



EMSL ANALYTICAL, INC.
TESTING LABS • PRODUCTS • TRAINING



MICROBIOLOGY LAB SERVICES GUIDE



EMSL CANADA, INC.
LABORATORY • PRODUCTS • TRAINING





Laboratory Services

- Air Quality Testing
- Allergen Testing
- Analytical Testing
- Antimicrobial Testing
- Bioburden Testing
- Biofilm Testing
- Contaminant Identification
- Cosmetic Testing
- Disinfectant Testing
- Drinking Water Microbiology
- Endotoxin Testing
- Environmental Testing
- Expert Witness Testimony
- Food Adulteration
- Food Testing
- Fungal Identification
- Kill Time Studies
- Kirby Bauer Testing
- Litigation Support
- Marketing Claim Support Metalworking Fluids
- Method Development
- Microbial Identification
- Microbial Limit Test
- Microbial Induced Corrosion Testing
- Minimum Inhibitory Concentration (MIC)
- Mold Testing
- Mold Identification Services
- Pathogen Detection
- Personal Care Products Testing
- Pharmaceuticals Testing
- Plastics and Composites
- Product Efficacy Testing
- Research Microbiology
- Specialized Custom Testing
- Stability Testing
- Sterility Testing
- Textiles and Fabrics
- Water Testing
- Zone of Inhibition



A National Leader in Microbiology Laboratory Testing

EMSL's network of nationwide laboratories has been providing quality analytical services since 1981. Today we are the most uniquely diversified independent contract testing laboratory network in the world. Our microbiology labs offer a wide array of analytical testing services to support the following industries or fields: Pharmaceuticals, nutraceuticals, cosmetics, personal care products, consumer products, disinfectants, antimicrobial products and device development, food safety and quality, biofouling, water quality, pathogen outbreaks, environmental investigations, and indoor air quality. We provide all the routine testing services as well as more advanced or special custom projects.

Our internal QA/QC program is ISO 17025 compliant, ensuring that you will receive scientifically sound, legally defensible data. EMSL offers customized method development and special project design for non-routine analyses using ASTM, AOAC, FDA BAM, CTFA, USP, EPA, APHA, JIS, MIL-SPEC, ASM as well as other international testing methodologies.





Our unmatched capacity coupled with a company-wide focus on customer satisfaction makes no project too large or too small. Our corporate research and development capabilities allow us to bring new methodologies online quickly to meet new industry challenges and client needs. Our dedicated staff of microbiologists include experts with advanced degrees in mycology, bacteriology, molecular biology, and other related disciplines. We are committed to providing reliable, defensible data in a standardized and user-friendly format. Rapid turnaround and competitive prices make the dependable laboratory testing results you get that much more valuable.

At EMSL, we're much more than another laboratory testing provider. We are your project partner! For more information on our lab testing services, pricing and sampling guides or products, call: East Coast: 1.800.220.3675 or West Coast: 1.866.798.1089 and we are committed to responding quickly to any questions or concerns that may arise before, during, or after an assignment.

Lab Testing Services

- Antimicrobial and Disinfectant Testing
- Cosmetic and Personal Care Testing
- Environmental Contaminant Testing
- Food Testing
- Microbiology Testing
- Pharmaceutical and Medical Device Testing
- Research and Development

Our nationwide laboratory testing network provides unmatched capacity, and our commitment to customer service is second to none in the industry. Thousands of customers turn to us again and again for our dedication in providing fast, consistent results in an easy-to-understand format while offering the best value of any testing laboratory in the country.



Cosmetic and Personal Care Product Testing

- Aerobic Plate Counts
- Antimicrobial Effectiveness (Challenge Test)
- Bioburden and Microbial Content
- Cosmetics Water Testing
- Endotoxin Testing
- Microbial Limit Test
- Minimum Inhibitory Concentration (MIC)
- Pathogen Screens for *S. aureus*, Bile-tolerant, *E. coli*, *P. aeruginosa*, *Salmonella*, *Clostridium*, and Yeast
- Preservative Testing
- Product Safety, Efficacy Tests
- Validation of Microbial Recovery
- Yeast and Mold Count
- Zone of Inhibition (Sensitivity Test)



