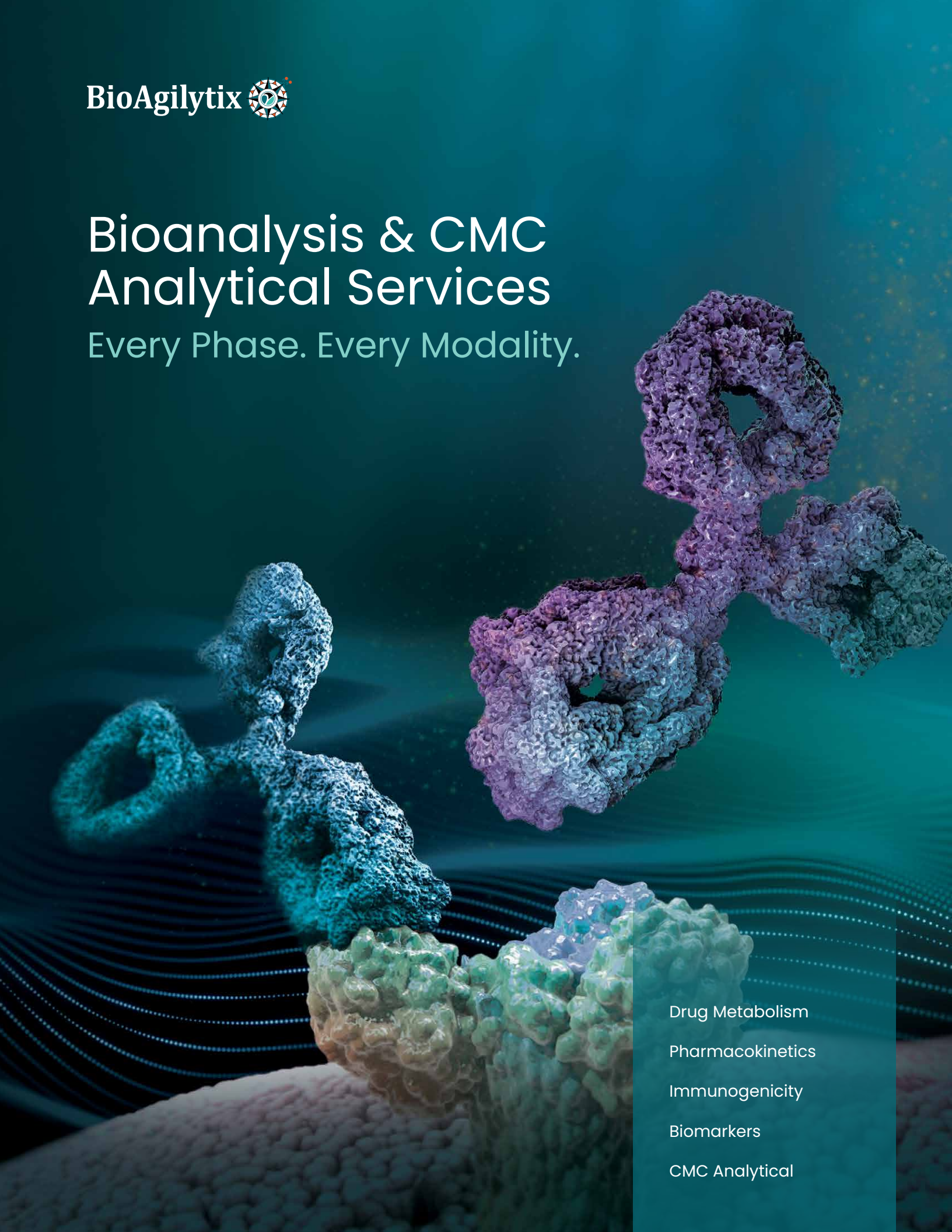


Bioanalysis & CMC Analytical Services

Every Phase. Every Modality.



