Company Information				
Company Name	Address	Phone Number	Date Founded	EIN / DUNS
Gillson Testing	PA: 4125 Independence Dr Suite 5 Schnecksville, PA 18078 Sampling Services additionally in San Diego CA and Raleigh NC	484.550.7709	2012 Azzur Labs 2025 Gillson Testing	33-2460625 11-9460474

Operations Director	Erin Thane / Erin.Thane@gillsontesting.com
Quality Director	Katie Neetz / Katie.Neetz@gillsontesting.com
President	Kym Faylor / Kym.Faylor@gillsontesting.com
Client Services	Brandi Thear / Brandi.Thear@gillsontesting.com
General Inquiries	notifications@gillsontesting.com
Accounting Address	4125 Independence Drive, Suite 5, Schnecksville PA 18078
Accounting Phone Number	484-550-7709
Accounting Email	AR@gillsontesting.com

Accreditations
Gillson Testing is an ISO/IEC 17025:2017 accredited laboratory through Perry Johnson Laboratory Accreditation, Inc (PJLA). Accreditation Number: 80916 Chemical and Biological Testing: Certificate L23-642-R1 Mechanical and Thermodynamic Calibrations for Temperature and Time: Certificate L23-641-R1
Our analysts participate in the Analytical Testing administered by ERA - A Waters Company, Laboratory Quality Assurance Program, for chemistry and microbiology. All calibration personnel participate in proficiency testing for calibration activities provided through ISO 17043 accredited Providers

Registrations	
US Department of Health and Human Resources - US Food and Drug Administration – Drug Establishment Registration	Last Audit: 09/2021 (VAI) under Azzur Labs FEI: 3036624327
US Department of Justice – Drug Enforcement Administration – Controlled Substance Registration.	Gillson Testing has fulfilled the requirements as an analytical laboratory to perform analysis on Schedule I through V controlled substances. Last Audit: 02/2017 under Azzur Labs
Pennsylvania Department of Health Drug, Device and Cosmetic Program	Certificate Number: 1000004554
NAICS Code	541380 Testing Laboratories

Quality Management System
Gillson Testing has an implemented, maintained, and documented quality management system in accordance with the requirements of ISO 17025:2017 and Code of Federal Regulations 21 Part 820, 210 and 211. ISO/IEC 17025:2017 accreditation allows Gillson Testing to acquire international recognition for incorporating quality management systems which assure compliance with regulatory requirements while increasing efficiency and reducing costs. Our clients can utilize Gillson Testing's capabilities, secure in the knowledge that the analysis will meet global regulatory and quality standards.
There is a written Quality Manual which contains our Quality Policy. Gillson Testing maintains Quality System Policies, Safety Plans, Standard Operating Procedures, and Protocols.
Gillson Testing maintains a Document Control System that controls records and documents that are required by the quality system. All test procedures, final reports, and other auxiliary documentation on file that Gillson Testing utilized for performing the testing required will contain sufficient detail to ensure traceability and reproducibility of results.
The document control system has a documented procedure defining procedures including issuing, distribution, revision, superseding, and archiving.
Management Reviews of the Quality System are conducted on a regular basis.
Records are maintained in compliance with ISO and CFR requirements for seven years.
Gillson Testing utilizes an electronic QMS that is compliant with CFR 21 Part 11 requirements
Review of Client Requests and contracts describes procedures and responsibilities of Gillson Testing and its clients with respect to requests, tenders, and contracts. The laboratory will ensure that test requirements and methods are defined, documented and understood, the laboratory has the capability and resources to meet test requirements and the appropriate test method is selected and is capable of meeting the customers' requirements.

Supplier Quality
The supplier Quality System selects suppliers based on established quality criteria. There are procedures in place for verifying that the purchased products conform to the standards that were provided.

Facilities
Gillson Testing maintains a 12,000 sq ft facility with controlled access from all points.
There are two cleanrooms maintained and certified to meet ISO 7 and ISO 8 standards. Within the ISO 7 room a certified BSC maintains ISO 5 standards.
Gillson Testing also employs use of the Vaisala Veriteq Continuous Monitoring System. This allows Gillson Testing to monitor the temperature of all controlled environments in the laboratory. It notifies the quality department as well as management if any controlled temperature chambers and sample storage areas fall outside its specifications.
Gillson Testing utilizes a backup generator that provides continuous power to critical systems in the event of a power failure. Our clients can be confident in the knowledge that their samples will not be compromised during a power outage.
Gillson Testing maintains a Validation Master Plan which outlines the intentions, approach, responsibilities, and scope for laboratory validation. This includes validation and suitability studies of test methods and qualification of equipment utilized by Gillson Testing. This plan provides an outline of activities and documents that are required for validation with the aim of meeting regulatory requirements. It contains the elements necessary to ensure that an infrastructure exists to plan and support equipment qualification activities.

