimen
- For donor cells/tissue:
  - Unique identification ID code on the storage device (not including the donor's name, social security number, or medical record number unless the tissue/cells are designated for directed donation)
  - Copy of the "Summary of Records" indicating the testing and screening results, the name and address of the laboratory making the eligibility determination, statement of donor status as eligible or ineligible, and the reasons for ineligibility, if applicable.

**NOTE:** For cryopreserved embryos created for a patient/couple labeled with identifying information that are subsequently made available for "anonymous embryo donation," it may not be possible to remove the patient identifiers from the cryostorage device without risking harm to the embryo(s). In this situation, the laboratory must take steps to ensure that the identity of the donating patient remains anonymous.

**REFERENCES**
1) U.S Department of Health and Human Services, Food and Drug Administration [https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products](https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products)
ANDROLOGY PROCEDURES AND TESTS

SEmen ANALYSIS GENERAL

Inspector Instructions:

- Sampling of manual and automated semen analysis policies and procedures
- Sampling of patient records or worksheets
- Sampling of patient reports

- What is your laboratory’s course of action when specimens yield a low percent motility?

- Follow a semen analysis from requisition, collection information, testing, reporting and recording of result. Determine if practice follows laboratory procedure.

The following five checklist requirements are applicable to both automated and manual semen analysis.

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.

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.
Evidence of Compliance:
✓ Patient report with concentration findings or appropriate comment indicating that concentration was not performed

REFERENCES
1) Evaluation of the Azoospermic Male. Fertil Steril. 2008; 90 (S74-7)

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

REFERENCES

RLM.03988 Viability Testing Criteria Phase I

The laboratory performs viability testing on specimens with low percent motility (eg, 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

REFERENCES

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

REFERENCES
AUTOMATED SEMEN ANALYSIS INSTRUMENTS

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

Inspector Instructions:

- Sampling of automated semen analysis policies and procedures
- Sampling of calibration/calibration verification records
- Sampling of QC records

What is your course of action when the concentration of the specimen is outside of the instrument measurement range?

- Further evaluate the responses, corrective actions, and resolutions for unacceptable calibration and/or calibration verification
- Review a sampling of QC data over the previous two-year period. 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

CALIBRATION AND QUALITY CONTROL

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

1. Multiple analyzed sperm specimens,
2. Stabilized preparations of sperm cells (eg, fixed or preserved),
3. Sperm surrogates (eg, latex particles),
4. Digital images/ videotaped sperm specimens.

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

RLM.04100 Calibration Materials

CALIBRATION is verified with materials appropriate to the reportable range of the instrument, and verification is recorded.

NOTE: 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. Laboratories must verify at least every six months that instruments are functioning correctly and are in control.

REFERENCES

RLM.04200  Daily QC

The laboratory performs and records quality control for the automated instrument during each day of use, following the manufacturer’s instructions or using at least two levels of control at different concentrations.

REFERENCES

RLM.04300  Recalibration

The test system is recalibrated when calibration verification fails to meet the established criteria of the laboratory.

REFERENCES

RLM.04400  Calibration Material Validation

The material used for calibration is validated using primary reference procedures (eg, manual counts).

Evidence of Compliance:
✓ Written procedure identifying calibration materials and validation of materials used AND
✓ Records showing accuracy of calibration materials used to include manufacturer’s certification/validation of commercial products OR in-house validation data

REFERENCES

RLM.04500  System Control

If a manual method is used as the system control for automated sperm counts, its accuracy is verified and recorded at intervals appropriate for laboratory volume.

REFERENCES

RLM.04600  Acceptable Limits - Controls

Acceptable limits are established for the value of each quality control sample.

Evidence of Compliance:
✓ Records of defined acceptable limits for control range of each lot

RLM.04700  Sperm Concentration Range

For automated sperm counts and motility, there is a written procedure to confirm that the concentration of the specimen is within the range appropriate for automated analysis.