Pharmaceutical and Medical Device Testing

- AET- Antimicrobial Effectiveness Testing USP 51 or Preservative Effectiveness Testing
- Accelerated Aging and Stability Testing
- Ames Mutagenicity Testing
- Antibiotic Assay USP <81>
- Bioburden Testing
- Cleaning Validations
- LAL Bacterial Endotoxin Test
- MIC/ MBC
- Microbial Identification for aerobes, anaerobes, yeast, fungi, Mycobacteria, Actinomyces (MicroSEQ, MIDI FAME, traditional methods)
- Microbial Limit Test USP <61> and <62>
- Sterility Test USP <71>
 - Direct Inoculation (Immersion)
 - Membrane Filtration (Steritest)
- Suitability Test for USP <61> and <62>
- USP <797> environmental samples analysis and identification services
- USP WFI Water Testing



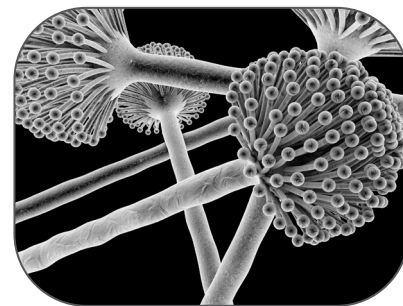
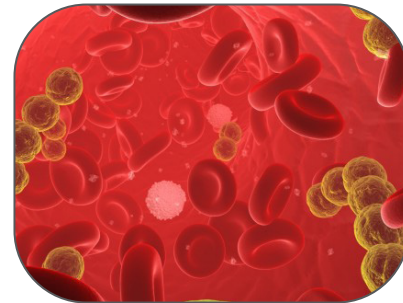


Indoor Air Quality and Environmental Microbiology Testing

- Algae
- Allergens (Dog, Cat, Dust Mites, Cockroach, Rat, Mouse, Latex)
- Anaerobic Bacteria
- Anthrax – *Bacillus anthracis*
- ARMI (American Relative Moldiness Index)
- Bacteria Identification (Culture, MIDI, BIOLOG, Biochemical tests, PCR)
- Bacteroides by PCR
- Bed bug identification by PCR
- Biofilm-Associated Bacteria (Group test: IRB, SRB, SLYME)
- *Clostridium chauvoei* by PCR
- *Cryptococcus neoformans* (PCR or Culture methods)
- Culturable Fungi (Air, Swab, Dust, or Bulk)
- Denitrifying Bacteria (DN)
- *E. coli* Detection by Colilert (Presence/Absence)
- *E. coli* Detection by Membrane Filtration
- Endotoxin Testing by Kinetic LAL
- Enteroviruses by PCR
- ERMI (Environmental Relative Moldiness Index)
- Fecal Coliform by Membrane Filtration
- Fecal *Streptococcus* by Membrane filtration
- Fungi by Direct Examination (Tape Lift, Bio-Tape, Bulk, or Swab)
- Gram Stain and Enumeration of Culturable Bacteria
- Heterotrophic Plate Count
- *Histoplasma capsulatum* detection (PCR or culture method)
- Iron-related, Sulfate-reducing, and Slime-forming Bacteria
- Legionella Detection (CDC method or rapid PCR)
- Lyme Disease (*Borrelia burgdorferi*) detection by PCR
- Molecular Identification methods (PCR, Sequencing)
- Mycobacteria Detection
- Mycotoxins
- *Naegleria fowleri* by PCR
- Nitrifying Bacteria (N)
- Pollen Identification and Enumeration
- *Pseudomonas aeruginosa* Detection
- Recreational Water Analysis (Total Coliform, Fecal Coliform, *Staphylococcus*, *Fecal Streptococcus*)
- *Salmonella* Detection and Enumeration
- Sewage Contamination in Buildings (Total Coliform, Fecal Coliform, *E. coli*, *Fecal Streptococcus*)
- Spore Traps (Total Fungal Spore Count, Pollen, Skin, Insect Fragments and Background Density)
- Total Coliform by Colilert (Presence/Absence)
- Total Coliform Count by Membrane Filtration
- Wood rot fungi identification by PCR

Dairy Testing

- Coliforms/*E. coli* (Plate Count)
- Coliforms – Total (MPN)
- Gram-Negative Bacteria Count (CVT)
- Inhibitory Substances-Antibiotics
- Lactic Acid Bacteria Count
- *Lactobacillus* Count
- Pre-incubated Bacteria Count
- *Pseudomonas* Count
- Psychrotrophic Bacteria Count
- *Salmonella*
- Standard Plate Count
- Yeast/Mold Count





