

Mastering Space, Supplies, and Storage Management in a Clinical Laboratory

A comprehensive guide for laboratory directors to ensure CLIA compliance, prevent errors, and optimize laboratory operations.

 **by Fertility Guidance Technologies**



Course Agenda

This comprehensive training will equip you with best practices for managing the physical aspects of your IVF laboratory, ensuring compliance with regulatory requirements while maximizing efficiency and minimizing errors.

- 1 Embryo Cryostorage Inventory**
Visual verification procedures and reconciliation practices to ensure accuracy and compliance
- 2 Embryo Discards and Documentation**
Proper protocols, consent requirements, and documentation processes
- 3 Reagents and Supplies Inventory**
Tracking systems, storage requirements, and inventory management best practices
- 4 Space Optimization & Lab Organization**
Strategies for maintaining an organized, efficient laboratory environment
- 5 Supply Chain & Ordering Systems**
Implementation of effective ordering workflows using ART Compass

We'll conclude with a comprehensive review of CAP guidelines related to storage and inventory management, followed by practical implementation strategies you can immediately apply in your laboratory.

Why Effective Storage Management Matters

The stakes in an IVF laboratory are extraordinarily high. Each cryopreserved embryo represents not just biological material, but the potential for human life and the hopes of the patients we serve. Proper management of these precious specimens is not merely a matter of organization—it's an ethical imperative.

Beyond the human impact, there are significant legal, regulatory, and financial implications to consider. Mismanagement of specimens can lead to:

- Devastating errors that affect patient outcomes
- Regulatory non-compliance and citations
- Potential litigation and reputational damage
- Unnecessary expenses from redundant orders or wasted materials



Implementing systematic approaches to inventory management ensures accuracy while providing peace

of mind for the laboratory staff and the patients.

Embryo Cryostorage Inventory: The Foundation of Lab Integrity

High-Risk Area

Cryostorage errors represent one of the highest-risk areas in the IVF laboratory. A single identification error can have profound consequences for patients and significant legal implications for your clinic.

Visual Verification

Regular visual inspection of tanks ensures that physical inventory matches electronic records, providing a critical quality control checkpoint that prevents errors from propagating undetected.

Compliance Requirements

CAP checklist item RLM.12000 specifically requires "records available for the current inventory of all specimens that have been stored in its cryobanks," necessitating regular reconciliation.

Financial Implications

Accurate inventory prevents billing errors, ensures proper storage fee collection, and provides documentation to support legal disputes regarding specimen ownership or disposition.

The integrity of your laboratory's cryostorage system depends on rigorous inventory procedures that connect physical specimens with accurate electronic records. This foundation supports everything from daily operations to long-term specimen management and patient care.

Visual Tank Check: Step-by-Step Protocol

A comprehensive visual tank check should be performed at least annually, though quarterly checks are recommended for high-volume laboratories. This process is most effective when conducted systematically:



Documentation Requirements

For each specimen checked, document:

- Patient/couple identification
- Specimen type and number
- Storage location (tank, canister, cane, level)
- Label condition and legibility
- Date of verification
- Names of verifying embryologists
- Any discrepancies found and their resolution

Use the "assign" function in ART Compass to document this quality assurance activity, providing verification that all staff have been trained in proper inventory procedures. When discrepancies are found, document the investigation process and resolution in detail to demonstrate due diligence.

Embryo Discard Workflow: Ensuring Compliance and Respect

When to Discard Embryos

Embryos are typically discarded under the following circumstances:

- Patient/couple provides explicit signed consent to discard
- Completion of family building with no desire for additional children
- Discontinuation of fertility treatment
- Non-payment of storage fees (after proper notification and in accordance with your clinic's policies)
- Poor embryo quality making them unsuitable for transfer (with prior consent)

Legal Requirements

The discard process must adhere to strict requirements:

