ovation

EBOOK

Five things to consider before starting a clinical lab

Table of Contents

1. Introduction
2. Funding
3. Test Selection
4. Equipment
5. Technology
6. Compliance Requirements
7. Adopting molecular diagnostics as an established clinical lab
8. About Ovation: The laboratory partner you need

Introduction

Establishing a clinical lab has the potential to be financially rewarding, but it can also be challenging. If you're considering starting one, you're certainly not alone.

The clinical laboratory space is expanding quickly. On average, the number of businesses in the U.S diagnostic & medical laboratories industry has grown 1.5% each year between 2016 and 2021. And it will likely continue to grow at a similar rate.

Interest in and utility for molecular diagnostics, in particular, has skyrocketed. The COVID-19 pandemic has created unprecedented demand for molecular diagnostic tests. Advancements in precision medicine, and the genetics field as a whole, have also contributed in no small part to this increased demand.

If you are looking to set up a clinical laboratory focused on molecular diagnostics, some major factors integral to its success must be carefully considered.

1 Funding

Funding is the starting point of nearly all business ventures. A molecular diagnostics lab requires a substantial financial investment to set up properly.

Securing a physical site, purchasing equipment, and hiring the first set of employees tend to be the most cost-intensive steps. And it's essential to plan how they'll be funded as early as possible.

There are different types of funding you can access. Each of them come with their own unique pros and cons:

Personal Funds

You can finance your startup molecular lab with your personal funds. This is probably the most accessible source of funding if it's available. Its advantages are notable. You retain full control and equity ownership of your lab. More, if you approach formal investors and institutions for additional capital in the future, it paints you in a positive light. Formal investors like to see that you have skin in the game.

But this type of funding comes with great risk. You risk losing your savings (or the portion you invested) completely. In reality, many lab owners combine personal funds with other sources of finance when starting.

Friends & Family

Seeking investments for your lab from family and friends can be a great way to get things off the ground. It could be in the form of a loan or funding in exchange for equity. Many startups go this route before eventually raising money from institutions or accredited investors. You get to retain full control of your company, but should the lab not succeed, it could place a strain on your personal relationships.

Loans

If your personal funds will not suffice — or you'd prefer not to touch them — and maintaining complete ownership of your lab is of great importance, then taking out a loan from a lending institution is an option.

Grants

The National Institutes of Health's Small Business Innovation Research (SBIR) and the Small Business Technology Transfer (STTR) programs offer grants for small businesses engaged in early/seed-stage research and development. Depending on the activities intended to be carried out, your lab may qualify. Non-governmental bodies such as foundations and patient advocacy groups also give grants to life sciences startups.

One major benefit of grants is that they do not dilute your equity in the business. And unlike loans, you do not need to pay them back. However, the application process for grants can be quite long and difficult, and there's no guarantee you'll get the funds. Auditing and maintaining accounts for grant organizations can be pretty burdensome too.

Venture Capital

You can secure venture capital (VC) funding to help start your molecular diagnostics lab. In exchange for funds for starting and running the lab, you will allocate equity ownership to the VC investors. Sometimes, VC funding agreements also come with terms allowing the investors to actively participate in the business's operations or to take a certain number of board seats. An advantage to getting venture capital is that, should the business not work out eventually, you do not have to pay back any of the funds they invested.

You're not limited to one funding source. You can decide to combine two or more funding sources to get your lab off the ground.

2 Test selection

Choosing the tests your new lab will offer should be a well-considered process. Your test menu will affect patient base demographics, operational workflows, instrumentation, billing, and revenue.

When selecting tests, here are some questions you should ponder:

? *Do you want your lab to be specialized in a particular medical field? That is, would you like to test for only infectious diseases? Only rare diseases? Only cancer? Only hematological diseases?*

OR

? *Do you want your lab to be generalist in nature and offer the most commonly needed tests across various specialties?*

? *How high is the demand for molecular tests in the area your lab will be situated. Are there particular tests more commonly ordered?*

These questions are vital because you need enough projected test volume to justify investing in equipment and staff to perform a test in your lab.

? *Who will be your primary target client? Will it be general physicians, specialists, clinics, or small hospitals?*

The test selection process is a critical one, so if you are not confident you are qualified to undertake it alone, you should consider hiring an experienced laboratory consultant to help.

