



**Global R&D Sample
Stability Storage Solutions
Safeguarding Every Sample**



R&D Sample Stability Storage – Safety & Compliance Solutions

Astorion has over 30 years of experience offering ICH Sample Stability Storage to R&D industries around the world. Our comprehensive portfolio of solutions include a full range of ambient storage temperatures, humidity-controlled environments and ICH global climatic zone capabilities.

ICH Q1A Sample Stability Storage Temperature Environments



Validated Ambient and Humidity-controlled Environments (Standard Offering)

- o 21°C/45% RH – Zone I
- o 25°C/60% RH – Zone II
- o 30°C/35% RH – Zone III
- o 30°C/65% RH – Zone IV
- o 30°C/75% RH – Zone IVb
- o 40°C/75% RH – Accelerated ambient



Ambient and Humidity-controlled Environments (Custom Request)

- o 25°C/40% RH
- o 30°C/25% RH
- o 40°C/NMT 25% RH

Cabinet Storage (50°C, 55°C, 60°C)

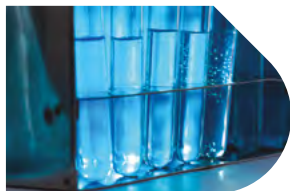
Intermediate Trial Conditions for Climatic Zones (I, II, III and IVa)

Long Term Trial Conditions for Climatic Zones (I, II, III and IVb)

Accelerated Trial Conditions for Climatic Zones (I - IV)

Our ICH Sample Stability Assessment Solutions

Our stability assessment experts will partner with you to discuss your regulatory compliant sample stability needs and advise you on our in-house or referral laboratory solutions.



Photostability Testing

Performed in line with the ICH 1Qb specification in normal ambient temperatures of up to 21°C, with capabilities of achieving a minimum of 1.2 million lux hours and 200-watt hours per square meter in fewer than 14 days.



Thermal Cycling

Reproducing deviating temperature conditions and cycle at various hour periods without disruption of product movement between chamber, to replicate transportation conditions safely and securely.



Secondary Accelerated Aging Time

Exposing medical devices to elevated temperatures to simulate long-term storage conditions, providing evidence of their stability and performance.



Leader in High-Quality ICH Sample Stability Storage

Astoriom's global stability storage facilities adhere to the highest international regulatory standards, ensuring full compliance with quality certifications and licenses. Our stability storage facilities maintain both international and country-specific quality certifications and licenses including:

- ISO 9001:2015, cGMP compliance standards
- (ICH) Q1A regulatory compliance for stability testing
- (ICH) Q1B compliance for photostability testing
- FDA registered and FDA 21 CFR Part 11 compliant
- European Union compliant for the storage of pharmaceutical products.
- MHRA compliant and DEA licensed for controlled drug storage in the UK.
- HPRa compliant for the storage of medicine and devices in Ireland.
- CAP accredited and CLIA compliant in the US.

Sample Stability Service & Validation Solutions

Astoriom sample stability storage experts partner with R&D customers to provide consistent, high-quality storage recommendations and validation processes that meet stringent guidelines for quality and safety, providing customers the confidence in the handling and preservation of their samples.

Expertise

Provide consultative guidance on stability storage planning and best practices.

Maintainence

On call equipment service and validation experts safeguard samples from equipment failures.

Management

Maintain equipment and document processes to safeguard sample integrity.

Redundancy

Back-up generators and redundant storage units are always validated and ready.

Monitoring

Data and equipment monitoring, stock inventory tracking and environment maintenance.





The Value of Partnering with Astorium for ICH Sample Stability Storage

Broadest Range of Controlled-Temperature Stability Storage

Our comprehensive portfolio of temperature-controlled ICH stability storage solutions provides you the most flexible options for storing your sample assets in a single location.

Storage Redundancy and Back-up

Our global regulatory compliant facilities, trained staff and validated back-up sample storage walk-in rooms and cabinets are validated, ready as needed and provide you greater sample security and maximum protection of your sample assets.

Cost-Saving CAPEX vs OPEX Model

Instead of large Capital Expenditure Projects, manage your stability projects as part of an operational budget. Typically, a customer pays only for the space used against a pay per use model. Reinvest savings back into advancing your R&D initiatives.

Improves Focus on Core R&D Priorities

Stability studies are typically long-term projects whereby required investments must be made in sizeable facility storage space, staffing, ongoing equipment maintenance, inventory tracking and data monitoring across the length of a project. Outsourcing stability storage enables you to reallocate internal staff and investment savings into higher revenue generating core activities.

Partner with Us!

Sample Stability Storage
Sample Biorepository Storage
Sample Storage Design

Sample Storage Service and Validation
Sample Disaster Protection & Recovery
Sample Inventory Intelligence

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