

Guide to Starting a Practice-Owned Lab or Small Reference Lab

Introduction Starting a laboratory can be a significant step for medical practices and entrepreneurs in the healthcare sector. Whether you are establishing a practice-owned lab (POL) or a small reference lab, understanding their differences, benefits, and challenges is crucial for making an informed decision.

1. Understanding the Difference

Feature	Practice-Owned Lab (POL)	Small Reference Lab
Ownership	Owned and operated by a medical practice	Independent or part of a larger network
Primary Clients	Exclusively serves the patients of the practice	Serves multiple external clients, including other medical offices and healthcare facilities
Testing Scope	Limited to routine tests necessary for patient management	Offers a broader range of tests, including specialized assays
Regulatory Requirements	CLIA-waived or moderate or high complexity	CLIA high complexity, subject to stricter regulations
Revenue Model	Increases practice revenue by capturing in-house testing	Operates as a standalone business with independent billing
Insurance & Billing	Primarily bills through the practice and has more insurance penetration through practice credentialing	Bills third-party payers and clients directly; lacks commercial payers

2. Pros and Cons of Each Model

Practice-Owned Lab (POL)

Pros:

- Faster turnaround time for patient results.
- Improved patient care and convenience.
- Increased revenue stream for the practice.
- Easier to integrate with existing practice operations.

Cons:

- Limited test menu may require outsourcing complex tests.
- Requires compliance with CLIA and potential COLA accreditation.
- Reimbursement policies can be complex and vary by payer.
- Start-up costs for equipment and staffing.

Small Reference Lab

Pros:

- Serves multiple clients, allowing for a more diverse revenue stream.
- Can offer specialized and high-complexity testing.
- Potential for higher profitability if volume is sufficient.
- Flexibility in business operations and partnerships.

Cons:

- Requires a more substantial initial investment.
- More extensive regulatory and compliance requirements (CLIA high complexity, CAP accreditation, state licensing, etc.).
- More complex billing and insurance negotiations.
- Requires marketing efforts to attract clients.

3. Steps to Start a Laboratory

A. Business Planning & Feasibility

- Determine whether a POL or a small reference lab fits your needs.
- Conduct a market analysis to assess demand.
- Develop a business plan, including financial projections and operational costs.
- Create a corporation or LLC and obtain a Tax ID Number from the IRS

B. Regulatory Compliance & Licensing

- Obtain a CLIA certificate appropriate for your testing complexity.
- Apply for state-specific laboratory licenses, if applicable.
- Meet accreditation standards (e.g., COLA, CAP, or The Joint Commission).
- Ensure compliance with HIPAA and OSHA regulations.

C. Facility & Equipment Setup

- Secure a suitable laboratory space that meets environmental and safety standards.
- Purchase necessary instruments based on test menu (e.g., hematology, chemistry, toxicology, molecular diagnostics).
- Validate or verify all instruments and assays before use.
- Implement a Laboratory Information System (LIS) for data management.

D. Staffing & Training

- Hire qualified personnel: Technicians require a four-year science degree for high complexity lab.
- Provide training on testing protocols, quality control, and compliance requirements. Create an extensive SOP including: General Policies and Procedures, Safety Policies (General, Fire, Electrical, Chemical Handling), Patient Test Management, Quality Management, Personnel and Training, Technical Operations, OSHA and Biomedical Compliance.

E. Reimbursement & Billing Setup

- Obtain necessary credentials with insurance payers and Medicare/Medicaid.
- Set up laboratory billing systems and revenue cycle management.
- Determine cash-pay pricing for uninsured or out-of-network clients.

F. Marketing & Growth Strategy

- For POLs, promote in-house testing to patients and referring physicians.
- For small reference labs, develop relationships with healthcare providers, assisted living facilities, and clinics.
- Consider digital marketing and networking to attract new clients.

4. Moderate vs. High Complexity Testing

Moderate Complexity Testing:

- Examples: Automated analyses, some microscopy procedures.
- Requirements: Adherence to CLIA regulations, including specific personnel qualifications and quality assurance protocols.

High Complexity Testing:

- Examples: Cytology, molecular diagnostics.
- Requirements: More stringent regulatory standards, advanced personnel qualifications, and comprehensive quality systems.

5. Staffing Requirements

Moderate Complexity Testing:

- Laboratory Director: Minimum of a bachelor's degree in a relevant field and appropriate laboratory experience.
- Technical Consultant: Bachelor's degree in medical technology or a related science and at least two years of laboratory training or experience.
- Clinical Consultant: MD, DO, or DPM.
- Testing Personnel: High school diploma or equivalent and documented training in the testing performed.

High Complexity Testing:

- Laboratory Director: Doctoral degree (MD, DO, DPM, or PhD) in a relevant field with board certification, if applicable.
- Technical Supervisor: Master's degree in a chemical, physical, biological, or clinical laboratory science with at least one year of laboratory training or experience in high complexity testing.
- General Supervisor: Bachelor's degree in medical technology or a related science and at least one year of laboratory training or experience in high complexity testing.

- Testing Personnel: Associate degree in laboratory science or medical laboratory technology.

6. Cost Considerations

- Startup Costs: Equipment, licensing, facility setup, staffing, LIS.
- Operational Costs: Reagents, consumables, salaries, maintenance.
- Revenue Projections: Test volume, reimbursement rates, contract pricing.
- Break-even Analysis: Timeframe to profitability based on projected cash flow.

7. Key Takeaways

- A practice-owned lab is an excellent choice for clinics that want to streamline patient care and capture additional revenue.
- A small reference lab is ideal for entrepreneurs looking to serve multiple clients and offer specialized testing services.
- Both models require careful planning, regulatory compliance, and a strategic approach to billing and revenue management.
- Understanding reimbursement policies and payer contracts is essential for financial success.

Final Thought: Whether establishing a POL within your practice or launching a small reference lab, thorough preparation, regulatory adherence, and financial planning will be crucial to long-term success.