Antimicrobial and Disinfectant Testing

- AOAC Chlorine (Available) in Disinfectants Germicidal Equivalent Concentration Test 955.16
- AOAC Disinfectants (Water) for Swimming Pools 965.13
- AOAC Fungicidal Activity Tests (955.17)
- AOAC Germicidal Spray Products Test
- AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Test (960.09)
- AOAC Sporadically Efficacy Test (966.04)
- AOAC Tuberculocidal Activity Test (965.12)
- AOAC Use Dilution Test (955.14, 955.15, and 964.02)
- AOAC Use Dilution Tests Modified for Spray Products (961.02)
- Bactericidal Efficacy Testing
- Contact Lenses Disinfectant Test
- Disinfectant Kill Time Test
- EPA Quantitative Suspension Method for Tuberculocides
- EPA Submission, DIS/TSS
- Fungicidal Efficacy Testing
- Minimum Inhibitory Concentration (MIC)
- Minimum Lethal Concentration (MLC)
- Tuberculocidal Efficacy Testing



Food Testing

- Aflatoxin Analysis
- Aerobic Plate Count
- Aerobic Spore Former Count
- Allergen testing
- Anaerobic Plate Count
- Anaerobic Sporeformers
- *Bacillus cereus*
- *Campylobacter*
- Canner's Test
- *Clostridium perfringens*
- Total Coliform/*E. coli*
- Contamination Source Tracking
- *Cyclospora* (P/A)
- *E. coli*
- *E. coli* O157:H7
- Enterobacteriaceae
- Flat Sour Spoilage Bacteria
- Food Authentication by DNA
- Food Pathogen Screens Including *Listeria*, *E. coli* O157, *Salmonella* and *S. aureus*
- GMO Testing
- Heat Resistant Mold
- Lactic Acid Bacteria Count
- *Lactobacillus* Count
- *Listeria monocytogenes*
- *Listeria*
- Meat Speciation by PCR
- Mesophilic bacteria
- Mold ID
- Mycotoxin Testing
- Osmophilic Yeast
- Pathogen Confirmations
- *Pseudomonas aeruginosa*
- Psychrotrophic Bacteria Count
- Quality Indicators: APC, Coliform/*E. coli*, Yeast and Mold
- *Salmonella*
- Sanitation Validation
- *Shigella* by qPCR & Culture
- Sporeformers
- *Staphylococcus aureus* (Coag. Positive)
- Thermophilic Aerobic Spore Former Count
- Thermophilic Anaerobic Spore Former Count
- Yeast/Mold Count



Aquatic Microbiology

- Algal Toxins
- Bacterial Abundance
- Bioaccumulation and Growth Studies
- Biomass
 - Chlorophylls
 - Biovolume
 - Ash free Dry Weight
- Diversity Indices
- Protozoa
 - Cryptosporidium
 - Giardia
- Taste and Odor Test
- Taxonomic Identification and Enumeration
 - Algae
 - Diatoms
 - Phytoplankton
 - Periphyton
 - Invertebrates
- Water Quality





DNA Testing Lab Services

- Animal Identification
- Bed-Bug Identification
- ERMI Fungal Identifications
- Feces Identification (Animal and Human)
- Fish Identification
- Food Authenticity
- Food Contaminants
- GMO Testing
- Human Identity (Origin)
- Lyme Disease Tick Identification
- Norovirus Testing
- Pathogen Detection and Identification
- Plant and Seed Identification
- Species and Strain Identification (Cultured / Uncultured Organisms)
- Unknown Biological Material Identifications Diversity Indices