Drug Metabolism
Pharmacokinetics
Immunogenicity
Biomarkers
CMC Analytical

CORPORATE SNAPSHOT

EVERY YEAR:

800+

assays developed

650+

assays validated

5,000,000

tests reported



OUR SCIENTISTS, YOUR SUCCESS

90%

industry-leading employee retention rate

10+ years

of bench experience on our science team

1,100+

employees

>50% PhD

and/or master's-level scientists

FACILITY SIZE

USA	160,000+ sq. ft. 14,860+ sq. m.
EUROPE	50,000+ sq. ft. 4,800+ sq. m.
AUSTRALIA	33,900+ sq. ft 3,150 sq. m.



DRIVING INNOVATION, DELIVERING RESULTS

21/25

We support 21 of the world's top 25 biopharma companies



90% choose to stay with BioAgilytix from Phase 1 to Phase 3

Over 90% of drug developers who start Phase 1 studies with BioAgilytix continue with us for their Phase 2 and 3 studies



~30% of biologics

BioAgilytix supported ~30% of FDA-approved biologics from 2020 to 2024

COMPREHENSIVE SERVICE OFFERINGS



IMMUNOASSAYS

- Pharmacokinetics (PK)
- Immunogenicity
- Biomarkers



CELL-BASED ASSAYS

- Neutralizing antibodies
- Potency assays
- Immunophenotyping



LC-MS/MS

- Biomarkers
- Pharmacokinetics (PK)
- Tissue distribution



MOLECULAR ASSAYS

- Pharmacokinetics/cellular kinetics
- Biodistribution
- Viral shedding



VIROLOGY

- Plaque assay
- Viral culture
- Microneutralization

Why BioAgilytix?

For nearly two decades, BioAgilytix has been driven by a singular passion: delivering innovative and reliable bioanalytical testing solutions. Our team of dedicated scientists is fueled by a deep curiosity for assay development, providing high-quality assays for PK, immunogenicity, and biomarker bioanalysis along with CMC analytical testing. This passion translates into premium, customized services designed to meet your specific needs.



A partnership that propels your programs forward, resulting in timely and high-quality results.

Quality and collaboration

BioAgilytix is a recognized leader in bioanalytical testing, committed to delivering premium scientific services which meet the highest quality standards. We excel in tackling the most demanding bioanalytical challenges, drawing on our extensive expertise and highly skilled team.

Support for every stage across the globe

With 30+ years of experience, we've mastered the art of delivering successful bioanalytical projects at every stage of drug development across the US and Europe, as well as in China and Australia.

End-to-end bioanalytical support for your drug development journey.

Discovery ▶ Preclinical ▶ Phase I ▶ Phase II ▶ Phase III ▶ Phase IV ▶ Manufacturing

Extensive expertise across a wide range of modalities

BioAgilytix offers industry-leading services and solutions designed to support even the most complex modalities.

LARGE MOLECULE

Trust our experts in bioanalytical testing services across a wide range of large molecules, including:

- Monoclonal antibodies
- Antibody-drug conjugates (ADCs)
- Biosimilars
- Bi-specific/tri-specific proteins
- Enzyme replacements
- Recombinant proteins

SMALL MOLECULE

Accelerate development by leveraging industry-leading small molecule bioanalysis for drug development, which includes an extensive suite of DMPK service offerings:

- Regulated studies
- Expert PK analysis
- High-throughput capabilities
- Discovery support

ATMPs

Support your ATMP bioanalytical needs with customized approaches for:

- Gene therapy
- Cell therapy
- CAR-based cell therapies
- RNA therapeutics
- Stem cell
- Oligonucleotides

VACCINES

Meet your unique program needs with deep expertise in complex biologics and a full range of phase-appropriate methods for vaccine assessments, including:

- Immunoassays
- Cell-based assays
- Virology
- Molecular assays



Working with BioAgilytix removes the guesswork. I always know the status of my project because their team of senior scientists communicates regularly.

– Clinical Manager,
Top 5 Pharma

A comprehensive suite of services



Drug Metabolism

Accelerate your drug development with comprehensive in vitro and DMPK assay services.

