General Company Information	
Company Name	Azzur Labs, LLC Headquarters
Address	4125 Independence Drive Suite 5 Schnecksville, PA 18078
Sample Submission Address	4125 Independence Drive Suite 5 Schnecksville, PA 18078
Laboratory Phone Number	484.550.7709
Accounting Address	P.O. Box 940 Southampton, PA 18966
Accounting Phone Number	800.726.0331
Website	Azzur.com/Labs
Date Founded	2012
DUNS	078426854

Contact Information		
Kym Faylor	President	Kym.Faylor@azzur.com
Katie Neetz	Quality Director	Katie.Neetz@azzur.com
Katie Neetz	Technical Support	Katie.Neetz@azzur.com
Veronica Medvinsky	Accounts Payable	Veronica.Medvinsky@Azzur.com

Accreditations
Azzur Labs is an ISO/IEC 17025:2005 accredited laboratory through the American Association of Laboratory Accreditation (A2LA). Certificate Number: 3484.01
All of our analysts participate in the A2LA Analytical Testing administered by ERA - A Waters Company, Laboratory Quality Assurance Program, for chemistry and microbiology.

Registrations	
US Department of Health and Human Resources - US Food and Drug Administration – Drug Establishment Registration	Last Audit 1/2015 (NAI) Registration Number: 078426854
US Department of Justice - Drug Enforcement Administration - Controlled Substance Registration.	Azzur Labs has fulfilled the requirements as an analytical laboratory to perform analysis on Schedule I through V controlled substances.
Pennsylvania Department of Health Drug, Device and Cosmetic Program	Certificate Number: 1000003444

Azzur Labs employees have obtained one or more of the following quality certifications:
Certified Quality Improvement Associate (CQIA) ASQ
Certified Quality Auditors (CQA) ASQ
Certified Manager of Quality/Organizational Excellence (CMQ/OE) ASQ
Regulatory Affairs

Quality Management System
Azzur Labs has an implemented, maintained and documented quality management system in accordance with the requirements of ISO 17025:2005 and Code of Federal Regulations 21 Part 820, 210 and 211 and 1271. ISO/IEC 17025:2005 accreditation allows Azzur Labs, LLC to acquire international recognition for incorporating quality management systems which assure compliance with regulatory requirements while increasing efficiency and reducing costs. Our clients are able to utilize Azzur Labs' testing 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. Azzur Labs maintains Quality System Policies, Safety Plans, Standard Operating Procedures, and Protocols
Azzur Labs 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 Azzur Labs utilized for performing the testing required will contain sufficient detail to ensure traceability and reproducibility of results from test interval to test interval.
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.
Review of Client Requests and contracts describes procedures and responsibilities of Azzur Labs, LLC 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.

Facility
Azzur Labs maintains a 10,000 square foot facility. The laboratory has controlled access from all points.
There are two cleanrooms within the facility maintained and certified to meet an ISO 7 and an ISO 8 standards. Within the ISO 7 room a certified BSC maintains ISO 5 standards.
Azzur Labs, LLC also employs use of the Vaisala Veriteq Continuous Monitoring System. This allows Azzur Labs quality department 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.
Azzur Labs, LLC 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.
Azzur Labs 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 Azzur Labs, LLC. 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
Azzur Labs maintains a calibration and maintenance program which assures that all equipment utilized in testing are qualified, calibrated and maintained according to Azzur Labs' requirements.

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

Internal and External Audits
Azzur Labs conducts and documents internal and external audits in compliance with ISO and cGMP requirements.

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

Corrective and Preventive Actions
Azzur Labs 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
Azzur Labs maintains the confidentiality of all client's testing results and products.

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

Corporate Responsibility in Procurement Activities
Azzur Labs has procurement standards in order 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. Azzur Labs constantly improves its socially responsible procurement by obtaining the understanding and support of suppliers for the policies and building strong partnerships.