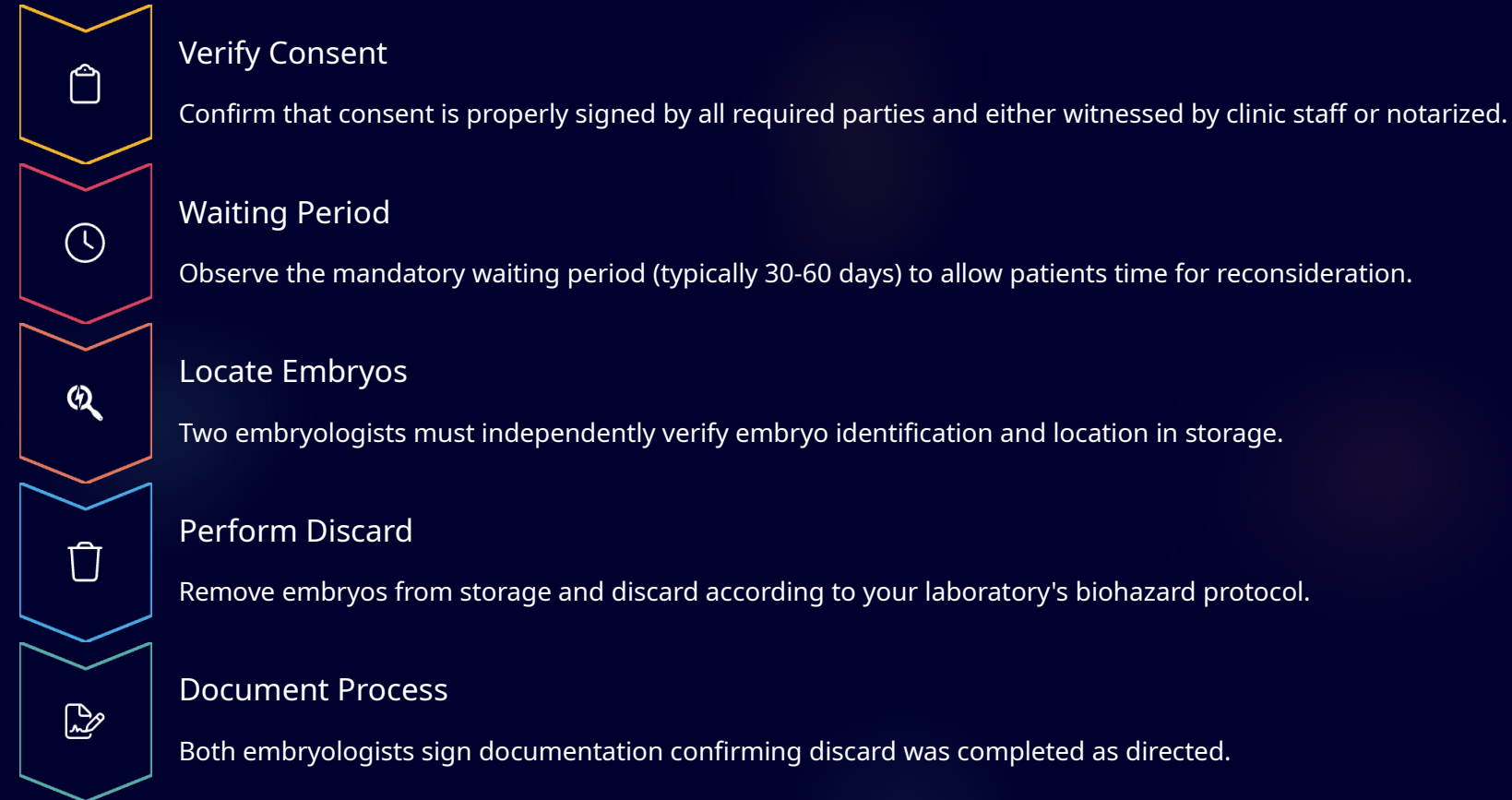
- Written consent from both genetic contributors (exceptions may apply for single patients or in cases of divorce/separation with prior legal agreements)
- Documentation of consent verification
- Adherence to any state-specific regulations regarding embryo disposition
- Permanent records of the discard process



⊗ **Critical Reminder:** Embryo discard is irreversible and legally sensitive. Never discard embryos without complete, properly executed consent documentation and secondary verification by another embryologist.

