COMPANION DIAGNOSTICS

Almac Diagnostics is a personalised medicine company focused on the discovery, development and commercialisation of diagnostic tests including companion diagnostics. Our approach to personalised medicine is poised to change the way that medicines are developed, regulated and prescribed.
COMPANION DIAGNOSTICS

An emphasis on scientific and technological excellence combined with a committed and passionate multi-functional team, puts Almac Diagnostics in a leadership position to take companion and other diagnostic tests all the way through development and to commercialisation.

BIOMARKER DISCOVERY

Almac have extensive experience in the discovery of clinically relevant and applicable biomarkers.

As part of our commercial CDx partnerships, we have discovered signatures that have been brought forward and developed into research assays, CLIA / clinical trial assays, and full companion diagnostics.

Services Include:
- Sample Design
- Sample Sourcing
- Retrospective Sample Collection
- Data Generation on Multiple Platforms
- Extensive Bioinformatics Support
- Proof of Concept Studies

RUO & CLINICAL TRIAL ASSAY DEVELOPMENT

Our key area of expertise is in the development and delivery of multiple RNA, DNA and protein based clinical and RUO assays. We specialise in working with formalin fixed, paraffin embedded (FFPE) samples and offer assays on multiple platforms including qPCR, microarray, NGS and IHC.

Services Include:
- Assay Design & Migration
- Platform Selection & Migration
- Control Gene Selection
- Analytical Validation
- Phase I & II Clinical Trial Testing

CDx DEVELOPMENT & COMMERCIALISATION

We are uniquely placed to partner with clients throughout the entire process of CDx development – from the fundamental research and discovery phase, through the conduct of clinical trials and the manufacturing of test kits, to the patient sample testing.

As a major global company, we have the financial stability to stand alongside our customers. We also have the organisational and logistical resources necessary to provide an end-to-end service, which can be scaled out to every major market from our clinical laboratory hubs in the USA, Europe and APAC.

Services Include:
- Design Control & Risk Management
- Sample Sourcing
- Assay Development & Validation
- Assay Software Development
- Manufacturing
- Regulatory Submissions
- Registration Trial Testing (IDE)

PLATFORM AVAILABILITY

- Illumina MiSeq®
- Illumina NextSeq
- Sanger Sequencing
- Nanostring nCounter
- Fluidigm BioMark HD
-Roche LightCycler
- Affymetrix SNP 6.0, DMET, OncoScan
-Thermo Fisher/Life Technologies QuantStudio Dx
-Affymetrix RUO & DX V2 Genechip Systems

BIOINFORMATICS AND BIOSTATISTICS

Our expert Bioinformatics and Biostatistics Department will partner with you throughout your study, fully supporting the discovery, development and delivery of biomarkers, providing efficient, customised and innovative solutions. We offer complete transparency throughout, with all methodology, programs and analytical methods available for verification.

Solutions Include:
- Study design
- Quality control
- Exploratory analysis
- Molecular sub-type discovery
- Functional analysis
- Biomarker discovery

REGULATORY SUPPORT

Our regulatory team has vast experience in working with regulatory agencies through our internal diagnostic pipeline as well as with our pharma partners in joint regulatory meetings. We currently manage regulatory plans for companion diagnostic tests in multiple global regions including USA, Canada, Europe, Japan and China.

Solutions Include:
- CDx and IVD pre-submissions
- IDE submissions
- EU device & performance evaluation registration
- Global regulatory strategies for CDx development
- Device classification assistance
- Analytical and clinical protocol design
- Regulatory submissions
- Regulatory agency liaison
- Medical device reporting
- Post-market support

QUALITY ASSURANCE

Our global high-tech laboratories based in Craigavon, UK and Durham NC, USA are ready to operate both research-use-only and clinical diagnostic assays. We have fully automated processing in place and a full laboratory information management system, which tracks samples from receipt to the completion of your study. You can make use of any of these services in a fee-for-service manner for routine genomic research. Partnering with us you’ll have access to extensive bioinformatics, project management and regulatory support. We also offer a range of supporting services, from sample sourcing and tissue processing to immune histochemistry and pathology review.

ACCREDITATIONS

- CLIA (US Clinical Laboratory Improvement Amendments)
- College of American Pathologists (CAP)
- UKAS to ISO17025
- EN ISO 13485:2012
- Human Tissue Act UK
- US State Licences:
  - New York (CLVF Permit)
  - Florida
  - Pennsylvania
- Samples with:
  - CLP
  - GDP
  - GCP

CERTIFICATIONS

- CLIA (US Clinical Laboratory Improvement Amendments)
- College of American Pathologists (CAP)
- EN ISO 13485:2012
- For design, development & manufacture of in vitro diagnostic nucleic acid technique-based assays for gene mutation and expression analysis.
WHY ALMAC?

ALMAC ARE FULLY COMMITTED TO THE DEVELOPMENT OF PRECISION MEDICINE AND OUR GLOBAL INFRASTRUCTURE, STRATEGIC PARTNERSHIPS AND FLEXIBLE COMMERCIALISATION MODELS ENABLE US TO DEVELOP DIAGNOSTIC TESTS WHICH WILL ULTIMATELY IMPROVE CARE IN A WIDE RANGE OF DISEASE AREAS.

INFRASTRUCTURE
- Global laboratories
- Multiple technology platforms
- Expert customer support
- Manufacturing & logistics

FLEXIBLE COMMERCIALISATION MODELS
- Single source lab assay
- IVD kit
- Strategic partnerships

EXPERIENCE
- CDx partnerships with large Pharma
- Various range of disease areas
- Multiple classes of drugs
- Supporting CLIA trial enrichment through to CDx commercialisation
- Extensive regulatory experience

COMPLETE PACKAGE
- Discovery
- Product development
- Trial management
- Test delivery
- Commercialisation

All our clients have unique needs. That's why we develop unique solutions.

This is the ALMAC TOUCH®

GET IN TOUCH

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