



cGMP Biostorage

- ✓ Stability
- ✓ Controlled Temperature
- ✓ Ambient
- ✓ Refrigerated
- ✓ Freezer
- ✓ Ultra-Cold
- ✓ Cryogenic LN₂ Vapor Phase
- ✓ Cryogenic LN₂ Liquid Phase

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- ✓ Long-Term Storage
 - ✓ Mirror Banking
 - ✓ Contingency Planning
 - ✓ Overflow Storage
 - ✓ Transitional Storage

Masy's biostorage service offers confidence at all temperatures

Masy's biorepository facility securely stores:

- cell banks
- clinical study samples
- vaccines
- drug compounds
- production stock
- medical devices
- and other biologic products

under precisely-controlled temperature and humidity requirements, ensuring the safety and integrity of your valuable materials.

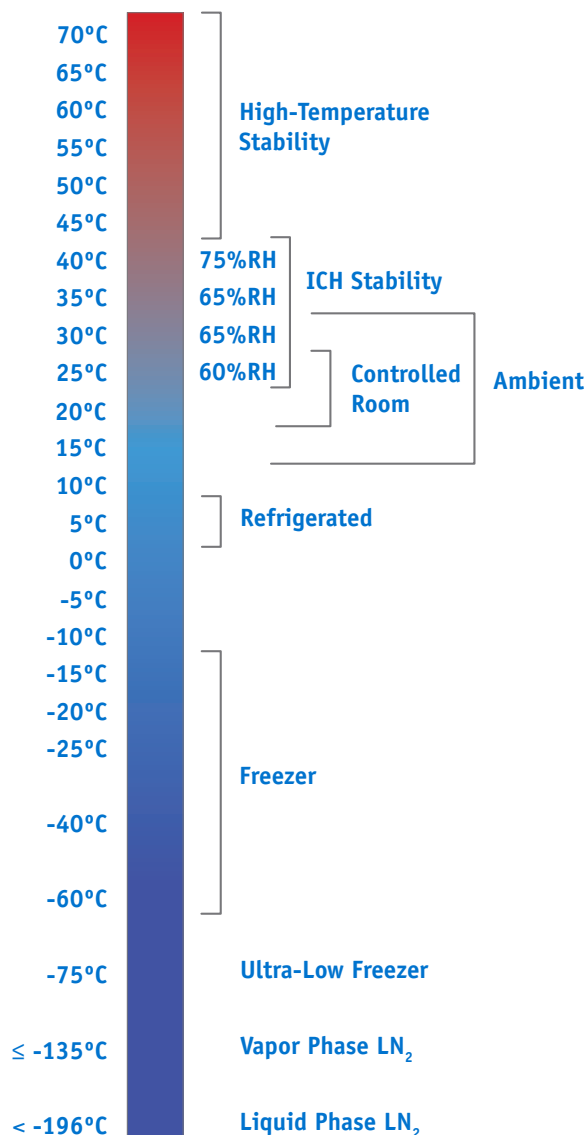
Masy has over 30 years of experience with cGMP practices and FDA regulations; we treat your critical materials as if they were our own.

You can have confidence that the materials you entrust to us will remain safe, secure, and compliant to your specifications and tolerances until you need access to them again.

Documentation, Work Instructions and Data Delivery

Our Biorepository staff is trained on written work instructions to bring your product into our facility, maintain temperature and security while your product is entrusted to us, and prepare your product to move to its next destination. Work instructions are regularly reviewed and updated as living documents reflecting actual current best practices.

Masy monitors and scrutinizes temperature and RH conditions in our storage rooms and chambers. Alarms are instigated as sensors begin to drift so there is sufficient time to intervene before conditions go out of specifications. Trends are available to our customers for areas your products are stored in for the duration of their stay, or as requested. Any condition that creates an alarm will be documented and addressed. Customers will be notified according to your preferences.



Multiple levels of redundancies, generators, and security

To ensure the safety of the valued items you have entrusted to our care, Masy has created multiple levels of redundancies. If street power fails, Masy has two oversized generators, each capable of running our entire operation, with auto switch over. Each -75°C, -60°C, and -40°C walk-in chamber has triple redundant heating and cooling systems, dual compressors, and alternatively LN₂. Ambient warehouses have redundant heating and cooling systems.

Multiple levels of security are employed to ensure your high value sensitive products are protected 24/7/365. Combination of swipe cards, limited access, Cyber Locks on all chambers, and video surveillance monitoring allows us and our customers to sleep well at night knowing protection is prevalent.