December is an ideal time for most IVF labs to perform backlogged discards, clearing space in tanks for the coming year's cycles while maintaining careful

Embryo Discard: Step-by-Step Procedure



Documentation Best Practices

Maintain comprehensive records of the discard process:

- Store physical discard forms in a dedicated binder
- Scan documents into a secure digital folder
- Update cryostorage inventory in ART Compass to mark specimens as "discarded"
- Send written confirmation to the physician and patient
- Ensure billing department is notified to stop storage fees

Use ART Compass's image archive function to document critical verification steps, permanently attaching these images to the patient record as evidence of proper protocol adherence.

Alternative Embryo Disposition Options

While discard is a common disposition choice, patients should be informed of all available options for their cryopreserved embryos. Laboratories should be prepared to facilitate various disposition paths according to patient wishes and applicable laws.

Research Donation

Embryos may be donated for scientific studies, including:

- Development of new cryopreservation techniques
- Improvement of culture methods
- PGT-A or genetics research
- Stem cell research (where legally permitted)

Education/Training

Embryos can be used to train junior embryologists in:

- Handling techniques
- Vitrification and warming procedures
- Embryo assessment skills
- Quality control testing

Embryo Donation

Patients may choose to donate embryos to other patients, requiring:

- Infectious disease testing
- Genetic screening
- Legal transfer of ownership
- Counseling for all parties

External Storage Transfer

Embryos may be transferred to specialized long-term storage facilities:

- Reprotech
- Cryopoint
- Fairfax Cryobank
- California Cryobank
- Ovation
- TMRW

Each disposition option requires specific consent forms and documentation processes. Laboratories should have standardized protocols for handling each type of disposition request, ensuring that patient wishes are respected while maintaining regulatory compliance.

Reagents and Supplies Inventory Management

The Critical Importance of Inventory Control

Proper inventory management directly impacts clinical outcomes, regulatory compliance, and operational efficiency. CAP checklist item GEN.61900 specifically requires "an effective supply inventory control system in operation."

Essential Data to Track for Each Item

Item identification: Name, catalog number, vendor information

Lot tracking: Lot number, manufacturing date

Timeline data: Date received, date opened, expiration date

Storage requirements: Temperature, humidity, light sensitivity

Regulatory status: FDA approval status, 510(k) clearance

Safety information: SDS documentation, hazard classifications

Quality control: COA documentation, QC testing results

Usage patterns: Rate of consumption, minimum stock levels

Tracking this information allows for traceability in the event of a recall or adverse event, ensures regulatory compliance, and facilitates efficient reordering processes.



Inventory Risks: Poor inventory management can lead to:

- Use of expired reagents affecting embryo development
- Stockouts disrupting laboratory operations
- Excessive costs from emergency orders

Implementing Effective Inventory Control in ART Compass

The Laboratory Quality Management System (LQMS) module in ART Compass provides a centralized platform for comprehensive inventory management, ensuring compliance with regulatory requirements while streamlining laboratory operations.

Create Master Inventory List

Navigate to the Documents and Forms section in ART Compass and create a master spreadsheet containing:

- Reagent/supply name
- Vendor information
- Catalog number
- Current pricing
- Minimum stock levels
- Reorder quantities

Track Usage and Status

Update the system when items are:

- Placed into service (opened)
- Found to be defective
- Approaching expiration
- Running low in stock
- Subject to recall

Document New Arrivals

When new supplies arrive:

- Log into the web version of ART Compass
- Navigate to the LQMS module
- Record lot number, expiration date, receipt date
- Use your phone to photograph invoices and COAs
- Attach these documents to the inventory record

Maintain Regulatory Documentation

Update SDS and 510(k) folders with current information:

- Access the Documents and Forms tab
- Navigate to pre-populated folders for major vendors
- Add documentation for new products
- Verify completeness during quarterly reviews

Storage Environment and Reagent Management

Monitoring Storage Conditions

Proper storage conditions are essential for maintaining reagent efficacy and ensuring consistent laboratory results. Key parameters to monitor include:

Temperature: Document refrigerator and freezer temperatures daily, with alarm systems for out-of-range conditions

Humidity: Maintain appropriate humidity levels in storage areas to prevent degradation of hygroscopic materials

Light exposure: Store light-sensitive reagents in amber bottles or cabinets that protect from UV exposure

Contamination control: Implement protocols to prevent cross-contamination between reagents

Temperature logs should be maintained and regularly reviewed as part of your quality management system. Digital monitoring systems that provide continuous recording and automatic alerts are highly recommended.