REFERENCES

**RLM.04900 Reportable Range**

*Upper and lower limits of all reportable parameters on instruments are defined, and results that fall outside these limits are reported properly.*

**NOTE:** Results that fall outside of these limits may be verified by repeating the test, using an alternative method or diluting/concentrating the specimen, as appropriate.

**Evidence of Compliance:**
- ✓ Written procedure defining the upper and lower reporting limits and verification of results
- ✓ Patient test verification records

**REFERENCES**

**RLM.05000 Calibration Verification Criteria**

*There are written criteria for method calibration verification.*

**NOTE:** Laboratories must either recalibrate or perform calibration verification at least every six months and if any of the following occur:

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 results or the control values
2. If QC shows an unusual trend or shift or is outside acceptable limits, and the system cannot be corrected to bring control values into the acceptable range
3. After major preventive maintenance or change of a critical instrument component
4. When recommended by the manufacturer

For automated semen analysis instruments, requirements for calibration verification may be considered met if the laboratory follows the manufacturer’s instructions for instrument operation and tests two levels of control materials each day of testing. The control results must meet the laboratory’s criteria for acceptability.

**Evidence of Compliance:**
- ✓ Written policy defining the method, frequency, and limits of acceptability of calibration verification for each instrument/test system
- ✓ Records of calibration verification at defined frequency

**REFERENCES**
MANUAL SEMEN ANALYSIS

Inspector Instructions:

- **READ**
  - Sampling of manual semen analysis policies and procedures
  - Sampling of manual semen analysis QC records
  - Sampling of stain QC records
  - Sampling of patient reports (classification system noted)
  - Sampling of patient records/worksheets

- **OBSERVE**
  - Stained smear (uniquely identified, properly stained, free of precipitate, uniform cell distribution, recognition of reportable cell types)
  - File of unusual slides
  - Counting chamber condition

- **ASK**
  - What do you do if there is difficulty distinguishing leukocytes from other round cells when performing sperm counts using bright-field microscopy?
  - How is the sperm motility method in use verified?
  - How do you ensure that morphologic observations are consistent among all personnel who report sperm differential results?
  - How long does your laboratory retain slides?

SPERM CONCENTRATION

**RLM.05100** Counting Chamber and Optical Grid Quality  
Phase I

*The lines in all counting or motility chambers, ocular micrometers, and optical grids are bright and free from scratches, dirt, or debris.*

**RLM.05150** Manual Cell Count Controls  
Phase II

*For manual sperm counts, at least one cell count control specimen is analyzed in duplicate, 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 materials must be tested 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

**REFERENCES**


**RLM.05200** Semen Analysis Procedure  
Phase II

*For manual sperm counts, each sperm sample is counted in duplicate.*
NOTE: Testing records must reflect the performance of the counts in duplicate for all counting chambers. Limits of agreement between replicate counts must be defined.

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

REFERENCES

SPERM MOTILITY

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.

REFERENCES

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 (ie, fourth or fifth edition).

REFERENCES

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

REFERENCES

RLM.06200  Motility Method Verification  Phase II
The sperm motility method is verified at least every six months (eg, video tapes/digital images of specimens with known percent motility and/or specific motion quality).

Evidence of Compliance:
✓ Records of method verification

REFERENCES
**SEmen Stained Smear - SPERM DIFFERENTIAL**

**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

**REFERENCES**

**RLM.06350**  
**Leukocyte 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 (eg, Wright’s, leukocyte alkaline phosphatase, or myeloperoxidase stains).

**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

**REFERENCES**

**RLM.06400**  
**Stain QC**  
**Phase II**

Quality control of all stains is performed and recorded to check for contamination and intended reactivity each day of use.

**Evidence of Compliance:**
✓ Written procedures for stain QC AND
✓ Records of stain QC

**REFERENCES**

**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 (ie, fourth or fifth edition) and the Kruger classification system, and discontinuing the use of older classification systems.

**REFERENCES**


RLM.06800 Slide Retention - Sperm Differential

Sperm differential slides are retained for at least seven days for future reference.

RLM.06900 Morphologic Observation Evaluation

The laboratory evaluates consistency of morphologic observation among personnel performing morphologic classification of sperm and other cells at least annually.

