

**Analytical Testing Services for:**

*Pharmaceutical*

*Biopharmaceutical*

*Medical Device*

*Biotechnology*

*Personal Care Products*



*FDA Registered and DEA Licensed  
cGMP and ISO 17025 Compliant*



**EMSL ANALYTICAL, INC.**  
**Laboratories • Products • Training**



**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 in the world.

Our cGMP laboratory is located in Cinnaminson, NJ (suburban Philadelphia) and offers a wide array of analytical testing services to support the pharmaceutical, medical device, biotechnology and personal care products industries in the following service lines:

- Materials Characterization and Physical Testing
- Microbiology and Sterility Testing
- PCR, DNA Sequencing, and mitochondrial DNA identification
- Stability Testing
- Chemistry
- Radiochemistry
- R&D, Method Development and Validation

Our 125,000 square foot facility houses state of the art equipment for all the above technical disciplines. Unlike laboratories that focus short term, EMSL is focused on long term strategic and organic growth. We evaluate new equipment and markets to offer you the latest in cutting edge analytical laboratory services.

Our internal QA/QC program is cGMP, and ISO 17025 compliant, ensuring that you will receive scientifically sound, and legally defensible data. EMSL offers routine analyses using ASTM, USP, BP, EP, JP, ICH, AOAC, FDA, PCPC (CTFA), EPA, and APHA methods as well as other validated testing methodologies. We also provide research in customized method development and validation.

EMSL's clients can be assured in the knowledge that their confidentiality and proprietary formulations will be protected by our employees. We regularly conduct Ethics Training as it pertains to laboratory operations and confidentiality of data. Every staff member fully understands the importance of ethical behavior and their responsibility for reporting data accurately. Proprietary formulations and results can be held in secure, controlled access areas if necessary. Moreover, information will never be released unless we have received written authorization from our customer to do so.

## **Materials Characterization, Failure Analysis, Nanoparticle and Physical Analysis**

EMSL Analytical is proud to possess some of the most advanced state-of-the-art testing equipment in the industry. Our highly specialized staff of materials scientists and chemists has substantial industry experience and academic credentials providing a wide range of unique services for a diverse range of clientele. Our area of expertise includes materials characterization, forensics, petrography, mechanical behavior of materials, nanostructures characterization, and microelectronics. We have a broad array of instrumentation such as electron microscopy, NMR, FTIR, XRD, XRF, ICP-MS, HPLC/LCMS, GCMS, GDL-OES, Auger spectroscopy, and mechanical testing equipment. EMSL applies a full spectrum of standard and customized analyses such as elemental and chemical analysis, structural characterization, particle size and distribution, contaminants, and failure analysis to define problems, to develop procedures and produce reliable, scientifically defensible results. EMSL also maintains an in-house machine shop to fabricate grips, holders, parts and equipment for customized materials testing.



## **Stability Testing**

From study design, storage, monitoring, and analytical testing, EMSL offers comprehensive stability testing according to ISO and ICH guidelines including real time, intermediate and accelerated studies. We offer a fully cGMP compliant, controlled access laboratory equipped with a wide variety of storage chambers including those for frozen, refrigerated and Zones I-IV ICH climate conditions. All chambers are continuously monitored and are connected to a back-up power generator.

## **Sterility Testing**

EMSL offers sterility testing by direct immersion, direct flush, and membrane filtration in our continuously monitored, controlled access, ISO 8 (Class 100,000) cleanroom equipped with a stainless steel, state of the art Class 5 (Class 100) isolator using a vaporized hydrogen peroxide sanitization unit.

## Microbiology

Our leading team of microbiologists includes experts with advanced degrees in mycology, bacteriology, molecular biology, and other related disciplines. We offer traditional culture dependent bioburden and identification methods, gram staining, and USP monographs as well as MIDI, VIDAS, BAX, and PCR culture independent identification methodologies. EMSL performs Endotoxin analysis using a state of the art, fully validated and cGMP dedicated LAL unit. All of our incubators, refrigerators, and freezers are continuously monitored and connected to a back-up power generator. We also supply sterilized bottles, agar plates, swabs and sampling equipment for water, environmental monitoring, USP 797 environmental monitoring, cleanroom and water validation testing.

## PCR Testing, DNA Sequencing, and Mitochondrial DNA Identification

EMSL offers an extensive qPCR and rtPCR laboratory for the identification of known bacteria and viruses as well as source identification using mitochondrial DNA barcoding identification. We can also develop the primers and probes for customized PCR projects and offer DNA sequencing using a cutting edge Microseq unit.



## Radiochemistry

EMSL's pioneering radiochemistry laboratory performs analysis to determine the radioactive properties of a sample and is continually at the forefront of the industry. Our certification covers Gross Alpha, Gross Beta, Gamma emitters, and Photon Emitters. Radiochemical analysis is usually performed for such entities as nuclear medicine and radiopharmaceuticals.

## Chemistry

EMSL's dedicated chemistry department specializes in raw material, API and excipient testing for drug manufacturers. We cover a broad range of organic and inorganic testing as well as TOC, melting point, Karl Fischer, and cleaning validation testing.

## Method Research and Development, Custom Method Development and Validation

Our experts are available for specialized projects from R&D through custom method development and validation regardless of the analyte class or composition. Our scientists have more than 15 years experience in this discipline. We conduct method validation under cGMP and non-cGMP conditions.

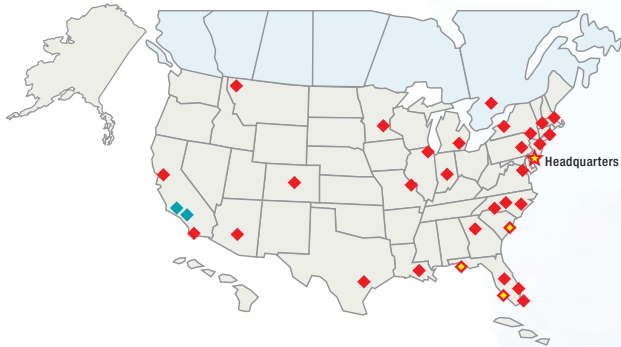




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[www.emsl.com](http://www.emsl.com)  
**800.220.3675**

EMSL Analytical Locations



**EMSL Analytical Inc. is an independent, contract testing lab specializing in Materials Analysis, Failure Analysis, Chemistry, and Microbiology**

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