



In-depth Discussion Regarding In-house Testing

If you are considering bringing your laboratory testing in-house, there are many factors involved in making such a decision. Before embarking on this process, here are a few things to consider. First, discuss your situation with your current external lab. If you have a good relationship with them, they will surely want to keep you as a customer. You may discover you can reduce costs and/or modify service to achieve your goals without having to establish an in-house lab.

If working with your current lab does not achieve your goals you will want to evaluate the pros and cons of the internal or in-house lab.

There are two basic categories of costs: 1) intangible or potential costs (including risk costs), and 2) actual or measurable costs.

Let's review some of the intangible or potential costs first. The most important are 1) liability, 2) capacity limitations for upside and downside production levels, 3) optimum utilization of assets, 4) sickness, vacation, or termination/resignation of your technician(s), and 5) priority conflicts.

- 1) In these litigious times, liability should always be a primary concern. Liability would result from a quality control accident where (possibly) contaminated product was shipped. You must protect yourself from litigation that might result from such a problem. There are four primary reasons why relying on an external lab can minimize that liability.
 - I. An external lab strengthens your defense by eliminating possible conflict-of-interest arguments.
 - II. You will benefit from the liability insurance the external lab already has in place without having to pay for your own additional insurance coverage.
 - III. The external lab will reduce the likelihood of a quality control accident. It has experienced scientists and technicians with established procedures as well as Federal and State certifications to

ensure maximum accuracy and consistency of their testing. The only reason for a testing laboratory to exist is to do testing; it necessarily has to be a core competency. Ask yourself if you can—or how quickly you can—internally establish that level of competency.

IV. The potential risk of your in-house lab being the SOURCE of a quality issue. If you bring pathogen testing in-house, your lab is now a possible source of contamination. The purpose of microbiological testing is to create environments where bacteria will not only grow but will actually thrive. Extreme caution must be exercised from growth to disposal.

- 2) An upturn in business could place demands on your internal lab such that it could not handle the load and would necessitate having to outsource the overflow. This would reduce the benefits of the internal lab as well as create additional work. On the other hand, if business turns down, your fixed costs would remain the same so that per-sample testing costs would increase, possibly to the extent that the internal lab testing costs would be higher than those of an external lab.
- 3) Situations may arise where your investment in the lab (inventory, equipment, personnel, and floor space) could limit production/sales growth. You may have financial, physical, and personnel resources committed to your lab that would complicate or possibly prevent expansion plans.
- 4) Consider the impact on quality of testing and productivity when one of your technicians goes on vacation, gets sick or injured, or leaves your company. Any of these occurrences would increase the possibility of a quality control accident. At the least, shipments could be held up pending delayed testing results. If your plant operates seven days a week, you will need to provide for testing capability over weekends since bacteria grow



continuously. At least two lab technicians will be necessary to achieve this and may add inconvenience and certainly cost. (Finding a technician willing to work seven days a week may be difficult.)

- 5) If you decide that your technician(s) will have testing responsibilities as well as responsibilities from some other area, situations may develop where responsibilities will conflict and one task or the other may not be adequately covered. An example of this could be when a technician has lab responsibilities as well as production duties. He/she might need to verify test results and at the same time also ship product creating a potential conflict.

As you can readily see, if any of these occur the impact on your business could be huge. Keep in mind this impact can be either eliminated entirely or greatly diminished by utilizing an external lab.

Determining actual dollar costs of an in-house lab is much simpler. These can be separated into startup costs and operational costs. Some important startup costs follow.

1. Many companies want to build inside their production facility because it is most cost-effective. If you want to do pathogen testing, your startup will be more complicated and expensive. The industry strongly discourages pathogen testing inside a production facility due to possible cross-contamination between production areas and the lab area. If you choose to do so, the design of your lab must restrict personnel access and provide substantial environmental isolation.
2. You will need to determine your desired tests. Then the equipment and supplies to conduct those tests will need to be ordered, set up, and qualified. If your lab will be internal it is likely you will have fewer and more costly tests to choose from to help prevent contaminating your production facility.
3. Personnel will need to be found, interviewed, and hired. Existing



employees will need training.

4. Tracking and documentation systems will need to be evaluated and purchased. A Quality Assurance plan to comply with Federal HACCP requirements will need to be developed.

Operational on-going costs are more easily quantified.

1. Direct testing costs, such as labor (including benefits) will be a significant cost portion. Costs for technician and administrative time to conduct required testing and complete necessary documentation as well as ordering and maintaining supplies can be calculated. An experienced technician will cost more than a cross-trained line worker but due to liability concerns mentioned previously, training someone from production or administration is not recommended. Cross-training an experienced technician for other responsibilities may ultimately increase the costs of labor for those other functions and will create the potential for conflict as mentioned in 5) above.
2. Consumable supplies will be an ongoing cost as well as the costs of hazardous waste disposal.
3. Costs (lights, heat, water, etc.) of the portion of the building in which the lab is housed. If your lab is located inside your plant, your lab cost may be reduced from actual costs of a lab located outside, but either way the lab has definite costs which can be calculated.
4. There will also be other fixed costs, including depreciation of the building and equipment, as well as potential scrapping costs of expired time-sensitive test kits and supplies.



Upon completion of your analysis you may learn that your company *could* reduce testing cost by establishing an internal laboratory. However you may realize that those savings are more than offset by including the potential impact of intangible costs and risks.

In summary,

- An external lab will share and limit liability that might result from a quality control accident.
- Using an external lab will save precious internal resources and control or fix testing costs.
- You will be relying on experienced, college-trained scientists to conduct your testing.

Discuss your specific situation with your current laboratory and enlist the laboratory's support in reaching your goals. If your current lab cannot meet your goals, consider contacting other labs in the area to see if they have the flexibility and capability to meet your specific needs.

Protect both your quality name and your bottom line by utilizing an experienced, qualified independent laboratory for your testing needs.