NOTE: The laboratory must ensure the identification of sperm and other cells is reported consistently amongst all personnel performing the microscopic analysis.

Suggested methods to accomplish this include:

1. Circulation of a pre-graded set of stained semen smears with defined specific qualitative abnormalities of sperm
2. Multi-headed microscopy
3. Use of published references
4. Digital images

Acceptability criteria for agreement must be determined by the laboratory director or designee. The laboratory must maintain records of performance and record corrective actions taken for personnel demonstrating significant discrepancies from the group consensus.

Evidence of Compliance:

✓ Written procedure defining the method and criteria used for evaluation of consistency AND
✓ Records of evaluation

REFERENCES


RLM.07000 Sperm Morphology Reference

There is a file of unusual slides or current atlas of sperm morphology available for training and reference.

REFERENCES


RLM.07100 Stain Quality

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

RLM.07400 Biochemical Tests - Daily QC

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

REFERENCES

ANTI-SPERM ANTIBODY (ASA) TESTS

Inspector Instructions:

- Sampling of ASA policies and procedures
- Sampling of ASA QC records

RLM.07500 Heat Inactivation

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

REFERENCES
1) Keel BA, Webster BW. CRC handbook of the laboratory diagnosis and treatment of infertility. Boca Raton, FL: CRC Press, 1994

RLM.07600 Motility Testing

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

REFERENCES
**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

**REFERENCES**
1) Keel BA, Webster BW. CRC handbook of the laboratory diagnosis and treatment of infertility. Boca Raton, FL: CRC Press, 19RLM.185

**SPERM PROCESSING FOR THERAPEUTIC INSEMINATION**

**Inspector Instructions:**

- Sampling of therapeutic insemination policies and procedures (includes maintaining specimen identity)
- How does your laboratory ensure specimen identity and integrity of the specimen from receipt to final disposition?

**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.

**REFERENCES**

**RLM.07900**  
**Sperm Preparation**  
**Phase II**

There are written procedures for preparing sperm for insemination (e.g., gradient, swim-up techniques).

**REFERENCES**

**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

**REFERENCES**
EMBRYOLOGY

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 requirements in the preceding SPERM PROCESSING FOR THERAPEUTIC INSEMINATION section and/or the ANDROLOGY section.

**Genetic testing on embryo biopsy specimens** must be performed by a CAP accredited laboratory or other laboratory meeting the referral laboratory selection criteria defined in the Laboratory General Checklist (GEN.41350).

If no embryology procedures are performed in the laboratory continue with the Cryopreservation of Sperm, Oocytes, and Embryos section.

OOCYTE AND EMBRYO HANDLING

**Inspector Instructions:**

- Sampling of policies and procedures for oocyte/embryo handling and embryo transfer
- Sampling of embryology records (time-out verification, embryo development stage, chain-of-custody documentation, catheter checks)
- Sampling of training and competency records

- Sterile technique environment

- How does your laboratory verify proficiency in its ability to assess the quality of embryos?

- Follow a patient procedure from handling, assessment, culturing and transfer of human sperm, oocytes and embryos. Determine if procedures and records are adequate.

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.
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 (eg, egg retrieval or embryo transfer)
3. Written physician’s order
4. Number of embryos to be transferred

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

REFERENCES

---

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

---

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.

REFERENCES

---

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 (eg, 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.

REFERENCES
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.

REFERENCES

**REVISED** 06/04/2020

RLM.08700  Disposition of Oocytes  Phase II

The laboratory has a written policy for the disposition of fertilized embryos (zygotes) with an abnormal number of pronuclei.

RLM.08800  Oocyte Examination  Phase II

There is a defined period for examination of oocytes for fertilization.

REFERENCES

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.

REFERENCES

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

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.

REFERENCES

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.

REFERENCES

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

RLM.09500 Catheter Check
Phase II

The laboratory records a check of the catheter for any embryos left after transfer.

