



PRIESTLY CONSULTING

Insightful strategies, impactful results.

Capability Statement
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Nationwide, United States

Company overview

Priestly Consulting is a specialized scientific and healthcare consulting firm helping laboratories and diagnostic innovators turn complex technical, regulatory, operational and reimbursement challenges into actionable plans and measurable progress. Primary sectors: clinical laboratories, molecular diagnostics, biotechnology, healthcare, research and life sciences. Licensed and based in the United States; serving clients nationwide. Working hours: Monday–Friday, 8:00 AM–8:00 PM.

Core competencies

01 Molecular Assay Development & Optimization	Assay development plans; technical protocols; optimization reports; feasibility and gap assessments.
02 Analytical Validation & Method Verification	Validation plans; protocols; data review; statistical summaries; final analytical validation reports.
03 Clinical Validation & Evidence Strategy	Clinical validation protocols; comparator analyses; evidence matrices; technical narratives.
04 Regulatory & Laboratory Compliance Support	Gap assessments; SOP suites; inspection-readiness plans; submission-support documentation.
05 MoIDx, DEX Z-Codes & Technical Assessment	Technical assessment responses; remediation roadmaps; submission checklists; supporting exhibits.
06 CPT / PLA Coding, Reimbursement & Market Access	PLA DOP drafts; coding/reimbursement strategy briefs; payer evidence packages.
07 Clinical Research, Data Analysis & Scientific Writing	Clinical evidence summaries; study reports; manuscripts; abstracts; data tables.
08 Laboratory Operations & Quality Improvement	Operational assessments; implementation plans; workflow SOPs; training and KPI dashboards.
09 Precision Medicine & Advanced Diagnostics	Test-menu strategy; validation frameworks; interpretation and reporting templates.
10 Scientific Leadership & Project Advisory	Strategic roadmaps; technical reviews; milestone plans; executive briefings.

Differentiators & specialized experience

- Molecular infectious disease: UTI, wound and respiratory testing; multiplex pathogen and antimicrobial resistance detection; individual and grouped targets.
- Regulatory and payer evidence: MoIDx technical assessment responses, validation gap remediation, DEX Z-Code strategy, AMA PLA descriptions.
- Platforms: real-time PCR, high-complexity molecular workflows, NGS and related clinical diagnostic technologies.
- Scientific reporting, clinical and research documentation, CLIA/CAP readiness, workflow redesign and multi-site operational planning.

Leadership

Priestly Penda — molecular diagnostics and clinical laboratory leader with experience in chief scientific leadership and laboratory operations in high-complexity diagnostic settings, and prior work as a Medical Laboratory Scientist in a Level II trauma-center environment. M.S., Microbiology and Cell Science (medical microbiology and biochemistry focus), University of Florida.

Independent consulting service; not a testing laboratory. Regulatory, coding and reimbursement services are strategic and documentation support, not legal advice or a guarantee of approval or payment.