Special Product Testing and Development

- Action of Microorganisms to Plastics by ISO 846
- Activity of Antimicrobials in Polymeric or Hydrophobic Materials by ASTM E2180
- Antibacterial Activity Assessment of Textile Materials: Parallel Streak Method by AATCC 147
- Antifungal Activity Assessment on Textile Materials by AATCC 30
- Antimicrobial Activity and Efficacy in Products by JISZ 2801
- Antimicrobial Activity Assessment on Carpet by AATCC 174
- Antimicrobial Activity of Immobilized Antimicrobial Agents by ASTM E2149
- Assessment of Antimicrobial Activity Using a Time-Kill Procedure by ASTM E2315
- Assessment of Antibacterial Finishes in Textiles by AATCC 100
- Enumeration of Viable Bacteria and Fungi in Liquid Fuel by ASTM D6974
- Fungi Resistance of Insulation Materials and Facings by ASTM C1338
- Growth of Mold on the Surface of Interior Coatings in an Environmental Chamber by ASTM D3273
- Mildew and Rot Resistance of Textile Materials by AATCC 30
- Mildew (fungus) Resistance of Paper and Paperboard by ASTM D2020
- Performance of Antimicrobials in or on Polymeric Solids against *Streptovorticillium reticulum* (pink stain) by ASTM E1428
- Resistance of Emulsion Paint in the Container to Attack by ASTM D2574
- Resistance of Plastics to Bacteria by ASTM G22
- Resistance of Synthetic Polymeric Materials to Fungi by ASTM G21
- Resistance to Fungal Growth and Performance in devices by MIL-SPEC 508.5



EMSL's Standard of Care and Commitment to Quality

EMSL Analytical, Inc.'s laboratory services are governed by our Quality Assurance Program (QAP) of Policies and Procedures which is described in our Quality Assurance Manual. This program follows the quality guidelines as documented in ISO/IEC 17025:2005 as well as program requirements of the A2LA, American Industrial Hygiene Association (AIHA), the National Voluntary Laboratory Approval Program (NVLAP), The NELAC Institute (TNI), and other applicable state and federal regulatory requirements associated with laboratory accreditations/certifications.

Our QAP has been designed to ensure that quality professional services and technical excellence is provided to our customers. It is a real and living program in that the QAP Policies and Procedures are integrated into our daily work and are continually reviewed and updated by Management. It is formally reviewed at least annually by the Corporate QA Manager as well as formal reviews performed any time a problem arises that indicates





a possible program flaw. In such instances, the Corporate QA Manager involves the Corporate Officers as well as National Directors, Regional Managers, Laboratory Directors, and Quality Control Department Personnel and Senior Analysts/Chemists to ensure that all necessary feedback is solicited from all staff levels of the operation.

Organizational Responsibility and Commitment

The corporate headquarters of EMSL Analytical, Inc. operates out of the Cinnaminson, New Jersey laboratory location. The corporate headquarters oversees the laboratory operation at the corporate lab location as well as all of the network laboratories nationwide and in Canada. The Corporate Management team recognizes the importance of our Quality Assurance Program and understands that company success comes from its performance and commitment to Quality. Management's policy for the laboratory is to perform all work in a responsive and efficient manner without compromising Quality. To accomplish this, the Corporate Management team makes the necessary financial resources for the equipment and staffing needed to ensure the following Quality Assurance Program goals are achieved:

- Delivery of the highest quality of professional services and technical excellence to our customers.
- Provide quality, accuracy, and integrity of analytical results in a responsive manner.
- Conformance with all approved analytical methodologies and SOP's.
- Fulfillment of the requirements of the American Industrial Hygiene Association (AIHA), the National Voluntary Laboratory Approval Program (NVLAP), and/or The NELAC Institute (TNI).
- Conformance with corporate mandated Quality Assurances and Quality Control (QA/QC) requirements.
- Ensuring the standards documented in ISO 17025:2005 are upheld in all company business activities.

Key Components of EMSL's Quality Assurance Program (QAP)

1. Use of Qualified and Properly Trained Staff
 - Establishment of minimum qualifications for education and experience
 - Job descriptions of each position clearly delineating responsibilities
 - Establishment of formal training requirements
 - Ethics and integrity awareness training and requirements
2. Adherence to Standard Operating Procedures (SOP's)
 - Good laboratory technique that ensures a contamination free environment
 - Assurance that national coherency is maintained
 - Proper documentation, document control, and record retention
 - Conformance with all approved analytical methodologies

- Use of appropriate analytical technology including review of current literature to capture recent applicable developments
 - Respect for customer confidentiality
 - A work atmosphere away from unreasonable productivity pressures
3. Extensive Quality Controls
 - Constant oversight of laboratory quality performance
 - Internal and external quality audit programs
 - Proper documentation and quality review of analytical data
 - Participation in round robin and/or proficiency testing programs
 - Method required calibration checks, use of reference standards, control blanks, replicate/duplicate sample analyses, etc.
 - Control of records and documents
 - Maintenance of accreditation and certification programs

Qualified and Properly Trained Staff

Sample analysis and testing requires special skills that come from a combination of industry experience and academic credentials, coupled with formal training. The individual training requirements for each person is based on the complexity of the test(s) that will be performed by the individual. EMSL will only allow a scientist to independently express results after they have met the requirements of the training program. Our programs address both the technical scientific aspects of the analytical process as well as Ethics and Integrity Training as it pertains to the process of providing data and results to our customers.