REFERENCES

EMBRYOLOGY PERSONNEL

The requirements in this section apply to embryology services only. Personnel requirements for andrology and other CLIA-related testing are found in the Laboratory General Checklist and Director Assessment Checklist. A table with information for identifying the applicable checklist requirements based on tests or services performed is found in the Introduction section of this checklist.

Inspector Instructions:

- Sampling of personnel files for educational qualifications (diplomas, transcripts, primary source verification reports) and training for the embryology laboratory director, embryologists, and embryology supervisors
- Sampling of training and competency assessment records
- Back-up personnel policy
EMBRYOLOGY LABORATORY DIRECTOR

RLM.10166 Embryology Laboratory Director Qualifications Phase II

The embryology laboratory director has proper qualifications through education and experience to provide direction and administration of the laboratory.

NOTE: The embryology laboratory director must have at least two years of experience in a laboratory performing in vitro fertilization or assisted reproductive technologies-related procedures and meet the following requirements:

- MD or DO licensed (if required) in the jurisdiction where the laboratory is located;
- or
- Doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; or
- Individual functioning as an embryology director on or before July 20, 1999.

Effective January 1, 2006, all new laboratory directors in laboratories located in the US and its territories must hold current HCLD (High Complexity Laboratory Director), ABB-ELD (American Board of Bioanalysis Embryology Laboratory Director), or equivalent certification. For laboratories located outside of the US, embryology laboratory directors must be an MD or DO licensed (if required) in the jurisdiction where the laboratory is located or have a doctoral degree in a chemical, physical, biological, or clinical laboratory science, and have at least two years of appropriate laboratory training and experience. Board certification is strongly encouraged.

If the laboratory is also performing testing for the purpose of diagnosis (eg, semen analysis, hormone assays), the laboratory director must meet the personnel requirements defined in the Director Assessment Checklist.

If more stringent state or local regulations are in place for supervisory qualifications, including requirements for state licensure, they must be followed.

For laboratories located in the US (including its territories), the training and qualifications of embryology laboratory directors trained outside of the US, newly employed on or after January 1, 2018, must be evaluated to determine equivalency to an education obtained in the US, with records of the evaluation available in the personnel file. Equivalency evaluations must be performed by a nationally recognized organization, such as the National Association Credential Evaluation Services, Inc. (NACES) (http://naces.org) and the Association of International Credential Evaluators, Inc. (AICE) (http://www.aice-eval.org). The following types of records may also be used to show equivalency: 1) license to practice medicine issued by the state in which the laboratory is located; or 2) laboratory personnel license in states where laboratory personnel licensure is required. Department of Defense laboratories must evaluate equivalency using a process approved by the Center for Laboratory Medicine Services.

Evidence of Compliance:

- Records of qualifications including diploma, transcript, current certification (if required), primary source verification report, current license (if required), or equivalency evaluation
- Records of work history in related field

REFERENCES
3) Practice Committee of the American Society for Reproductive Medicine; Practice Committee of the Society for Assisted Reproductive Technology; Practice Committee of the Society of Reproductive Biologists and Technologists. Minimum standards for practices offering assisted reproductive technologies: a committee opinion. Fertil Steril 2020;113(3):S36-41.
Assisted Reproductive Technology (ART) - Personnel Qualifications  Phase II

All embryology laboratory personnel performing assisted reproductive technology (ART) procedures meet the following minimum requirements:

- Bachelor’s degree in a chemical, physical, biological, medical technology, clinical, or reproductive laboratory science from an accredited institution*; or
- Individuals performing ART laboratory procedures prior to January 1, 2012, meet laboratory-defined personnel qualifications and have records of training for the ART laboratory procedures performed.

NOTE: If more stringent state or local regulations are in place for personnel qualifications, including requirements for state licensure, they must be followed.

Embryology personnel who perform testing for the purpose of diagnosis (eg, diagnostic semen analysis, hormone analysis) must also qualify under the testing personnel requirements defined in the Laboratory General Checklist (GEN.54750).

