

## COMPANY INFORMATION

General Information	
<b>Company Name</b>	Analytical Lab Group
<b>Address of Facility</b>	33 Nagog Park, Acton, MA 01720
<b>Phone Number</b>	877-287-8738
<b>Website</b>	www.analyticallabgroup.com
<b>DUNS Number</b>	829542689
<b>Products and Services</b>	Microbiology testing services, Training & Consulting
<b>Founded</b>	1993
<b>Number of Permanent Employees</b>	28
<b>Number of Quality Employees</b>	6
<b>Facility Size</b>	10,000 sq.ft.
<b>Corporate</b>	Alan Roth, CEO, Analytical Lab Group, LLC 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121
<b>FDA FEI Number</b>	1000148174
<b>Expiration Date</b>	December 2020
<b>Last FDA Audit</b>	January 2019
<b>ISO/IEC 17025:2017 Certificate Number</b>	3383.01
<b>Expiration Date</b>	January 2021
<b>Last ISO Renewal Audit</b>	November 2019

### Attachments:

- FDA Drug Establishment Current Registration
- Scope of Accreditation to ISO/IEC 17025:2017
- DBA Information

### Available Upon Request:

- Current Document Master List
- GMP Equipment List
- PDFs of specific Standard Operating Procedures (SOPs)
- References
- Organizational Charts
- Facility Map
- Quality Manual

# ALG-EAST COAST QUALITY INFORMATION

Key Personnel Information		
Name	Title	Email
Alan Roth	CEO Analytical Lab Group	alan.roth@analyticalabgroup.com
Joseph Gajewski	Director of Operations	joe.gajewski@analyticalabgroup.com
Patrick Tierney	Quality Manager	patrick.tierney@analyticalabgroup.com
Elaine Cung	Quality Supervisor	elaine.cung@analyticalabgroup.com
Aaron Bisceglia	Technical Project Manager	aaron.bisceglia@analyticalabgroup.com
Ryan Burke	Environmental Monitoring Manager	ryan.burke@analyticalabgroup.com
Matthew Green	Lab Manager	matthew.green@analyticalabgroup.com
Stephanie Shepard	Director of Inside Sales	stephanie.shepard@analyticalabgroup.com
Bonnie Sweeney	Accountant	bonnie.sweenet@analyticalabgroup.com

Quality Assurance Information	
<b>Name and Title of QA Director</b>	Patrick Tierney, Quality Manager
<b>Telephone Number</b>	978-393-4101
<b>Email Address</b>	patrick.tierney@analyticalabgroup.com
<b>Reports to</b>	Alan Roth, CEO
<b>Number of QA Employees</b>	6
<b>Quality Agreement signed upon request?</b>	Yes
<b>Confidentiality Agreement signed upon request?</b>	Yes
<b>Audit/facility tour available upon request?</b>	Yes

# ALG-EAST COAST QUALITY INFORMATION

## QUALITY ASSURANCE CONTROLS & MANAGEMENT SYSTEM

1. Have any ALG-East Coast personnel been disbarred by the FDA? **No**
2. Are you subject to inspections by local authorities? **Yes**
3. Is there a formal employee training program? **Yes**
4. Are employees tested for proficiency? **Yes**
5. Are employees hired to meet specific job descriptions? **Yes**
6. Is annual GMP training and lab safety provided to all appropriate employees? **Yes**
7. Are internal audits performed according to a pre-established schedule? **Yes**
8. Are all suppliers that provide critical materials and/or external calibration services audited by ALG-East Coast? **Yes**
9. Are there programs established for Deviation Reports (DR) and Corrective Action Preventive Action (CAPA)? **Yes**
10. Are CAPAs evaluated for efficiency? **Yes**
11. Does the QA unit have the authority to halt laboratory, manufacturing, validation or calibration testing activities? **Yes**
12. Does QA approve all Certificates of Analyses (C of A) after a thorough review of all associated raw data? **Yes**
13. Is there a system in place for continuous improvement and management review? **Yes**
14. Is there a pest control program in place? **Yes**
15. Is there a security system and SOP in place and access to the facility controlled at all times? **Yes**
16. How long are records maintained at ALG-East Coast? **All raw data is stored on-site for a minimum of 3 years at ALG-East Coast, unless otherwise instructed per Quality Agreement. All data is scanned and stored indefinitely on a server which is backed up by a third-party company.**
17. Are procedural changes approved by QA and controlled to ensure that the most current version of the SOP is in use? **Yes**
18. Is there a change control program? **Yes**
19. Is there an Out of Tolerance (OOT) control program SOP? **Yes**
20. Is there a formal customer complaint SOP in place? **Yes**

