



# Excellence in Anti-Infective Clinical Trials

Laboratory test results often serve as the primary study endpoint in anti-infective clinical trials. Our goal is to provide services that ensure specimen viability, timely, accurate test results and one comprehensive database for analysis.

Clinical development programs for new anti-microbial compounds necessitate a unique level of central laboratory support. As a global laboratory, dedicated exclusively to clinical trials, we have extensive experience with anti-infective studies. As a result, when ICON Central Laboratories is selected to support your anti-infective trials, we assign staff members who work closely with you to provide:

- Expedited transport to the laboratory to maximize sample viability;
- Quality microbiology services to ensure accurate result reporting;
- Special data management services that format numeric and text results to facilitate data analysis.

## Specimen Collection Supplies

As a part of each study's setup, we work with trial sponsors to identify the most effective specimen collection and transport system, based upon the source of the specimen and the organisms being targeted. In addition to considering specimen viability, our staff considers ease of use of collection supplies by personnel at the investigator site. ICON Central Laboratories maintains various types of collection systems for such studies and will also special order additional supplies if necessary. These supplies, along with other specimen collection tubes required for the study, will be packaged in visit specific kits for the convenience of the investigator sites.



## Illustrated Specimen Collection Instructions and Investigator Support

ICON Central Laboratories knows that the collection technique used at the clinical investigator site is critical to the quality of microbiology testing. For that reason, we develop a study-specific investigator manual with fully illustrated, step-by-step instructions for collecting, preparing and shipping each specimen. For global studies, these instructions can be translated to meet the special language needs of investigator site personnel.

## Logistics and Shipping Support

Expedited transport of microbiology samples from the investigator site to our laboratories is critical to producing quality test results. Our highly experienced Logistics Department can assist trial sponsors with information about transit times, shipping regulations and other information that is useful in making appropriate investigator site selections or supporting existing sites. ICON Central Laboratories has preferred vendor agreements with multiple courier companies that enable us to offer competitive pricing and make the best courier selection on a site-by-site basis. As part of our responsibilities as a full service central laboratory, we continually monitor each courier's performance to make certain that it meets the needs of the site and the turnaround times required by the protocol.

## Extensive Microbiology Testing Capabilities and Experience

Our laboratories offer particular strength in microbiology. Our staff is always willing to discuss any special testing requirements that may be necessary for a specific protocol. ICON Central Laboratories utilizes its own laboratories in the United States and Ireland to support North America and Europe. To better support the special requirements associated with microbiology, ICON Central Laboratories has close working relationships with affiliate laboratories located in Brazil, Argentina, Mexico, Australia, South Africa, Southeast Asia and India. This approach offers our clients access to important study populations worldwide, shorter specimen transit times and better specimen viability while continuing to provide one global result database. Our testing services include:

### Cultures

- Blood
- Body Fluid
- Cervical
- Ear
- Eye
- Fungal
- Genital
- Mouth
- Nose
- Sputum
- Stool
- Throat
- Urethral
- Urine
- Vaginal
- Wound

### Sensitivities

- Kirby-Bauer
- MIC
- Fungal
- MBC

### Other Microbiology Testing Services

- *Cryptosporidium* Stain
- *C. difficile* Toxin A/B
- *H. pylori* Antibody by EIA
- *Cyclosporium* Stain
- Ova and Parasites, Stool

## Adult and Pediatric Trial Experience

- *H. pylori* Infections
- *Cytomegalovirus* Retinitis
- Acute Gastroenteritis
- Pharyngitis
- Urinary Tract Infections
- MRSA
- Dermatitis
- Sinusitis
- Endocarditis
- Pelvic Infections
- Genital Herpes
- Otitis
- VRE Infection
- Skin and Soft Tissue Infections
- Pneumonia
- Bronchitis

## Data Management Services that Meet the Special Challenges of Microbiology Testing

At ICON Central Laboratories we understand that quality data is the ultimate product we provide our pharmaceutical and biotechnology clients. That's why we work very closely with sponsors whose clinical trials involve microbiology or other types of testing services that generate both numeric and commented results. Such circumstances create an added level of complexity in receiving and analyzing laboratory data. An ICON Central Laboratories Data Manager is an important part of our project support team. Our Data Manager will listen to the special needs of the trial sponsor and draw upon our extensive experience in this area to offer a custom data solution.



For more information regarding our central laboratory services for anti-infective clinical trials, please contact:

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