Education and Experience

Minimum education and experience requirements are listed for each position within the company. Additionally, all technical staff (analysts, microbiologists, technicians, etc.) must successfully complete an EMSL training program prior to performing analysis independently.

Training Programs

Laboratory Managers are responsible for ensuring that appropriate training is provided to the technical staff and that they are qualified to perform the test method. At a minimum, training consists of formal instruction and hands-on training with the instruments and systems related to the analytical process and methods. Additionally the training includes formal tracking and documentation of a person's "Demonstration of Capability" (DOC) which is required before they can independently process samples. Annually, ongoing training and review of ongoing demonstration of capability is performed.

Ongoing training is provided to all employees on a consistent basis which may include but not be limited to the following:

- Laboratory Staff Meetings – Typically include a variety of topics but often address technical updates on analytical methods, customer service training issues, health & safety incidents and training, etc.



- Laboratory Audit Review – Staff are encouraged to consult with internal and external auditors for advice on various topics related to the audit findings and recommendations and/or deficiencies.
- Workshops provided by professional organizations, agencies and/or by instrument/equipment vendors.

Health and Safety Training

Health and Safety training is provided to all EMSL employees as described in our written Chemical Hygiene Plan. The Chemical Hygiene Plan defines work practices and procedures that ensure the employees of EMSL Analytical, Incorporated are protected from health risks associated with the potential exposure to hazardous chemicals and is compliant with the standard promulgated by OSHA entitled “Hazardous Work in Laboratories”, 29CFR 1910.1450. Biosafety is addressed in the Chemical Hygiene Plan as well.

Code of Ethics Training

One of the objectives of the QAP is to ensure that staff at EMSL are provided information with regard to ethics as they pertain to laboratory operations. The goal of the EMSL ethics training and policy is for each staff member to understand their responsibility to provide true and accurate information and the consequences of unethical conduct. The QAP addresses the Code of Ethics by including the following:

- Specific guidelines and interpretations which define “Right and Wrong” as it relates to real-world job situations.
- Reinforcement of the consequences of unethical decisions and the understanding of the impact of our actions.
- Direction to employees to report or inquire about situations that may be ethically questionable.
- Procedures which ensure that all employees are free of unreasonable pressure and stress.

Standard Operating Procedures

Instructions and procedures for the activities related to the analytical process are developed by subject matter experts and are clearly defined and documented in our Standard Operating Procedure (SOP) Manuals. These technically specific SOPs are located at each laboratory facility and include the step-by-step procedures for each analytical test method performed inclusive of the initial acceptance and handling of samples, sample control throughout the process, sample preparation, analysis, and reporting of the data. EMSL utilizes companywide standard procedures incorporated in each specific SOP which comply with our QAP and adhere to the following protocols:

Acceptance of Work

Our services are generally offered as unit cost tests which reference documented methodologies. Laboratory services are typically requested by the customer as “open order” requests meaning that samples may be delivered to the laboratory at any given time, without a firm documented arrangement (contract). EMSL accepts the customer Chain-of-Custody (COC) as the

open-order authorization which specifies the analytical test, turn-around-time (TAT), and quantity of tests to be completed. In the absence of a formal contract agreement, work-order, and/or purchase order, EMSL’s Terms and Conditions will apply. Modifications to the standard Terms and Conditions must be documented and agreed upon by both EMSL and the customer.

Sample Acceptance Criteria

The acceptance of custody of the samples at time of delivery does not imply that samples are acceptable for analysis. Since often the condition of samples cannot be determined prior to preparation, final sample acceptance does not occur until samples are prepped or analyzed. At that time, samples are inspected and evaluated to determine if they conform to laboratory acceptance criteria. If they do not, or if the Lab has any questions as to the validity of the sample, then the sample is further scrutinized by the lab manager or designated person who will then determine whether the questionable condition is sufficient to require rejection of the samples. Samples may also be rejected if its condition or contents at time of delivery is unsuitable (e.g., improperly packaged) or may pose a risk in handling or processing. Rejection of samples will be followed up by immediate notification to the customer for further direction.