24/7 Monitoring and Call List

Masy monitors the conditions of our chambers and your valuable products 24/7/365 with two independent validated monitoring systems. We have three monitoring sensors installed in each chamber and room, based on the results of validation mapping studies. One sensor is installed at the warmest location; one at the coldest location and one at the mean location. These hot and cold sensors are programmed to provide performance alerts to protect your product, first as a warning, so there is sufficient time to intervene before the chamber goes out of specification.

We have three independent monitoring communication systems in place, based on hard phone lines, cable, and

cellular, with voice, text, and email notifications. The call list is supported by trained technicians with backup assistance, who follow written procedures to solve the problem within the chamber first, and if necessary, relocate your product to a safe environment while repairs are underway.

Maintaining conditions in the Biorepository common areas is crucial to allow our chambers to operate at optimal conditions. Similar to our chamber monitoring, the common areas are also monitored and will provide performance alerts to on call staff if a heating or cooling system is drifting outside normal operational parameters, before out of tolerance conditions provide alarm notifications.

Protocols, Audits, and Best Practices

Recognized GMP Facility - Masy abides by guidelines and requirements at the request of our customers to provide the service and support needed. We proudly note our recognition in MA and Japan as a GMP facility.

Audits - Masy agrees that our customers will audit our facility to review documentation, practices, and processes so your questions can be answered and we can earn your trust.

Masy is also audited by outside agencies to ISO 9001 and ISO 17025 to maintain our certification and accreditation.

Masy is willing to share industry best practices with our customers, and reciprocally welcome such advice from our customers so we can continually improve to deliver the service you need.

Efficiencies, Storage, Packaging and Transportation

Masy works with our customers to create the best possible conditions for packaging and transportation. In addition to our large inventory of traditional shippers and dataloggers, we also offer the Masy created "**Masy Transporter**" to deliver cold products. We perform mock transportation runs with our storage and packaging equipment, and make system modifications specific to our customer's needs. We work with our customers to find and implement the strategy and solution that works best for them.



Since Masy believes your products deserve a stable environment while in our care, we have worked with two specialty manufacturers to create the best possible conditions for your products: Bahnson and Stirling Chambers.



Bahnson Environmental Specialties, Inc. created all of our distinctive walk-in chambers from -75°C to stability rooms. Bahnson understands that maintaining conditions in our chambers is vitally important to Masy and to our customers.

Stirling Ultralow created environmentally friendly freezers using a new technology in this industry - the Stirling engine. Using less energy to create cold environments is cost effective and reduces our carbon footprint. They are the product of the future.



Your valued products are in the requested condition throughout their stay at Masy due to our quality chambers, redundancies, efficiencies, and vigilance.



Masy Quality

Our quality department assures that Masy maintains compliance to ISO standards by overseeing our training program management, documentation control management, and contract administration. They offer management review oversight; LEAN education and implementation; conduct internal and extrinsic audits; monitor customer feedback and quality metrics while investigating errors and providing corrective actions and continuous improvements.

Many of our Quality staff are certified through American Society for Quality (ASQ). They have completed the required training and earned the following certifications:

- ASQ-CMQ/OE - Certified Manager of Quality/Organizational Excellence
- ASQ-CQA - Certified Quality Auditor
- ASQ-CQT - Certified Quality Technician



Metrology & Calibration

NVLAP-accredited, NIST-traceable calibration of your primary reference standards and laboratory instruments with minimal measurement uncertainties



Qualification & Validation

Comprehensive IQ/OQ/PQ protocols for controlled temperature units, environmental chambers, warehouse mapping, sterilizers, autoclaves, lyophilizers, and more



cGMP Biorepository Storage

Secure, monitored off-site storage of temperature-sensitive samples and products, at conditions from 70°C to liquid-phase LN₂ (-196°C). Within those conditions, ICH stability storage and custom conditions can also be provided.



Continuous Monitoring Systems

Reliable 24/7 environmental monitoring systems with 21 CFR Part 11 compliance meet GMP requirements for critical spaces, featuring excursion alerts and remote viewing and reporting



Preventive Maintenance Systems

Monitoring the critical parameters of integrated systems to prevent unforeseen equipment failures before chamber or component failure or product loss



Equipment Rental and Sales

Calibration and validation equipment for rental or purchase, including weight sets, Validators, dataloggers, thermocouples, sensors, Fluke products, and gaskets and clamps

ISO 17025 Accredited



Masy BioServices is one of a select number of metrology laboratories in North America that meets the rigorous qualifications for National Voluntary Laboratory Accreditation Program (NVLAP) accreditation to ISO 17025. Our current NVLAP scope can be viewed at masy.com/accreditation.



Masy BioServices is certified to ISO 9001 in recognition of our adherence to a robust quality management system.

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