

# CLINICAL IMMUNOLOGY SOLUTIONS

**Strengthen your clinical trial. Interrogate the immune system.**

**Data you can trust to evaluate your drug's clinical toxicity, immunogenicity and efficacy**



ABL has the capabilities, expertise and quality systems in place to provide high quality clinical solutions through immunological evaluations. Our scientific staff work as an extension of your clinical operations team providing study design support, expert data analyses, and technical guidance throughout your clinical program. We are prepared to exhaustively evaluate vaccines and therapeutics for today's top health challenges, such as RSV, Ebola, HIV and cancer, among others.

Whether you need an assay developed to detect PK responses to your novel antigen or a small change in a cellular endpoint, such as a PD marker, we have the experts to get you reliable results. ABL's service offerings include development, validation and execution of activities from functional assays to immunoassays. We also offer multiplexing assays which are particularly useful in conserving sample volume and the simultaneous assessment of numerous analytes. Sometimes small changes can have large impacts, and it is possible that your novel product may have biomarkers that are difficult to measure. For these projects, we have ultra-sensitive detection capabilities, including Quanterix, Singulex, and droplet digital PCR platforms. To this end, ABL is platform agnostic, helping clients determine the technology best suited for measurement of their target.

**Clinical Screening and Response Characterization**

## **Cell-Mediated Immune Responses**

- Immunophenotyping
- Trucount – Absolute Cell Enumeration
- Intracellular Cytokine Staining
- Cytokine ELISpot
- T Cell Activation Assay
- Lymphoproliferation
- Molecular Monitoring of Transcript/Gene and Host Immune Responses

## **Humoral Immune Responses**

- Multiplexing Biomarker Detection
- Ultra-Sensitive Biomarker Detection Assays
- B Cell ELISpot
- FACS-Based B Cell Characterization
- ELISA
- Anti-Drug Antibody Assays (ADA)
- Western Blot
- Neutralizing Antibody Assays

## **Available Instrument Platforms**

- BD FACSCanto
- BD LSR II
- BD LSRFortessa
- CTL ELISpot readers
- SpectraMax
- Luminex 200
- MesoScale Diagnostics QuickPlex SQ120
- Singulex Erenna
- Quanterix Simoa
- Aushon Cirascan
- Bio-Rad QX200 Droplet Digital PCR System

## **Flexibility and Responsiveness**

We have diverse technologies and applications to ensure you have access to the most appropriate tools to meet your goals. We provide timely results, providing the capacity to execute assays for adaptive trial designs. ABL has established standard protocols and trained personnel to accommodate rapid study set-up at facilities in the U.S. and in Europe. We also have extensive assay development and validation experience for clients who would like assistance in the selection of appropriate assays and are looking for a customized approach, from development all the way through to validation.

Whether methods are developed at ABL or elsewhere, we routinely transfer assays in-house or to external laboratories. We can also train staff at clinical sites on sponsor-specific protocols to eliminate the geographical challenges often encountered with global trials.

ABL's sample processing services are flexible. We can process samples received from multiple clinical sites nation-wide or manage the logistics with

any local site. ABL can then perform the downstream assays in house to obtain large, timely data sets without compromising sample integrity.

- Whole Blood Processing for PBMCs, Serum, Plasma
- Processing of Tissues

## Quality Systems

ABL's U.S. location is accredited for Good Clinical Laboratory Practices (GCLP) standards and is ISO 9001 accredited, while ABL's European site is also accredited for ISO 9001. GCLP is an international standard developed by the World Health Organization (WHO) aimed at closing the gap between GCP, which does not define requirements for non-diagnostic laboratory testing, and GLP, which is for preclinical work.

An analytical plan is created at project initiation to define key deliverables of the study and to ensure that all parties are working from a singular understanding. ABL welcomes client audits and keeps a permanent audit record detailing each audit performed, results, corrective actions taken, and follow up verification of the final outcome. Contact one of our sites today to see how ABL can help you advance your product!

- U.S. contact
- Europe contact

ABL purchased ABL Lyon (formerly Platine Pharma Services) in 2014 for their preclinical and clinical immunological service offerings based in Lyon, France. For more information, visit the ABL Lyon website.

Contact Us Today

## PBMC NETWORK

ABL has developed a network of international laboratories for timely and high quality PBMC processing & storage.

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**ABL & AUSHON BIOSYSTEMS ANNOUNCE ADOPTION OF THE CIRA™ PLATFORM**

Aushon BioSystems and ABL announced that ABL has adopted the Cira platform for multiplex and ultrasensitive biomarker analysis.

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