BioAgilytix performs industry-standard DMPK assays, custom drug metabolism research, and IND-enabling studies, to assess drug-drug interaction potential, metabolic stability, metabolite profiling, and protein binding. Whether you are in the discovery, lead optimization, or candidate selection phase of your study, we will work with you to define the appropriate, fit-for-purpose assays and data to address your needs.

Pharmacokinetics

Rely on a team of experienced scientists to develop PK assays and generate reproducible and reliable results to support your drug program.

BioAgilytix provides PK assay development, validation, and sample testing, as well as PK data analysis and reports to support all drug modalities at any phase of development.

We have a proven track record developing PK assays for small molecules, large molecules, and advanced drug modalities. This breadth of experience allows us to design assays specifically tailored to your unique therapeutic, ensuring you make the right bioanalytical method selection from the very beginning.

Immunogenicity

Optimize drug safety with industry-leading immunogenicity and testing expertise.

BioAgilytix scientists were involved in characterizing one of the first cases of unwanted biotherapeutic-induced immunogenicity. Today, this legacy of leadership continues. We are a world-renowned authority on the subject, offering our highly specialized knowledge to support your immunogenicity projects through all phases of drug development, from protein therapeutics, peptides, oligonucleotides, to cell and gene therapies.

Our comprehensive suite of immunogenicity services encompasses expert oversight of labeling reagents and surrogate positive control antibody generation, along with the development, qualification, and validation of assays for both humoral and cellular immunogenicity assessment:

- Anti-drug antibody (ADA) assays
- Neutralizing antibody (NAb) assays
- Cellular immunogenicity assays
- Cytokine quantitation

Our experience extends to supporting immunogenicity studies in a variety of species, including humans, non-human primates, and rodents. We follow the standard practice of tiered immunogenicity testing, including screening, confirmatory, and characterization assays such as titer, neutralizing antibody, and domain specificity.

Biomarkers

Support clinical trial efficacy and safety with comprehensive, fit-for-purpose biomarker analysis and a focus on future value to your program.

Whether you leverage our extensive menu of over 120 off-the-shelf biomarker assays or collaborate with us to develop novel assays for your program, our team of industry-leading biomarker assay experts can be your partner in this endeavor.

We work closely with you to identify the optimal solution for your specific biomarker project, considering disease state, development phase, and unique project needs to ensure a streamlined and cost-effective approach to your therapeutic development.

We offer extensive experience across various platforms and a deep understanding of regulatory requirements, ensuring the development, optimization, and validation of assays that meet the purpose required for your program.