3 Equipment

Preparation for purchasing equipment involves deciding what methodology your lab will adopt. For instance, many molecular labs choose real-time polymerase chain reaction (RT-PCR) over traditional PCR because it is faster, has better sensitivity and specificity, and has a reduced risk of contamination.

The methodology you choose will determine the equipment and instruments you buy. At the basic level, molecular diagnostics labs need most or all of these equipment and supplies below:

- DNA extractor
- PCR machine/thermocycler
- RT-PCR machine
- Gel electrophoresis equipment
- DNA sequencer
- Refrigerators and freezers
- Consumables such as buffers, gloves and tips
- Safety apparatus and supplies

Things you should take into account during equipment purchasing:

Vendor shopping

To get the best equipment cost-effectively, you should explore multiple options from at least 2 or 3 different vendors.

Alternative acquisition strategies

Aside purchasing new equipment outright, there is always the option to lease more expensive equipment or buy pre-owned. You can also create agreements with other labs to use their equipment for particular processes and tests. This might be useful for tests/processes you foresee won't be performed regularly.

Flexibility

Laboratory equipment and instruments continue to change year after year. To prevent your lab equipment from quickly becoming obsolete, you need to prioritize flexibility when acquiring them. Think modular equipment and infrastructure, for instance.

Maintenance

Having service agreements is essential to preventing unnecessary expenses and downtime, prolonging equipment life span, and making sure you always meet future compliance requirements. A service agreement typically covers the maintenance and servicing of instrumentation and equipment by the vendor. It specifies the level, frequency, and costs of care for these equipment.

4 Technology

Setting up and running a molecular diagnostics lab can be very complex, and the technology used behind the scenes can make or break it.

Laboratory Information Management System (LIMS).

To ensure the full cycle of lab functions are executed efficiently — and the movement of samples from the point of order to the final report is smooth — you need to implement a modern LIMS.

Without one, your running costs will be high off the bat, your new staff will be overburdened with manual labor, and it may be difficult for your lab to acquire and retain clients.

The LIMS you choose to manage your new molecular diagnostics lab should tick the following boxes:

1. Do its functionalities encompass order entry, order accessioning, processing, result validation, and reporting? ☐ YES ☐ NO
2. Can it grow and adapt with your lab? ☐ YES ☐ NO
   {Being cloud-based and having good connectivity to external platforms (such as EHRs and billing software) are signs that it can. Having the flexibility to let you modify and add new lines of tests is also another promising sign}.
3. Is it purpose-built for molecular diagnostics labs? ☐ YES ☐ NO
4. Will it deliver a seamless, user-friendly experience when clients place orders? ☐ YES ☐ NO
5. Will it streamline and simplify your sample processing operations to ensure turnaround times are as short as possible from day one? ☐ YES ☐ NO
6. Will it provide you with visibility into your lab performance to get actionable insights and grow your lab? ☐ YES ☐ NO
7. Does the company offer hands-on implementation support, and is their overall customer support superb? ☐ YES ☐ NO

To be confident you're choosing a suitable LIMS to embark on your laboratory business journey with, consider different options. Have the vendors run comprehensive demos for you, ask for testimonials/ case studies, and speak to other labs that are their customers.

You may also benefit from employing an experienced laboratory consultant.

Technology for other core business functions

Aside from molecular testing processes, your lab will have other core business functions that need advanced technology to run.

It would be beneficial for you to invest in leading billing/revenue cycle management software to ensure your lab's finances are managed properly; customer relationship management platforms to grow and maintain your new client base; and clinical interpretation tools to support your diagnostic report generation activities.

5 Compliance Requirements

Accreditations and regulations governing lab activities ensure quality control by allowing credible third parties to assess and certify your lab's ability to perform specific tests precisely, accurately, and safely. Accreditation also signifies to potential clients that they can rely on and trust your lab for their needs.

The Clinical Laboratory Improvement Amendments (CLIA) are federal regulations that serve as the primary governing framework for clinical labs in the U.S. Some labs also go further to acquire other accreditation certificates, such as from the College of American Pathologists (CAP) accreditation programs.