Sample Tracking and Control Chain-of-Custody

In order to ensure the integrity of any sample, records of its custody must be maintained from sample collection in the field until relinquishment of the samples and acceptance by the laboratory. Since the customer collects the sample, EMSL does not accept responsibility for the validity of the sample collection and delivery protocols, nor the sample information reported by the customer. As needed and/or requested, we can recommend sampling media, volumes, sample size, and other items which we have found to have an effect on the quality of the analysis due to the sample condition.

Once the sample is accepted for analysis by the laboratory, the EMSL “Internal Chain of Custody” is used to document the handling of the samples throughout the analytical process. In instances when samples are internally transferred to a different EMSL lab in the network, the samples are accompanied with a completed “Sample Relinquish Form” which includes internal custody transfer sign-off and customer/project information for tracking purposes. A copy of the completed form is also maintained in a tracking manual at the initial lab that received the samples. Whenever samples are transferred to another lab, EMSL will request customer approval for the transfer unless a standing agreement is in place.

Sample Log-In

EMSL’s sample tracking and control starts from the time the samples arrive at the laboratory at “sample receiving/log-in”. Log-in of samples is normally done by the log-in department and/or the administrative coordinator but may also be done by other employees trained and familiar with the process. Information is entered for the samples received by the laboratory into the Laboratory Information Management System (LIMS). LIMS is a computer based management system which serves to track



all samples from receipt through prep, analysis, reporting, and billing processes. If requested, the LIMS system will send an email notification automatically to the customer when the samples are received by EMSL. The email notification includes when the samples were received, sample log-in information (tests, sample numbers, etc) and the scheduled due date for results.

Archival and Disposal of Samples

Samples which are not completely consumed in analysis are retained as detailed in the area-specific quality assurance modules which specify sample retention schedules. In accordance with this schedule, samples are then disposed of by a licensed contractor, where required, and a copy of the waste manifest is obtained and kept on file.

If requested, samples will be returned to the customer. If a customer has specific requirements for sample storage or retention times beyond standard EMSL policy, this should be discussed at the time of sample delivery, documented, and approved by EMSL and the customer.

Subcontracting

Other than utilizing our internal network of labs, EMSL generally does not subcontract analytical work to outside laboratories. However, in the event such services are required, the laboratory manager will ensure all procedures are performed by laboratories that comply with the quality management system as addressed in the EMSL QA Manual and the policies of the accreditation program(s) currently held by the original laboratory. Laboratories must subcontract to outside laboratories that maintain accreditations appropriate for that analysis unless otherwise directed by the customer.

Sample Processing and Procedures

Quality of Materials

The high quality of materials used in the laboratories is ensured through specific purchasing and verification procedures and proper handling techniques. Selection of the appropriate grade of reagent(s) is designated in the reagent section of each analytical SOP and in addition may be specified by the laboratory manager in unusual circumstances. As a general practice, reagents will be of at least ACS reagent quality.

Reagents and standards are purchased in accordance with the analytical needs of the laboratories as determined by the laboratory manager. When received by the laboratory, these items' labels are dated and initialed with the date received and expiration dates provided by the manufacturer, or as assigned by the laboratory. Labels are also dated and initialed when opened and/or when reagent mixtures are prepared.

Verification of reagents will consist of confirming that the priority grade recorded on the reagent label conforms to the requirements of the SOP unless analysis difficulties indicate a possible problem or regulatory agency requirements specify otherwise. In the latter case, the analytical SOP will identify the appropriate reagent.

Equipment/Instrument Maintenance

The quality and maintenance of equipment plays a critical role in providing quality analytical services. The laboratory manager determines whether each instrument is maintained and repaired in-house or by an outside source following EMSL administrative procedures. Additionally, servicing will be performed when a need has been identified by calibration or other QC checks. Where regular maintenance schedules are necessary, the schedules are documented in the analytical SOPs and tracked by the laboratory manager to ensure that all maintenance schedules are met. Maintenance repair/service files are maintained for all equipment which includes documentation of the scheduled and unscheduled maintenance and repair activities.

Contamination Management

Proper observance of laboratory procedures is necessary to guarantee accuracy of results and the safety of laboratory staff members. Contamination of samples, the environment, and reagents used in analysis must be avoided to provide the highest quality, legally defensible data to our customers. In order to achieve this goal, laboratory staff must adhere to various preventative measures and use defined testing procedures for contamination detection as established by the QA Manager.

