



Excellence in Anti-Viral Clinical Trials

We deliver custom study management, advanced testing methods and a single comprehensive study database. Our clients tell us it's this willingness to go above and beyond the standard service package that sets ICON Central Laboratories apart from the others.

ICON Central Laboratories has made the support of anti-viral clinical trials an important focus in our service offerings to pharmaceutical and biotechnology companies. Our commitment in this area has prompted trial sponsors of both conventional and entry inhibitor therapies to select ICON Central Laboratories for their project support. We are proud to have been selected to support anti-viral trials placed on "fast track" status by the FDA, demonstrating clients' confidence in our ability to expedite project setup, testing and data services.

We recognize that having advanced test methodologies and standardized testing platforms are essential in global anti-viral studies. We are pleased to offer the most advanced molecular biology methods available, including:

- Roche Cobas Amplicor® HIV-Standard
- Roche Cobas Amplicor® HIV-Ultrasensitive
- Roche Amplicor® HIV-DNA Assay
- Siemen's Tru-Gene HIV Genotyping
- Roche Cobas Amplicor® HCV-Qualitative
- Roche Lightcycler qPCR
- INNO-LIPA HBV Genotyping
- VERSANT® LiPA HCV Genotyping
- Roche Cobas Amplicor® GC/Chlamydia
- Roche Cobas TaqMan HCV
- Roche Cobas TaqMan HBV
- Roche AmpliPrep/Taqman HIV
- Roche AmpliPrep/Taqman HCV

In addition, ICON Central Laboratories performs the following tests of interest to sponsors of anti-viral trials:

- Basic screening and safety testing
- Cellular Immunophenotyping
- CMV Antibody
- HAV Antibody
- HBV Core Antibody
- HBV Surface Antigen
- HBV Surface Antibody
- HCV Antibody (RIBA)
- qPCR
 - EBV
 - CMV
 - HSV 1/2
 - VZV
- Abbott Real Time HIV
- Abbott Real Time HCV
- Abbott Viroseq HIV Genotyping



At ICON Central Laboratories, our service extends well beyond high quality test methods. Our MD, PhD and Master's level scientific staff members are available as valuable technical resources throughout the planning and management of your clinical development program. We assist our clients in identifying the most appropriate assays for the limits of detection required. In addition, we will work with sponsors requiring the setup and validation of specialized test methods.

Genomic Extraction and Pharmacokinetic Sample Storage Capabilities

ICON Central Laboratories' facilities provide long term storage services in controlled, alarmed freezers. The freezers are supported by backup generators that provide frozen storage at -20° , -80° or -180° C, as necessary.

For sponsors requiring support for DNA extractions, ICON Central Laboratories has developed procedures that produce high quality and high yield DNA. We use a modified salt precipitation method as our primary process for extraction. This method produces an average yield of 229 μ g and a concentration of 489 μ g/ml of DNA. The quality material rendered from this extraction process is acceptable for PCR, Southern blotting and SAIP downstream testing. Our laboratories also extract high quality RNA with an average yield of 6-10 μ g of total RNA, depending upon the source of extracted material. Such extractions are well suited for downstream applications such as Northern analysis, RT-PCR and gene chip sequencing.

We will always work closely with your selected PK and pharmacogenomic laboratories to ensure our services fully support future testing requirements.

Comprehensive Project Support

When you select ICON Central Laboratories to support your clinical trial, you can be assured that your study will be set up and managed to meet its specific requirements.

Our comprehensive service package includes:

- An experienced project manager and project support team assigned to work with each sponsor to thoroughly understand both company and protocol needs;
- Study-specific alert criteria to monitor clinically significant results and inclusion/exclusion parameters;
- Custom delta flagging to closely monitor changes in study subjects' test values;
- Study and visit-specific collection kits;
- Comprehensive logistics support to ensure that investigator sites will receive the highest quality, most expeditious specimen shipping services;
- Investigator site support services that include presentations at investigator meetings, protocol specific investigator manuals with illustrated collection and shipping instructions and multi-lingual support personnel to answer questions;
- Client-driven data management services that include custom data formats as well as flexible modes and intervals of data delivery;
- ICOLabs™, a powerful and secure web-based remote data access tool.



For more information regarding our central laboratory services for anti-viral clinical trials, visit www.iconplc.com, or email us at labinfo@iconplc.com.



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