Segregation Practices

Implement strict segregation policies to prevent inadvertent use of inappropriate materials:

Expired materials: Clearly mark and physically separate from current inventory

Quarantined items: Designate specific areas for items awaiting QC testing or verification

Research vs. clinical: Maintain complete separation between research-grade and clinical-grade materials

Potentially contaminated: Isolate any materials suspected of contamination pending investigation



Supply Chain Management for Laboratories

Developing an Efficient Ordering System

Small Lab Approach	Medium Lab Approach	Large Lab Approach
For laboratories processing fewer than 200 cycles annually:	For laboratories processing 200-500 cycles annually:	For laboratories processing more than 500 cycles annually:
<ul style="list-style-type: none">• Designate a single embryologist responsible for inventory• Implement a physical or digital "need to order" list where staff can note depleting supplies• Conduct weekly inventory checks of critical supplies• Place orders on a consistent weekly schedule• Maintain a simple spreadsheet of common orders with vendor information	<ul style="list-style-type: none">• Create a shared digital ordering document in ART Compass• Implement minimum stock level indicators for all supplies• Rotate inventory responsibility among senior embryologists• Establish relationships with vendor representatives• Negotiate volume discounts based on annual usage projections	<ul style="list-style-type: none">• Implement a comprehensive inventory management system• Designate a dedicated inventory coordinator position• Develop automated reordering triggers based on usage patterns• Establish direct ordering relationships with manufacturers• Implement just-in-time delivery for high-volume consumables

Weekly Ordering Workflow Example



Space Optimization: Year-End Clean-Up Strategies

December provides an ideal opportunity for comprehensive laboratory organization and deep cleaning, preparing your space for the coming year's cycles. A systematic approach ensures no area is overlooked.

Cryostorage Optimization

- Complete backlogged discards** to free up valuable tank space
- Reorganize canisters** to maximize capacity utilization
- Evaluate tank performance** and identify candidates for replacement
- Forecast storage needs** based on previous year's cycle numbers
- Research high-capacity options** like MVE 6000 or Vitrostash if expansion is needed
- Calculate fill rate** to project when additional storage will be required
- Prepare shipments** to long-term storage facilities for applicable specimens

Laboratory Deep Clean

- Discard expired reagents** from refrigerators, freezers, and cabinets
- Clean all equipment** according to manufacturer recommendations
- Sanitize storage areas** while they are emptied for inventory
- Reorganize workstations** for optimal workflow efficiency
- Review equipment maintenance schedules** and arrange service for overdue items
- Check calibration status** of all measuring devices
- Update equipment logs** with cleaning and maintenance activities

Records Management

- Archive completed cycle records** according to retention policy
- Update electronic databases** to reflect current inventory status
- Review and update SOPs** for the coming year
- Verify regulatory documentation** is complete and accessible



Laboratory Organization: The "Place for Everything" Principle



Comprehensive Labeling System

Implement a standardized, consistent labeling approach throughout the laboratory. This includes clear labels for:

- Storage shelves, cabinets, and drawers
- Refrigerator and freezer sections
- Solution bottles and aliquots
- Equipment and workspace designations

Labels should be waterproof, resistant to laboratory chemicals, and easily readable from a distance.



FIFO Inventory Rotation

The "First In, First Out" principle ensures that older stock is used before newer arrivals, preventing waste from expired products:

- Position newer stock behind older inventory
- Use color-coded labels to indicate expiration timeframes
- Implement monthly checks for approaching expiration dates
- Train all staff on proper rotation procedures

Consider using inventory management software that alerts you to approaching expiration dates.