For laboratories located in the US (including its territories), the training and qualifications of personnel trained outside of the US, newly employed on or after January 1, 2018, must be evaluated to determine equivalency to an education obtained in the US, with records of the evaluation available in the personnel file. Equivalency evaluations must be performed by a nationally recognized organization, such as the National Association Credential Evaluation Services, Inc. (NACES) (http://naces.org) and the Association of International Credential Evaluators, Inc. (AICE) (http://www.aice-eval.org).

Evidence of Compliance:
✓ Records of qualifications including degree or transcript, current license (if required), equivalency evaluation, and work history in related field, as applicable

REFERENCES
2) Practice Committee of the American Society for Reproductive Medicine; Practice Committee of the Society for Assisted Reproductive Technology; Practice Committee of the Society of Reproductive Biologists and Technologists. Minimum standards for practices offering assisted reproductive technologies: a committee opinion. Fertil Steril 2020;113(3):536-41.

Embryology Training  Phase II

There are records that all embryology laboratory personnel have satisfactorily completed initial training for each assisted reproductive technology (ART) technique performed.

NOTE: There must be a training program for personnel, using animal model systems or discarded human materials. The training must include all techniques performed by each individual, such as gamete collection, preparation, fertilization, micromanipulation, embryo biopsy, and cryopreservation. It must also include the process for identifying and labeling individual reproductive tissues (gametes, embryos, and biopsy specimens) to maintain the identity of the specimen throughout receipt, storage, processing, and disposition and to ensure that records of genetic testing performed on biopsy specimens can be correlated to the native embryo.

Retraining must occur when problems are identified with personnel performance.

If the laboratory contracts with an agency or individual to perform embryology procedures on a temporary or per diem basis, the laboratory must have the following records:

- Site-specific orientation AND
- Training performed on site, by the contracting agency, or at another laboratory on each embryology procedure to be performed

Evidence of Compliance:
✓ Records of training AND
✓ Records of competency assessment for embryology personnel reflecting the specific skills assessed and the method of evaluation AND
✓ Written procedure defining the method and frequency for assessing competency

REFERENCES

**REVISED** 09/22/2021
RLM.10254 Competency Assessment of Embryology Personnel Phase II

The competency of each person performing embryology procedures, including micromanipulation and other assisted reproductive technology techniques is assessed.

NOTE: Competency assessment evaluates an individual’s ongoing ability to apply knowledge and skills to achieve intended results.

Competency must be assessed at the following frequency:
- At least semiannually (first assessment within seven months from initiation of embryology duties and second assessment no later than 12 months from the start of duties) during the first year of an individual’s duties (new employee).
- At least annually after an individual has performed assigned duties for one year*.
- When problems are identified with an individual’s performance.

*The annual assessment of competency can be performed throughout the entire year to minimize impact on workload.

For each embryologist, competency assessment must include all applicable elements described below for each procedure performed. Elements of competency assessment include, but are not limited to:

1. Direct observations of routine embryology procedures, including, as applicable, patient identification, specimen collection, handling, and processing
2. Monitoring the recording and reporting of embryology cycle events
3. Review of intermediate test results or worksheets quality control records, proficiency testing results, and preventive maintenance records
4. Direct observation of performance of equipment maintenance and function checks
5. Evaluation of problem-solving skills

The competency assessment procedure must outline the practices and procedures used to evaluate competency. Assessment of the elements of competency may be coordinated with routine practices and procedures. Laboratories often use a checklist to record and track elements assessed. Records supporting the assessment must be retained (copies of worksheets, maintenance logs, etc. or information traceable to the original record).

The following includes examples of how competency assessment can be coordinated with routine practices and procedures:
- Assessment of the recording of quality control results and instrument maintenance data in element #3 during the monthly supervisory review process of these records.
- Assessment of problem-solving skills in element #5 from monthly reviews of corrective action logs where problems with an embryology procedure, quality control, or instrument function were investigated.

For embryologists performing embryology procedures at multiple laboratories within a health care system (different CAP numbers), the laboratory director may determine how competency will be assessed for each site. If there are variations on how procedures are performed at the different
laboratories, those variations must be included in the competency assessment specific to the laboratory.

