AVANCE BIOSCIENCES

FDA IVD Testing & Validation Services

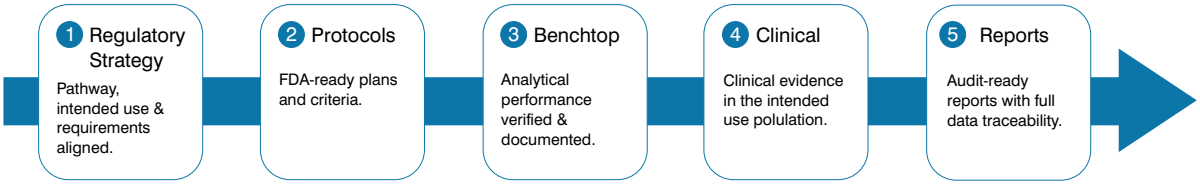
End-to-End Support for FDA Diagnostic Assay Submissions

We provide comprehensive analytical and clinical testing services to support FDA diagnostic (IVD) submissions, including 510(k), De Novo, PMA, EUA, and CLIA Waiver pathways. Our studies are designed to meet FDA and CLSI expectations and generate submission-ready data you can rely on.

Our Expertise

Leveraging the power of genomics, cell biology, microbiology, immunoassays, and other advanced technologies, Avance Biosciences has extensive experience supporting clients with testing and validation of diagnostic assays and companion diagnostics for their IVD submissions. Our comprehensive approach ensures precise, reliable, and clinically relevant results, facilitating the generation of FDA-ready data packages, clear traceability from requirements to results, and a more efficient regulatory review process.

End-to-End Support for FDA Diagnostic Assay Submissions



Assay Types We Supports

Assay Type	Benchtop Testing	Analytical Performance	Clinical Performance	Point of Care (POC)
Molecular (PCR/NGS)	✓	✓	✓	✓
Immunoassays (ELISA/LFA)	✓	✓	✓	✓
Clinical Chemistry (LC-MS/MS)	✓	✓	✓	

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Regulatory Pathways We Supports

Submission Pathway	Description	Testing Required
510(k) Premarket Notification	**For assays with a predicate device** We design and execute analytical and clinical performance studies to demonstrate substantial equivalence to a legally marketed predicate.	• Predicate comparison strategies • Full analytical performance testing • Clinical performance studies (when required) • Submission-ready reports
De Novo Classification	**For novel assays with no predicate** We support first-of-a-kind diagnostics by generating the data needed to establish a new Class I or II device classification.	• Risk-based study design • Analytical and clinical validation • Data supporting special controls • Future 510(k) predicate positioning
Premarket Approval (PMA)	**For high-risk diagnostic assays** Our PMA-grade testing programs generate the independent evidence required to demonstrate safety and effectiveness.	• Comprehensive analytical validation • Clinical performance studies • IDE support (as applicable) • PMA-level documentation and traceability
Emergency Use Authorization (EUA)	**For declared public health emergencies** We deliver accelerated analytical and clinical studies aligned with FDA emergency expectations.	• LoD and analytical sensitivity • Inclusivity and cross-reactivity • Rapid protocol development • Emergency-aligned reporting
CLIA Waiver by Application	**For point-of-care and home-use tests** We design studies demonstrating that your assay is simple to use and has a low risk of erroneous results.	• Flex studies • Dual CLIA + 510(k)/De Novo support

Our IVD Testing Services

Service	Description	Testing Required
Benchtop Testing	Analytical Performance	• Limit of Detection (LoD) and Limit of Quantitation (LoQ) • Accuracy and method comparison • Precision (repeatability, intermediate precision, reproducibility) • Linearity and measuring range • Analytical specificity (cross-reactivity, interference, carryover)
	Sample & Matrix Studies	• Matrix equivalency (serum, plasma, whole blood) • Sample type validation • Stability (real-time, freeze–thaw, transport conditions)
	Reagent & System Robustness	• Real-time and accelerated stability • Open-vial and on-instrument stability • Environmental stress testing • Operator variability simulations
Analytical Performance Protocols	FDA-ready protocols designed to withstand regulatory review.	• Study design and statistical analysis plans • CLSI and FDA guidance alignment • Predicate and reference method strategy • Pre-submission protocol support • Deviation management and justification
Clinical Performance Studies	Clinical evidence demonstrating how your assay performs in real-world patient populations.	• Clinical sensitivity and specificity • Comparator method alignment • Patient sample testing • Multi-site study coordination • IDE support when required