CLIA Certification

The Centers for Medicare & Medicaid Services (CMS) regulates all lab testing (excluding research) performed on humans in the U.S. via CLIA.

The only clinical labs not subject to CLIA standards are those that perform 'waived tests' — simple tests with minimal chance of error or risk. As this is not the case with molecular diagnostics tests, you should understand CLIA compliance thoroughly.

Here are some major requirements you need to be aware of:

- All lab workflows and standard operating procedures in your lab must be documented to meet CLIA regulations.
- Your lab will need at least two CLIA certifications. The Certificate of Registration is issued to permit labs to conduct moderate or high complexity tests until they are determined to comply with the CLIA regulations. And then the Certificate of Compliance, which is issued to labs after they've been inspected and found to be in compliance with all applicable CLIA requirements.
- The staff you hire for the lab must have the proper credentials and certifications needed to uphold the stipulated CLIA standards. The CLIA specifies the roles and responsibilities of lab personnel.
- Finally, you should look into local and state regulations as they may require additional compliance steps.

A good way to ensure that your new lab is compliant at all times is to hire solid management personnel. They are the ones who'll be in the best position to ensure adherence, accuracy, and quality control in the lab.

Adopting Molecular Diagnostics as an Established Clinical Lab

Are you thinking of adding a molecular diagnostics unit to your lab? In light of the COVID-19 pandemic and many advances in precision medicine, adding molecular testing to your lab's menu could be very lucrative.

At this stage, your lab is already CLIA certified, you have standard lab infrastructure, and you've learned how to successfully staff lab technicians, so you're not starting from scratch.

However, there are still a few matters you should consider before embarking on this expansion.

- You will need to hire new personnel with experience or specialized training in molecular pathology. This includes but is not limited to a unit director, a supervisor, and a technician.
- You will also need to purchase new equipment, instruments, and supplies designed specifically for molecular diagnostics.
- Training staff on new test offerings and how to sell your services to different market segments will also be critical.
- And you will need to engage in marketing and awareness campaigns to let your client base and the public know that you now offer molecular testing services.

All of these — hiring, purchasing equipment, training, and marketing — require a substantial investment. You can re-invest revenue from your lab or source new funding from lending institutions, venture capital firms, or grant organizations.

Ovation

The Lab Partner You Need

Ovation is the laboratory partner you can rely on at all stages of your lab's growth.

We understand the needs and challenges of new molecular diagnostics labs, and our expert team is always available to help your lab excel in every sphere. We go beyond supporting your lab in using our lab management platform. Our consultative team sets you up for success to win and keep more business today and in the future.

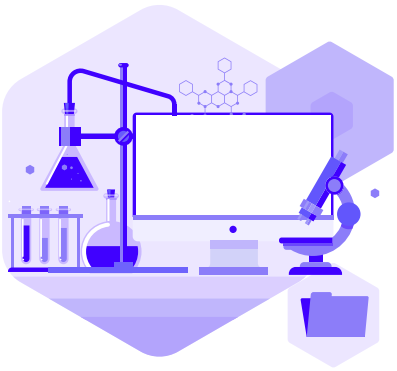
Ovation was selected because it was an organization that we could grow with. Their LIMS was agile enough to suit our needs with the testing we were doing at the time, and we knew if the business pivoted in any way, we could leverage our partnership with Ovation to succeed. Ovation was definitely instrumental in switching with us to address the needs of the community during the pandemic. They were with us hand-in-hand, 100% of the way.

William Dutton
Lab Systems Admin/Project Manager

geneIQ INTELLIGENT TESTING

About Ovation LIMS

Startup molecular labs use Ovation LIMS to speedily get their businesses up and running the right way—with efficient and adaptable workflows from day one. With it, you'll meet and exceed your clients' needs and establish yourself as a convenient, reliable source for testing.



What it delivers:

- Molecular diagnostics-specific features
- Excellent connectivity with leading EMRs, RCM platforms, and clinical interpretation platforms
- A high level of customizability
- Hands-on implementation
- Ongoing personalized support and training

"With Ovation, we have a LIMS system that makes us stronger in the market and helps us truly make a difference. It's just like no other."

Grady Phillips, President
PCR-Dx DIAGNOSTIC