If the laboratory contracts with an agency or individual to perform embryology procedures on a temporary or per diem basis, the laboratory must have records of competency assessment on each embryology procedure to be performed. The laboratory may either perform on-site competency assessment or obtain records of competency assessment performed by the contracting agency or at another laboratory within the last 12 months. The competency records must show that all five elements of competency were assessed, as applicable.

The CAP provides example competency assessment templates, which can be downloaded from cap.org in e-Lab Solutions Suites - Accreditation Resources - Templates.

Evidence of Compliance:
✓ Records of competency assessment for new and existing embryology personnel reflecting the specific skills assessed and the method of evaluation at the required frequency AND
✓ Written procedure defining the method and frequency for assessing competency

REFERENCES

--REVISED-- 09/22/2021

RLM.10255 Embryology Laboratory Director Visits

For laboratories that do not have an on-site embryology laboratory director, there must be records of visits from the embryology laboratory director at a minimum of once per quarter.

NOTE: If the laboratory performs andrology testing, national, federal, state (or provincial), and local requirements for director visits must be followed, which may be more stringent.

The embryology laboratory director must be available (eg, on-site or virtual) during CAP inspections to participate in an interview and answer questions.

REFERENCES
2) Practice Committee of the American Society for Reproductive Medicine; Practice Committee of the Society for Assisted Reproductive Technology; Practice Committee of the Society of Reproductive Biologists and Technologists. Minimum standards for practices offering assisted reproductive technologies: a committee opinion. Fertil Steril 2020;113(3):536-41.

RLM.10260 Oversight Responsibility

For laboratories that do not have an on-site, full time embryology laboratory director, or the medical director is also the embryology laboratory director, there is a designated on-site individual qualified as an embryology supervisor, to provide oversight of daily activities and assist with troubleshooting or other unusual situations.

NOTE: The intent is to ensure that the laboratory continues to function properly in the embryology laboratory director's absence and to ensure that resources are available to quickly assist with unusual problems to minimize any adverse impact on patient care.

REFERENCES
2) Practice Committee of the American Society for Reproductive Medicine; Practice Committee of the Society for Assisted Reproductive Technology; Practice Committee of the Society of Reproductive Biologists and Technologists. Minimum standards for practices offering assisted reproductive technologies: a committee opinion. Fertil Steril 2020;113(3):536-41.

RLM.10265 Embryology Supervisor

Embryology supervisors must have at least one year of supervisory experience in all aspects of embryology performed by the laboratory or a minimum of 60 cycles over a period of not less than six months.
NOTE: Technical supervisor certification is highly recommended. If the laboratory performs andrology testing, personnel requirements defined in the Laboratory General Checklist must be followed.

REFERENCES
1) Practice Committee of the American Society for Reproductive Medicine; Practice Committee of the Society for Assisted Reproductive Technology; Practice Committee of the Society of Reproductive Biologists and Technologists. Minimum standards for practices offering assisted reproductive technologies: a committee opinion. Fertil Steril 2020;113(3):536-41.

**REVISED** 09/22/2021
RLM.10832 Back-up Personnel Phase II

The laboratory has a well-defined written plan for providing back-up laboratory personnel as needed, to ensure timely embryology services.

NOTE: Staffing levels must be appropriate for the size and volume of the program. If routine staffing of the laboratory does not provide sufficient back up for laboratory personnel, the laboratory must have a written plan describing how patient care needs will be met for its laboratory services in the event of a staffing shortage or emergency.

The plan may include alternative protocols for handling workload, reassignment of internal personnel to complete duties, and written agreements with outside individuals or services to provide the necessary staffing. The laboratory director is responsible to ensure that the qualifications and training of each individual are adequate for the duties to be performed.

For laboratories that are not staffed full-time, appropriately trained personnel are available to routinely monitor storage conditions for cryopreserved specimens.

REFERENCES
2) Practice Committee of the American Society for Reproductive Medicine; Practice Committee of the Society for Assisted Reproductive Technology; Practice Committee of the Society of Reproductive Biologists and Technologists. Minimum standards for practices offering assisted reproductive technologies: a committee opinion. Fertil Steril 2020;113(3):536-41.