Scheduled Maintenance Routines

Develop a calendar of regular cleaning and organization activities:

- Daily quick-tidy protocols for workstations
- Weekly cleaning of common areas and equipment
- Monthly deep cleaning of specific laboratory sections
- Quarterly comprehensive inventory and organization

Assign specific responsibilities to staff members and use checklists to ensure consistency and accountability.

Effective organization isn't just about aesthetics—it directly impacts laboratory efficiency, error prevention, and compliance. A well-organized lab reduces the cognitive load on staff, allowing them to focus on the precision their work requires rather than searching for supplies or navigating cluttered spaces.

CAP Guidelines: Regulatory Requirements for Storage and Inventory

The College of American Pathologists (CAP) establishes specific requirements for specimen storage, disposition, and inventory management that all accredited laboratories must follow. Understanding these requirements is essential for maintaining compliance and passing inspections.

Specimen Storage

GEN.40506 & GEN.40507: Require secured specimen storage and defined retention and storage conditions for each specimen type. This includes maintaining the chain of custody and ensuring specimens remain in an appropriate environment when not in use.

RLM.08000: Mandates a system to verify and maintain specimen identity throughout receipt, storage, processing, and disposition.

Long-Term Disposition

RLM.12400: Requires written procedures regarding the length of storage, informed consent, and long-term disposition of cryopreserved gametes or embryos.

RLM.03975: Mandates records that allow for tracking the disposition of all gametes or embryos handled or stored by the laboratory.

Records Security

GEN.40509: Requires chain-of-custody records, security logs, and testing records to be retained for at least two years in a limited-access, secured area accessible only to authorized personnel.

Inventory Control

GEN.61900: Mandates an effective supply inventory control system.

RLM.12000: Requires records for the current inventory of all specimens stored in cryobanks.

Compliance with these guidelines requires implementing comprehensive systems that integrate physical storage management with detailed record-keeping. The procedures outlined in this training are designed to ensure your laboratory meets or exceeds these regulatory requirements.

Practical Implementation: Monthly Quality Assurance Activities

Implementing a structured monthly schedule for QA activities related to space and supplies ensures consistent attention to these critical areas throughout the year. Here's a framework for December's focus on tissue inventory, supplies management, and discard workflows:



The lab director or quality manager should initiate each month's Quality Audit by setting the status to "In Progress" and assigning tasks to appropriate staff using ART Compass's assignment function. This approach documents both continuing education and quality assurance activities in one integrated system.

Competency Assessment: Staff Review Checklist

Regular competency assessment ensures that all laboratory staff maintain proficiency in critical procedures related to space and supplies management. This checklist can be used both for training new staff and for annual competency verification of experienced embryologists.

1

Visual Tank Check

- Correctly accesses cryostorage tanks following safety protocols
- Accurately identifies specimen locations within the storage system
- Properly documents inventory findings in electronic records
- Correctly identifies and resolves discrepancies
- Follows all safety procedures when handling liquid nitrogen

2

Embryo Disposition

- Correctly verifies consent documentation requirements
- Properly identifies specimens for disposition
- Follows dual-witnessing protocols accurately
- Documents disposition according to laboratory standards
- Updates electronic records to reflect completed disposition

3

Inventory Management

- Accurately records new inventory in LQMS
- Properly documents lot numbers and expiration dates
- Correctly identifies and removes expired materials
- Maintains proper storage conditions for reagents
- Updates inventory records when supplies are depleted

4

Documentation and Records

- Maintains accurate and complete records of all activities
- Properly files and organizes regulatory documentation
- Correctly uses ART Compass for quality management
- Understands retention requirements for different record types
- Demonstrates knowledge of applicable CAP requirements

This competency assessment should be performed annually for all staff and documented in their training records. New staff should demonstrate proficiency in these areas before being permitted to perform these procedures independently.