## ESTABLISHED LABORATORY CONTROLS & SYSTEMS

1. Do personnel eat, drink or smoke in the laboratory areas? **No**
2. Is Environmental Monitoring (EM) and trending performed on a routine basis? **Yes**
3. Are there procedures dictating cross contamination prevention and lab cleaning? **Yes**
4. Is preventive maintenance, validation and calibration programs controlled by SOPs and performed according to a predetermined schedule? **Yes**
5. Are equipment calibration standards traceable to the N.I.S.T or other certification body? **Yes**
6. Are computer software programs validated? **Yes**
7. Are there procedures in place for the receipt of client samples, raw materials, reagents, standards and equipment? **Yes**
8. Is there a quarantine procedure, labeling system and dedicated area in place for incoming materials? **Yes**
9. Are C of As filed for all incoming materials? **Yes**
10. Is the first in, first out rule enforced for all materials? **Yes**
11. Are any subcontractors used? **Yes, and they are qualified suppliers.**
12. What is the typical sample retain process at ALG-East Coast? **Samples are retained for 30 days unless the client requests otherwise.**
13. If a client sample is Out of Specification (OOS), is a formal investigation performed? **Yes**
14. Are USP methods kept current upon revision? **Yes**
15. Are personnel knowledgeable of FDA current Good Manufacturing Practices (cGMP), CFR part 11, GLP, ICH, ISO and USP requirements? **Yes**

## FDA DRUG ESTABLISHMENT CURRENT REGISTRATION

Firm Name ▲	FDA Establishment Identifier ▼	DUNS ▼	Business Operations ▼	Address ▼	Expiration Date ▼
Microbiology Research Associates, Inc	1000148174	829452689	ANALYSIS;	33 Nagog Park, Acton, Massachusetts (MA) 01720, United States (USA)	12/31/2020



SCOPE OF ACCREDITATION TO ISO/IEC 17025:2017

ANALYTICAL LAB GROUP (EAST COAST)  
33 Nagog Park  
Acton, MA 01720  
Mr. Patrick Tierney Phone: 978-263-2624  
pat@mra-bact.com

**BIOLOGICAL**

Valid To: January 31, 2021

Certificate Number: 3383.02

In recognition of the successful completion of the A2LA evaluation process, accreditation is granted to this laboratory to perform the following tests on injectable, topical, and oral pharmaceuticals, raw materials, personal care products, cosmetics, medical devices, water, biological indicators, and controlled environments:

<u>Test:</u>	<u>Test Method(s):</u>	<u>Internal Method(s):</u>
Antimicrobial Effectiveness Testing	USP <51>; CTFA M-3 and M-4	P002, P017, P019
Biological Indicators BI Population Verification	USP <55>	QC006
Endotoxin Testing	USP <85>	P013, P016, P026, P037
Environmental Evaluation of Clean Rooms <sup>1</sup>	USP <1116>, <797>	P010, P041
Microbial Examination of Nonsterile Products: Microbial Enumeration Tests and Tests for Specified Microorganism	USP <61>, <62>	P030
Sterility Testing	USP <71>; ASNI/AAMI ISO 11137	P004, P006, P012
Water Microbial Testing Total Heterotrophic Plate Count, Coliform Test	USP <1231> Water for Pharmaceutical Methods	P003

<sup>1</sup> This laboratory meets A2LA R104- *General Requirements: Accreditation of Field Testing and Field Calibration Laboratories* for this test.



## Accredited Laboratory

A2LA has accredited

### ANALYTICAL LAB GROUP (EAST COAST)

Acton, MA

for technical competence in the field of

### Biological Testing

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communiqué dated April 2017).



Presented this 17<sup>th</sup> day of January 2019.

A blue ink signature of a person, likely the Vice President of Accreditation Services.

Vice President, Accreditation Services  
For the Accreditation Council  
Certificate Number 3383.02  
Valid to January 31, 2021  
Revised February 27, 2019

*For the tests to which this accreditation applies, please refer to the laboratory's Biological Scope of Accreditation.*



## Helping Protect Life™



To whom it may concern,

In February 2019, Microbiology Research Associates, Inc. rebranded to add a dba of Analytical Lab Group in an effort to bring clarity and focus to our mission of Helping Protect Life™ with a single company name. With this rebranding, our legal name remained unchanged as Microbiology Research Associates, Inc.

At this time, any payment received will still need to reference our legal name of Microbiology Research Associates, Inc. We have included the detail below regarding how to submit each form of payment. In addition, we have included our current W-9 with this communication for your reference.

**Lockbox Address for Checks:**

Microbiology Research Associates, Inc.  
PO Box 855356  
Minneapolis, MN 55485-5356

**ACH Payment Instructions:**

Beneficiary Bank: Wells Fargo Bank, N.A.  
Bank Address: 420 Montgomery St.  
San Francisco, CA 94104

ABA Number: 121000248  
Beneficiary Acct Number: 4247812308  
Beneficiary Acct Name: Microbiology Research Associates, Inc.

If you prefer to pay via *wire transfer*, the instructions are:

**Wire Instructions:**

Beneficiary Bank: Wells Fargo Bank, N.A.  
Bank Address: 420 Montgomery St.  
San Francisco, CA 94104

ABA Number: 121000248  
Beneficiary Acct Number: 4247812308  
SWIFT Code: WFBIUS6S

If you have any questions surrounding this matter, please reach out to Katy Gainey, Controller ([Katy.Gainey@analyticalabgroup.com](mailto:Katy.Gainey@analyticalabgroup.com) or 612.965.5289).

Thank you,



Katy Gainey

[analyticalabgroup.com](http://analyticalabgroup.com)

Analytical Lab Group • 33 Nagog Park • Acton, MA 01720 • USA  
Tel. (877) 287-8378 • [info@analyticalabgroup.com](mailto:info@analyticalabgroup.com)