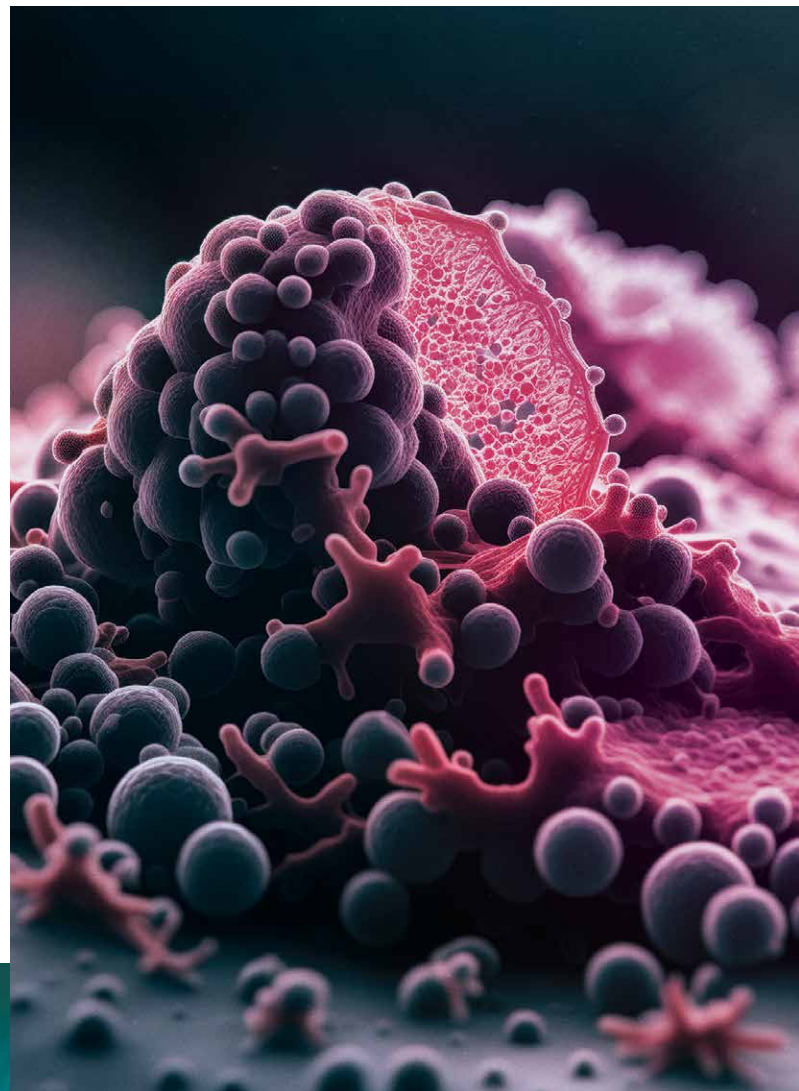
At BioAgilytix, we are more than just a service provider — we are your trusted partner in bioanalytical innovation. Together, let's accelerate the development of life-changing therapies for patients in need.

CMC Analytical

Leverage our CMC team to guide the design of your analytical control strategy for your therapeutic.

Since 2008, our team of experts has provided CMC analytical support for biologics and ATMPs from pre-IND to commercial release testing. We have deep technical expertise in cell-based potency assays, molecular assays, MS characterization, and many other analytical test methodologies and have supported commercial batch release since 2014.

We specialize in solving challenging analytical problems, and our science-forward approach leads to the best solutions for our clients. We offer cGMP testing at our Durham, North Carolina, and Hamburg, Germany laboratories.





Learn about Australia as a destination for early phase clinical trials

Discover our speed, cost, and quality advantages and comprehensive bioanalytical services offered at 360biolabs, a BioAgilytix company. Australia's pragmatic regulatory environment, internationally recognized quality systems, and competitive R&D tax incentive positions 360biolabs as a strategic bioanalytical partner for your early-phase clinical trials.

SPEED



Australia offers a fast and pragmatic regulatory environment for early-phase clinical trials (no IND required to start your clinical trial).

COST

The Australian government offers an attractive R&D tax incentive of 43.5% to eligible companies.



QUALITY



Australia is an Organisation for Economic Co-operation and Development country (OECD) and a member of the OECD Mutual Acceptance of Data (MAD) system. Data from studies conducted in Australia can be used to support international regulatory applications.



Ask us about our global advantage in Australia.
To learn more email bd@360biolabs.com or visit 360biolabs.com.



Size and scale to meet
your needs around the world.



GLOBAL HEADQUARTERS

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Durham, NC 27713

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Morrisville, NC 27560

Bradford building
5827 S. Miami Blvd.
Morrisville, NC 27560

BOSTON

1320 Soldiers Field Road
Boston, MA 02135

SAN DIEGO

9050 Camino Santa Fe
San Diego, CA 92121

HAMBURG

Lademannbogen 10
22339 Hamburg, Germany

BRISBANE

37 Kent St, Woolloongabba
Queensland, 4102, Australia

MELBOURNE

549 St Kilda Road, Melbourne
Victoria, 3004, Australia

PARTNER LABS

Beijing, China



SPEAK WITH A SCIENTIST

Let's talk scientist-to-scientist about the
bioanalytical needs of your project.

BIOAGILYTIX.COM