CRYOPRESERVATION OF SPERM, OOCYTES, AND EMBRYOS

Inspector Instructions:

- Sampling of cryopreservation policies and procedures (includes labeling and tracking of specimens)
- Current inventory records
- Sampling of specimen storage, retention, retrieval and disposition policies and procedures
- Sampling of record storage and retention policies and procedures

- How does your laboratory ensure specimen identity and integrity?
- How does your laboratory ensure viability and measure recovery rates?
If responses to the above questions indicate problems or concerns, further evaluate the laboratory’s corrective actions and resolutions. Follow the records of randomly selected cryopreserved sperm and embryos from receipt, preparation, storage and use. Determine if inventory procedures are functioning correctly.

**RLM.11500 Cryopreservation**  
**Phase II**

The laboratory has a written procedure(s) for cryopreservation of sperm, oocytes, and/or embryos.

**REFERENCES**
2) Lasalle B, Testart J. Human embryo features that influence the success of cryopreservation with the use of 1,2 propanediol. *Fertil Steril.* 1985;44:645-651

**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

**REFERENCES**

**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

**REFERENCES**
1) American Association of Tissue Banks. Standards for tissue banking, 1997

**RLM.11700 Record Retention - Patients and Donors**  
**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

**REFERENCES**
1) American Association of Tissue Banks. Standards for tissue banking, 1997

**RLM.11800 Duplicate Record Storage**  
**Phase II**

Duplicate records are retained 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).

REFERENCES

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.

REFERENCES
1) American Association of Tissue Banks. Standards for tissue banking, 1997
2) Practice Committee of the American Society for Reproductive Medicine; Practice Committee of the Society for Assisted Reproductive Technology; Practice Committee of the Society of Reproductive Biologists and Technologists. Minimum standards for practices offering assisted reproductive technologies: a committee opinion. Fertil Steril 2020;113(3):536-41.

RLM.12100 Lost Inventory

Phase II

There is a procedure to investigate inventoried samples that cannot be located in the bank.

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

REFERENCES
1) American Association of Tissue Banks. Standards for tissue banking, 1997

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.

REFERENCES
3) American Association of Tissue Banks. Standards for tissue banking, 1997
DONOR REPRODUCTIVE CELLS/TISSUES

This section applies to laboratories that are collecting, processing, storing, or transplanting donor tissues and cells, including donor sperm, donor eggs, gestational surrogacy, and/or embryo donation.

Inspector Instructions:

- Sampling of reproductive cells/tissues policies and procedures (includes labeling, tracking, quarantine, storage)
- Applicable FDA registration
- Sampling of cells/tissue storage records
- Sampling of donor eligibility determination records

- Quarantined donor cells/tissues

- How are you informed of an adverse reaction to implanted cells/tissue?

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

RLM.12411 Reproductive Donor Cell/Tissue Program

The authority, responsibility and accountability of the reproductive donor cell/tissue program are clearly defined.

NOTE: This includes donor testing and reproduction-related medical procedures.

Evidence of Compliance:

✓ Written policy defining authority, responsibility and accountability for program

REFERENCES
1) U.S Department of Health and Human Services, Food and Drug Administration https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products

RLM.12444 Regulatory Document Availability

For US laboratories, the following documents are readily available:

1. Applicable sections of 21CFR
2. FDA guidelines.

REFERENCES
1) U.S Department of Health and Human Services, Food and Drug Administration https://www.fda.gov/vaccines-blood-biologics/biologics-establishment-registration/tissue-establishment-registration
**RLM.12455  FDA Registration**  

The laboratory is registered with the FDA for all appropriate human cells, tissues, and cellular and tissue-based products (HCT/P).

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

**REFERENCES**
2) U.S Department of Health and Human Services, Food and Drug Administration https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products

---

**RLM.12466  Record Retention - Donor Reproductive Cells/Tissues**  

Donor records are retained at least 10 years after the date of transfer or distribution, disposition or expiration, whichever is latest.