Troubleshooting Common Inventory Challenges

Inventory Discrepancies

Challenge: Physical inventory doesn't match electronic records

Solutions:

- Implement **barcode scanning** to reduce manual entry errors
- Require **immediate documentation** when items are removed from inventory
- Perform **more frequent spot-checks** of high-turnover items
- Investigate **patterns in discrepancies** to identify systemic issues
- Consider **restricted access** to supply areas for better control

Storage Space Limitations

Challenge: Insufficient space for growing inventory needs

Solutions:

- Implement **just-in-time ordering** to reduce on-hand quantities
- Evaluate **usage patterns** and adjust par levels accordingly
- Use **vertical storage solutions** to maximize available space
- Consider **off-site storage** for rarely-used items
- Negotiate **more frequent deliveries** from key suppliers

Expired Products

Challenge: Reagents expiring before use

Solutions:

- Implement **automated alerts** for approaching expiration dates
- Review **ordering quantities** to match actual usage
- Use **visual indicators** (colored stickers) for expiration timeframes
- Coordinate with other laboratories for potential reagent sharing
- Negotiate **returns/exchanges** with vendors for near-expiry products



Technology Solutions for Modern Inventory Management

While traditional inventory methods can be effective, leveraging technology can significantly enhance accuracy, efficiency, and compliance in IVF laboratory inventory management.



Barcode Systems

Implementing barcode scanning for both specimens and supplies can dramatically reduce identification errors and streamline inventory processes:

- Generate unique barcodes for all cryopreserved specimens
- Scan supplies upon receipt to automatically update inventory
- Use mobile scanning devices for convenient inventory checks
- Integrate with ART Compass for seamless record-keeping



Automated Monitoring

Digital monitoring systems provide continuous oversight of critical storage conditions:

- 24/7 temperature and liquid nitrogen level monitoring
- Automatic alerts for out-of-range conditions
- Data logging for regulatory compliance
- Remote access capabilities for off-hours monitoring



Cloud-Based Inventory

Cloud systems like ART Compass provide significant advantages for inventory management:

- Real-time access to inventory status from any device
- Automatic backups preventing data loss
- Integration with ordering and quality management systems
- Scalable storage for growing documentation needs



Advanced Storage Systems

Next-generation storage technologies are transforming cryostorage management:

- Automated retrieval systems minimizing specimen exposure
- RFID tracking for specimen location verification
- Integrated inventory management and specimen tracking
- Enhanced security features with access logging

When evaluating technology solutions, consider integration capabilities with your existing systems, the level of technical support provided, and the total cost of ownership including training and maintenance. The ideal solution should scale with your laboratory's growth while maintaining the highest standards of accuracy and security.

Key Takeaways and Implementation Plan

Core Principles for Effective Management

- **Systematic Verification**
Regular visual inspection of cryostorage inventory and reconciliation with electronic records is essential for preventing errors and ensuring regulatory compliance.
- **Meticulous Documentation**
Comprehensive record-keeping for all specimen handling, storage, and disposition activities provides the foundation for quality assurance and regulatory compliance.
- **Proactive Inventory Management**
Systematic tracking of reagents and supplies ensures availability while preventing waste from expired materials, directly impacting laboratory efficiency and clinical outcomes.
- **Optimized Laboratory Organization**
Implementing the "place for everything" principle with clear labeling and consistent storage protocols reduces errors and improves workflow efficiency.

Next Steps

1. Conduct a gap analysis comparing current practices to the procedures outlined in this training
2. Develop an implementation timeline for addressing identified gaps
3. Update SOPs to reflect best practices for inventory management
4. Train all staff on revised procedures and documentation requirements
5. Schedule your next visual tank check and comprehensive inventory review



✔ **Excellence in laboratory management directly translates to excellence in patient care.** By implementing these best practices for space, supplies, and storage management, you are ensuring that your laboratory operates at the highest standards of quality and compliance, ultimately supporting optimal outcomes for your patients.

Remember that ART Compass provides integrated tools to support all aspects of laboratory management. Take advantage of these resources to streamline your processes while maintaining comprehensive documentation for regulatory compliance.