Contamination is prevented through a combination of good laboratory practice and housekeeping, as well as analysis of blank samples and ambient air and surface wipe samples taken from the laboratory. If contamination is detected in any situation, the source of contamination must be traced and the problem resolved to prevent recurrence. All actions taken to resolve a contamination circumstance will be documented properly and completely in the laboratory files.

Reporting Results

The customer report is, ultimately, our "final product". The quality of our report reflects on our standard of quality. Final customer reports are released only after data has been approved by the laboratory manager or designated qualified reviewers. This review includes evaluation of quality control results, calibration measurements, and other controls specified by the method, SOP, and our QAM.

Electronic Data Deliverables (Exported Data)

EMSL delivers lab data in several different electronic data formats to many different customers in custom and industry standard formats, including SEDD, custom CSV formats, excel, PDF, word, and RTF formats. The electronically delivered data is not intended to replace hard copy results. Final, signed customer reports are delivered via mail in addition to delivery by email or diskette. In this way, exported data can be verified. Electronically transmitted results must meet the requirements of the QA policies with the export formats implemented and controlled by the corporate IT staff, which has the flexibility to implement new export formats as required.



Results On-line via LabConnect®

Lab Reports, Chain-of-Custody, and Invoices are available 24/7 via the internet on a secure customer website portal. Documents are posted “real-time” which allows remote customers to see their COC as soon as EMSL processes the samples at log-in. Once the report is reviewed and approved by an authorized signatory, the report with electronic signature is posted to the site as well. These PDF documents can be printed by the customer and/or inserted in the customer’s reports or on the customer’s common share sites, if necessary. The customer can do a search query for a result by the customer project number or project name, sample submittal date, or the type of analysis. Customer billing statements are also available on LabConnect® and credit card payments can be made as well.

Customer Communications

EMSL seeks feedback from our customers regarding Lab performance via our Customer Survey (www.emsl.com –customer survey) as well as maintaining an open dialogue policy between the customer and the lab manager and/or National Directors, the corporate team and/or the quality assurance department. The goal of our open dialogue policy is clear, continuous, and open communication between the laboratory and the customer which is one of the keys to maintaining a successful, quality operation. Communication should be established prior to the start of any work so that any special instructions, precautions, and/or customer specific needs are clearly understood between laboratory and the customer.

Customer complaints regarding the quality of data received are thoroughly investigated by EMSL laboratory management. Where errors are found, they will be documented as a non-conformity and handled via EMSL’s corrective action procedures. Typically, if a customer makes a valid complaint about a test result, the sample in question will be reanalyzed where possible. If the second result agrees with the original, the laboratory manager shall advise the customer in writing that a quality control check has confirmed the original analysis.

The laboratory manager or designee will promptly communicate with the customer as it relates to the performance of the analysis and turnaround time. The laboratory must notify the customer if:

- Analysis is to be done at another EMSL network location,
- Analysis cannot be performed on time,
- Integrity of the sample has been jeopardized (either by the laboratory or the customer or customers shipping/delivery carrier),
- A discrepancy in the analysis has been found during QC analysis. If this deficiency directly affects customer results, the customer will be notified immediately of the problem.

Confidentiality

It is understood that confidentiality and proprietary rights must be respected throughout the performance of services for any customer or for those that may include national security concerns. Information will not be given to those for whom it is not intended

and the proprietary rights of our customer will be protected. Data reports and/or other related information will not be given out to any person or agency other than the customer unless we have received prior approval from the customer.

Quality Controls

Quality control is the routine application of procedures for obtaining prescribed standards of performance in the analytical process. EMSL’s quality control program is established and managed by the QA Manager in cooperation with the National Directors and ensures our laboratories are producing quality data. This process ensures fulfillment of our commitment to our customers that our data is legally defensible, and that all personnel perform their responsibilities properly.

Quality control is performed continuously throughout the course of laboratory sample analysis regardless of laboratory workload and is made part of the normal course of laboratory sample analysis. QC data is graphed on control charts designed specifically for each analysis type. Quality control is tracked and reviewed daily by the lab manager as part of the sample process and final report approval process. Additionally, quality control summary reports are reviewed by the corporate Quality Assurance Department on a monthly basis.

