

Almac Diagnostic Services

Almac Diagnostic Services is a precision medicine company specialising in biomarker-driven clinical trials. We offer clients multiple solutions across three core service lines: Multi-Omic Services, Clinical Biomarkers & CDx Development, and Clinical Testing.

Why Almac?

We offer complete flexibility for your biomarker strategy on a fee for service model.

FLEXIBILITY:

Multiple platform & chemistry options, multiple sample types, multiple diseases.

CUSTOMER EXPERIENCE:

A true partnership approach. Transparent communication & responsive support.

QUALITY:

Optimised lab processes & quality data output from highly experienced scientists.

Core Services

Multi-Omic Services

We support biomarker discovery across genomic and proteomic platforms including NGS, qPCR, ddPCR, nanoString, single cell RNASeq, IHC, ELISA, FISH, ISH, spatial transcriptomics and proteomic solutions. Our Data Sciences team delivers proprietary bioinformatics to generate actionable insights. We also provide full sample management, including bespoke specimen collection kit manufacturing and integrated logistics service for your clinical trials.

Clinical Biomarkers and CDx Development

We develop molecular and proteomic assays for patient selection in clinical trials, supporting RUO, IUO and CDx development. Our services include development, validation, and associated regulatory consultancy including IVDR and Almac hold Health Institution Status. We offer flexible CDx manufacture and commercialisation models such as Single Site, IVD Kit and Hybrid approaches. Platforms include NGS, qPCR, nanoString and IHC.

Clinical Testing

Almac Diagnostic Services has extensive experience setting up global clinical trials and provide testing across multiple technologies. We deliver global clinical testing from laboratories in the USA, Europe and APAC (China), offering a menu of assays, fast turnaround times and dedicated support. Using Almac's integrated specimen collection kits, site training and logistics service improves site and patient outcomes and increases valid eligibility calls for clinical testing.

Global Lab Locations

We operate CLIA and CAP accredited laboratories in Craigavon (Northern Ireland, UK), Durham (NC, USA), and have strategic partner labs in China. We support global clinical trial assay development, validation and clinical trial testing across UK, EU, USA and APAC regions.

		
UK/EU	USA	China
		
Craigavon, UK	Durham, NC	Partner Laboratories



NOTE: Almac's unique Northern Ireland lab location gives sponsors a convenient base that is IVDR-compliant within the UK. Health Institution Status ensures faster EU trial enrolment and reduced costs.

Supporting Services

Our comprehensive support services include:

Data Sciences:

Bioinformatics, Biostatistics, Software & machine learning solutions.

Regulatory Support:

Global regulatory strategy & submissions support (US, UK & EU, APAC).

Project Management:

Dedicated project managers for end-to-end biomarker programme support.

Clinical Support:

Medical oversight and clinical trial delivery expertise.

Regulatory Experience

Almac Diagnostic Services has extensive experience working with global regulatory agencies including the FDA and MHRA. We support studies under US IDE regulations and have supported CPS studies under IVDR. Our team engages in joint drug/diagnostic regulatory meetings and ensures compliance with FDA QMS and IVDR regulations.

Instrumentation

Platform	Instrumentation	
PCR	Roche Lightcycler 480 & 480 II, Roche Cobas 480, Qiagen RotorGene Q, ThermoFisher QuantStudio Dx & 5 Dx, Bio-Rad QX200 ddPCR, Fluidigm Biomark HD	  
NGS	Illumina NovaSeq X Plus & 6000, MiSeq & MiSeq Dx, NextSeq 500, 550 & Dx, ThermoFisher Ion Torrent Genexus System, ThermoFisher Ion PGM Dx	 
NanoString	nCounter FLEX Analysis System	
Single Cell	10x Chromium X - Single Cell RNA Sequencing	
Spatial Transcriptomics	10x Visium HD	
Proteomics	Fluidigm Biomark HD, Multiple Olink proteomic panels	
IHC Staining	Dako Omnis, Ventana Benchmark Ultra, Leica BondMAX, Leica ST5010	  
Microscopy & Slide Scanners	Leica Aperio GT450, Leica Aperio AT2, Leica DM2500 LED, Olympus BX53	  

Accreditations

- CLIA
- CAP
- ISO15189



Permits, Licences & Regulations

US State Licences:

- New York (CLEP Permit)
- California
- Pennsylvania
- Maryland
- Rhode Island

Human Tissue Act UK:

- HTA Licence



Compliant with the principles of:

- GCP
- GCLP

Certifications

EN ISO 13485:2016

For design development and manufacturing on in vitro diagnostic nucleic acid technique-based assays for gene mutation and expression analysis.

ISO14971

IEC62304

GLP