**Evidence of Compliance:**
✓ Written record retention policy

**REFERENCES**
2) U.S Department of Health and Human Services, Food and Drug Administration https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products

---

**RLM.12499  Donor Cells/Tissues Tracking**  

Each donor cell/tissue product is assigned a unique identification code that relates to the donor and to all records pertaining to that product, with maintenance and tracking of this identifier throughout receipt, storage, issuing of the product, and disposition.

*NOTE:* Unless the donor cells/tissue is for directed donation, the labeling number and information may not contain the donor's name, social security number, or medical record number. An institution may choose to use a unique identification code for cells/tissues intended for sexually intimate partners and directed donations.

For cryopreserved embryos created for a patient/couple labeled with identifying information that are subsequently made available for "anonymous embryo donation," it may not be possible to remove the patient identifiers from the cryostorage device without risking harm to the embryo(s). In this situation, the laboratory must take steps to ensure that the identity of the donating patient/couple remains anonymous.

**REFERENCES**
1) U.S Department of Health and Human Services, Food and Drug Administration https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products

---

**RLM.12510  Donor Cells/Tissues Labeling**  

Donor cells/tissues are labeled with the following information in accordance with the intended use:

- Unique identification code
- Description of the type of cells/tissue(s)
- Expiration date (if any)
- Warnings (if any)
- Name and address of the establishment that made the eligibility determination and made the cells/tissue(s) available for distribution
NOTE: The information may either appear on the label or in the accompanying documentation; however, the unique identifier must be on the storage device.

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) and include the following types of statements, as applicable:

- Tissues not evaluated for infectious substances
- Warning: Advise recipients of communicable disease risks
- Warning: Reactive test results for (name of disease agent or disease)
- Advise recipients that screening and testing of donor(s) were not performed at the time of cryopreservation of the reproductive tissue, but have been performed subsequently

REFERENCES

RLM.12521 Donor Cells/Tissues Quarantine Phase II

For facilities involved in donor sperm banking and/or donor egg banking, reproductive donor cells/tissues are placed in quarantine until completion of the donor eligibility determination.

NOTE: Cells/tissue in quarantine status must be easily distinguishable from cells/tissues available for release and distribution. If cells/tissues 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 cells/tissues

REFERENCES

RLM.12532 Donor Record Statement/Summary Phase II

Donor records include a statement of eligibility or ineligibility and a summary of the records used to make the donor-eligibility determination.

NOTE: The summary must include the following:
- Results of all communicable disease testing and screening performed
- Name and address of the establishment making the donor eligibility determination
- Statement noting the reason for determinations of ineligibility.

REFERENCES

RLM.12543 Release From Quarantine Phase II

For facilities involved in donor sperm banking and/or donor egg banking, there is a written procedure to release reproductive cells/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 cells/tissues, cells/tissues from deferred donors, and cells/tissues for which testing is incomplete are not inappropriately released. The disposition of these cells/tissues must be controlled and recorded. Records must allow for an audit for compliance with the release from quarantine.

REFERENCES
Reproductive Laboratory Checklist

**RLM.12554 Reproductive Cells/Tissues - Ineligible Donors**  
**Phase II**

For reproductive cells/tissues from donors determined to be ineligible, cells/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 cells/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 cells/tissues

**REFERENCES**
1. U.S Department of Health and Human Services, Food and Drug Administration [https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products](https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products)

**RLM.12587 Donor Infection/Adverse Events Investigation**  
**Phase II**

There are written procedures for investigating donor infections or adverse events after reproductive donor cells/tissues are received or implanted.

**NOTE:** Possible cell/tissue-transmitted infections and other adverse events must be investigated and reported to the reproductive cells/tissue source facility when appropriate. If the 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 cell/tissue recipient when appropriate.

**Evidence of Compliance:**
- ✓ Records of investigation of cell/tissue-transmitted infections or adverse events AND
- ✓ Records from source facility recalls indicating action taken

**REFERENCES**
1. U.S Department of Health and Human Services, Food and Drug Administration [https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products](https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products)