QA Oversight of Laboratory Quality - Analytical Performance Criteria

Quality control is performed according to the scope of the laboratory’s accreditation status and quality control requirements for each type of analysis. Performance criteria are maintained for both individual analysts and for the entire laboratory. The standards for acceptance criteria are documented in the EMSL Standard Operating Procedures and the QA Manual. EMSL continuously monitors the analytical performance of each laboratory and analyst. Performance is determined using the following criteria:

- Results from intra/inter-analyst, and/or intra/inter laboratory QC results and round robin testing plotted against control/acceptance limits.
- Results from calibration measurements plotted against control/acceptance limits.
- Lab performance in proficiency testing programs.
- Results of internal and external on-site quality audits. These audits will verify compliance with all QA and QC policies as documented in the EMSL Quality Assurance Manual and related SOPs.

Demonstration of Traceability

The quality assurance program is designed to provide a method which achieves traceability of data to national standards. This is accomplished by setting requirements, which include:

- Use of Standard Reference Materials (SRMs) as certified and traceable to the National Institute of Standards and Technology (NIST). SRMs are used for QC analysis and



training for achieving performance evaluations of analysts and overall laboratory accuracy.

- Calibration of instrumentation against NIST traceable standards
- Laboratory participation in independent (non-EMSL) proficiency testing programs
- Analysis of consensus standards

Procedures for Dealing with Non-conforming Work

Whenever a deviation from established requirements (i.e., a non-conformity) is discovered, a corrective action report will be initiated in order to determine the root cause of the problem and decide on what action can be taken to prevent reoccurrence. This report may include a review of QC data, sample tracking, data transcription, instrument calibration, training documentation and discussion with personnel. If the non-conformity resulted in a deficiency that directly affects customer results, the customer will be notified immediately of the problem. After the implementation of corrective actions, the laboratory will conduct follow-up activities to ensure the effectiveness of those actions.

Customer Support and Access to QC Information

EMSL provides quality assurance information and technical support to the customer to assure continued quality service. The support and information provided in relation to the work performed includes:

- Availability to Lab Accreditations/Certifications applicable to the analysis provided,
- Availability of pertinent QC records;
- Access to the Quality Assurance Department for technical assistance,
- Security of data (confidentiality),
- Reasonable access to the relevant areas of the laboratory for the witnessing of analysis;
- Archive and record retention programs.

Accreditation and Certification Programs

EMSL Analytical, Inc. maintains various accreditations and certifications all of which require active and efficient QA/QC programs, participation in proficiency testing programs, etc. with renewals typically requiring on-site audits and continued acceptable performance in proficiency testing. Labs obtain necessary accreditations/certifications based on the testing they provide and the state in which they do the work. For individual state certifications, multiple labs in the network maintain that state's certification to ensure ample network support. If a customer requests new or additional field-of-testing (FOT) certification for a project or program, EMSL may seek to add that certification dependent on the lab capability and the amount of work associated with the request.

EMSL lab accreditation programs and certification (see lab listing on our website for specific branch lab accreditations) typically include NVLAP, AIHA, NELAC, A2LA, CDC ELITE, and home state certifications as required such as NY ELAP, CA ELAP, NJ DEP, PA DEP, FL DEP, LA DEQ, TX CEQ etc.

Document Preparation and Control

In order to prepare and distribute documents in an organized fashion, procedures for initiation, preparation, review, approval, and issuance of controlled copies will be followed. EMSL's document control program is a coordinated effort involving both technical review and custodial control. Laboratories are to use only approved, controlled and current documents for all calibrations, analyses, final reports, and other activities performed in this laboratory.

Archive and Record Retention Policies

All records associated with analytical data are stored in an organized, safe, and retrievable fashion. EMSL stores all records for a minimum of 5 years unless otherwise stipulated by customer contract or external agency requirements.

External agency requirements are listed below:

Agency	Agency Record Retention Requirement
AIHA – EMLAP	3 Years*
NYS ELAP <i>Water Data</i>	5 Years 10 Years
California ELAP <i>Water Data</i>	3 Years* 10 Years*
Texas Department of Health	30 Years
Louisiana Department of Environmental Quality	10 Years
The NELAC Institute (TNI)	5 Years
CDC ELITE Program for <i>Legionella</i>	5 Years

*EMSL retains all records for a minimum of 5 years even when external requirements allow shorter retention times.

The following records are examples of documents that are retained:

- Copy of Chain of Custody documents
- Original analytical data recording worksheets
- Quality control data
- All other records relating to the preparation of the customer report