Calibration/Maintenance
Gillson Testing maintains a calibration and maintenance program which assures that all equipment utilized in testing are qualified, calibrated and maintained according to Gillson Testing requirements.

Customer Feedback
There is a formal customer complaint system that meets the requirements of cGMP and ISO standards.
Gillson Testing maintains a system to address and document customer complaints including their investigation and resolution.

Internal and External Audits
Gillson Testing conducts and documents internal and external audits in compliance with ISO and cGMP requirements.
Gillson Testing hosts onsite and remote customer audits.

Control of Non-Conforming Product
There is a documented system to ensure that raw materials that do not conform to product requirements are identified and controlled to prevent its unintended use.

Corrective and Preventive Actions
Gillson Testing has implemented a CAPA, change control, observation, deviation, and equipment failure program.
This program is maintained in accordance with ISO and cGMP requirements. Procedures are in place for root cause analysis within the program.

Confidentiality
Gillson Testing maintains the confidentiality of all clients' testing results and products.

Diversity
Gillson Testing is an Equal Opportunity and Affirmative Action employer committed to a culturally diverse workforce. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, national origin, disability, protected veteran status, or any other characteristics protected by applicable law.

Corporate Responsibility in Procurement Activities
Gillson Testing has procurement standards to conduct fair and equitable transactions throughout the supply chain. The policies cover matters including legal compliance, respecting human rights, labor, safety, and health, as well as environmental protection such as biodiversity preservation and risk control of chemical contents and information security. Gillson Testing constantly improves its socially responsible procurement by obtaining the understanding and support of suppliers for the policies and building strong partnerships.

VERSION HISTORY

Quality Self Assessment (v13.0)

Approved: 25-MAR-2025 | **Effective**: 25-MAR-2025 | **Retired**: N/A
Updates to reflect Gillson Testing

Quality Self Assessment (v12.0)

Approved: 04-SEP-2024 | **Effective**: 04-SEP-2024 | **Retired**: 25-MAR-2025
Update for Organizational Change to reflect the PA site for Azzur Labs.

Quality Self Assessment (v11.0)

Approved: 29-JUL-2024 | **Effective**: 29-JUL-2024 | **Retired**: 04-SEP-2024
Update director contacts for PA and NC labs

Quality Self Assessment (v10.0)

Approved: 15-MAR-2024 | **Effective**: 15-MAR-2024 | **Retired**: 29-JUL-2024
Update of Azzur Labs Boston site.

Quality Self Assessment (v9.0)

Approved: 19-JAN-2024 | **Effective**: 19-JAN-2024 | **Retired**: 15-MAR-2024
Corrected typographical error

Quality Self Assessment (v8.0)

Approved: 11-DEC-2023 | **Effective**: 11-DEC-2023 | **Retired**: 19-JAN-2024
Removal of IL lab location. Update of Sr personnel at SD site.

Quality Self Assessment (v7.0)

Approved: 26-SEP-2023 | **Effective**: 26-SEP-2023 | **Retired**: 11-DEC-2023
Updated ISO 17025 Certificate Numbers

Quality Self Assessment (v6.0)

Approved: 30-AUG-2023 | **Effective**: 30-AUG-2023 | **Retired**: 26-SEP-2023
Corrected address for Raleigh lab to refelct NC instead of PA.

Quality Self Assessment (v5.0)

Approved: 28-JUL-2023 | **Effective**: 28-JUL-2023 | **Retired**: 30-AUG-2023
Update NC location; add San Francisco site

Quality Self Assessment (v4.0)

Approved: 06-MAY-2022 | **Effective**: 06-MAY-2022 | **Retired**: 28-JUL-2023
Update for CA lab location/size

Quality Self Assessment (v3.0)

Approved: 30-NOV-2021 | **Effective**: 30-NOV-2021 | **Retired**: 06-MAY-2022
Update DUNS number for Chicago lab; update ISO 17025 certificate numbers and FDA inspection history for PA Lab.

Quality Self Assessment (v2.0)

Approved: 10-AUG-2021 | **Effective**: 11-AUG-2021 | **Retired**: 30-NOV-2021
Moving document into a live reference instead of controlled chart. Updating for all labs.

Quality Self Assessment (v1.0)

Approved: 10-SEP-2020 | **Effective**: 10-SEP-2020 | **Retired**: 11-AUG-2021
Initial ZenQMS Implementation; increasing version number to comply with ZenQMS requirements.

ELECTRONIC SIGNATURES

Approvals

Katie Neetz Quality Director katie.neetz@gillsontesting.com	**Document Author** I am the author of this document. Signed 06:58:34 PM UTC 25-MAR-2025