MEDPACE®

COMPREHENSIVE MICROBIOLOGY SERVICES

Medpace's central laboratories offer comprehensive microbiology capabilities that support the specific testing required for each study. Our state-of-the-art microbiology suites, located at Medpace's Cincinnati, OH and Shanghai, China central lab are equipped with advanced technology and staffed by experienced medical microbiologists, ensuring high-quality and reliable results while adhering to the strictest national and international standards.

By combining traditional microbiological methods with cutting-edge molecular techniques, we deliver comprehensive insights that drive the success of your clinical trials. Our team works closely with Sponsors to design customized testing protocols that meet study requirements, enhancing the efficiency and efficacy of the drug development process. Our labs also maintain strict adherence to regulatory standards and follows Good Clinical Practice (GCP) and Clinical Laboratory Improvement Amendments (CLIA) regulations. For standards, we follow Good Clinical Laboratory Practice (GCLP) and College of American Pathologists (CAP).

ENSURING SPECIMEN VIABILITY AND STABILITY

The viability and stability of microbiology specimens are critical for clinically reliable results. At Medpace, we leverage our scientific expertise to maintain optimal specimen conditions throughout their journey from patients to our central lab. Our in-house, PhD-level medical microbiologists offer expert guidance on the most effective specimen collection and transport protocols, ensuring the longest stability and specimen integrity for reliable outcomes.

MAKING THE COMPLEX

SEAMLESS®

SERVICES INCLUDE:

- Traditional Microbiology
  - Quantitative culture and isolation of target pathogens from clinical specimens (cfu/mL; urine)
  - Semi-quantitative culture (urine, wound, stool, respiratory, etc.)
  - Gram stain
  - Organism identification (MALDI-TOF MS and/or biochemical testing)
- Re-Identification of Isolates
  - Identification and/or confirmatory identification of isolates
  - Susceptibility testing
- Stool EIA Testing
  - *Clostridioides difficile* GDH & Toxin A & B detection
  - Enterohemorrhagic *E. coli* (EHEC) – Shiga toxins 1 and 2 detection
  - *Campylobacter*-specific antigen detection
- Antimicrobial Susceptibility Testing (AST)
  - AST methods:
    - Broth microdilution (MIC)
    - Kirby-Bauer disk diffusion
    - E-test
    - Agar dilution
  - Breakpoint interpretation using CLSI, EUCAST, and FDA breakpoints
  - Customized MIC Panels – including research compound versus comparator drugs
- Mycology
  - Culture and isolation of yeasts from clinical specimens
  - Identification of yeasts and yeast-like microorganisms
  - Antifungal susceptibility testing
    - Broth microdilution (MIC) – CLSI Reference Method
- Molecular Characterization
  - Syndromic testing (BIOFIRE, GeneXpert, QIAstat)
  - Antimicrobial resistance gene detection
  - Whole genome sequencing of isolates

CLIENT FEEDBACK TELLS THE STORY

Your project's success rests on the quality we deliver. To ensure we are meeting high quality expectations, Medpace compiles site satisfaction surveys on a regular basis. This site survey consists of 15 attributes relating to Medpace project performance. The results include feedback from 2,000 sites. We earn an average of 99% positive responses (satisfactory or excellent ratings) across all attributes rated.

POSITIVE QUALITY RATINGS

Personal attention: Sponsors, sites and Project Managers build one-on-one relationships. Among our clients, we are known for delivering a remarkably high level of personal attention. Sponsors and sites know what to expect, and can easily communicate with Medpace via the Project Manager.

99.8%
Quality of laboratory data

99.4%
Availability of staff for issue resolution

98.9%
Data query resolution

99.0%
Knowledge of personnel

Response times: Medpace Project Managers take ownership of your project and ensure timelines are met. Follow-up with Sponsors and sites is heavily emphasized in training and at the outset of every project. Responding to Sponsors and sites via phone or email occur promptly, assures customers of the importance of their project. Items that are escalated are quickly addressed and resolved.

Consistency: Medpace ensures consistency in instrumentation, methodology and processes, across all four global labs. Consistent processes are a result of excellent training of all operational groups involved in the study and the stringent company-wide SOPs and processes.

Team: From project managers, medical technologists and laboratory scientists, to logistics teams, and data managers, Medpace is dedicated to providing the highest degrees of service and quality results. We provide exceptional expertise in the various testing areas that ensures high-quality data at the end of the trial.

FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically-driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective.

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