Choosing an Analytical Lab

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developed in cooperation with the Analytical Laboratories Committee of the American Herbal Products Association (AHPA)

Before you purchase a consumer good, professional tool or service, it helps to identify what you need. Identifying what you need from an analytical lab will set you on course toward your identified goal.

Contract laboratories can provide an extensive—if not amazing—variety of services. Contracting for analytical lab services can be a very cost effective way to, among other things, test for product identity, quality and stability; help guide purchasing decisions; and help develop claim substantiation and label information.

It may be obvious, but it is often not recognized that different analytical labs have different areas of expertise. If you require only microbiological testing, then the services of a food lab may be sufficient for your needs. However, be sure that the lab has experience in testing dietary supplements or pharmaceuticals as the methods for some tests vary widely.

Testing for pesticide residues is often done at food labs and certainly in laboratories that specialize in environmental testing. However, environmental labs specialize in Environmental Protection Agency (EPA) methods for items such as soils and sludge. Food and environmental labs that do pesticide residue analysis are familiar with materials that have a high moisture content. If dried botanical materials are tested only with methods validated for standard food crops, the data may be in error.

Your search for an analytical laboratory partner should start by identifying your needs. Once you have clearly identified the project and the types of assays required, you can compare this to what different labs offer. You may need help with raw material identification for purchasing or routine quality assurance (QA) purposes; your identification requirements may be different for these two functions. Perhaps you would like to quantify marker compounds, test for heavy metals or have a bioassay performed to assess potency. Or perhaps you have completely different needs. Whatever your analytical requirements are, it is a tremendous help if you are able to determine whether your needs match the services offered by a particular laboratory.

Custom work can add another dimension to your search. If you require custom work, it is even more important to conduct a careful search because not every lab provides this service. Many just do routine analyses. If you need help determining what your specific requirements are, you will either need to obtain in-house expertise to guide you, speak with a qualified consultant or find a lab that is customer service oriented enough to take the time to understand your needs, determine how it can help you meet those needs and explain testing results to you. It is reasonable that such a lab may justifiably expect to receive compensation or considerable business while acting in such a capacity.

Choosing a Lab for Analytical Analyses

Obviously, analytical labs do analytical testing; however, the quality of work between labs may vary. Just as quality guidance is an invaluable manufacturing tool, the same orientation and review are important to analytical labs.

A good analytical laboratory should have a quality control (QC) manual. When selecting a lab, ask whether it has such a manual and request to see an outline of the manual or a table of contents. Unless you are doing a site audit, labs are not likely to send their entire QC manual. Ask whether the particular method you are considering having them use has acceptance criteria. Ask whether the data will be QC reviewed. Beware of advertisements claiming Food and Drug Administration (FDA) or EPA laboratory certification. Contrary to popular advertisements, there is no such thing as an FDA approved or certified laboratory. While labs may be certified or accredited by EPA under various state programs, few, if any, of these programs have a direct bearing on analysis of dried botanical materials.

If you ask a potential lab partner whether it follows Good Laboratory Practices (GLPs), be aware GLPs apply to a limited scope of animal, drug and environmental testing. There are not yet established GLPs for dietary supplement testing. The best situation is finding a lab that modeled its quality program on GLP protocol. GLPs are designed for studies where a study director is involved, not as much for routine

The Top 10 List of What To Ask Your Lab

1. Do you have an independent quality assurance (QA) department? Is your lab accredited with any organization? If so, which one(s)? Do you follow any published standard of good laboratory practices?
2. What information can I provide that will be helpful in the analysis of my product?
3. Will any of the sample testing be outsourced to another lab?
4. Please describe how you handle samples from the time of receipt, through lab analysis, report issuance and data archiving.
5. Do you have written procedures and schedules for instrument and equipment maintenance and calibration? If so, how can you substantiate this?
6. Do written valid test methods exist for the sample analysis? Do you disclose to the customer upon request the test procedures and methods your lab uses? How do you assure the test result(s) is both accurate and precise?
7. How much experience does your lab, and the analyst working on the sample, have in dealing with this analyte and matrix?
8. Do you record raw data in bound books (laboratory notebooks) or in other laboratory information systems? Is there a way to track a final report to the original raw data? What is the time period for retaining raw data and will you provide such data upon request?
9. Based on your experience with this test/matrix and the current lab workload, do you anticipate on-time delivery of the results?
10. If I receive unexpected results, what policies and procedures do you follow to assure those results are valid?

analysis. If you are interested if a lab is ISO 17025 certified, you should know ISO 17025 certification is on a per-method basis. If the lab has ISO 17025, ask for which methods.

You can also ask whether a lab is audited and request a copy of a recent audit. However, most labs are probably not willing to send volumes of confidential data about their facility to anyone who calls. Don't expect a lab to fill out a huge questionnaire or submit to a site audit if your company will only submit a few samples for it to analyze in a limited project. Clients that have ongoing contracts for analysis with a certain annual financial commitment often audit labs. A lab may request a letter of intent or contract conditional on completing an audit in which you agree to a certain testing volume.

For example, as a contract manufacturer, would you send a prospective client your SOPs, batch records and other confidential information when that client might not even use you? Would you spend hours filling out forms for a $200 job? It is important to keep a balanced perspective when evaluating labs. If a lab is completely unwilling to work with you, that should raise suspicion. The lab director or quality assurance (QA) officer should be able to answer basic questions regarding analytical protocol and QC issues.

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Because you are paying for information that you may wish to independently verify, ask whether the lab's method of analysis is available and if it includes information sufficient for another lab to duplicate its test. Important questions are whether the method is written, where it came from, and whether it is validated and to what level. If it originated from an official compendium, has it been modified? Ask in advance if the lab is using a proprietary or licensed technology for a particular analysis. Even if the method is proprietary, the lab should be able to provide you with a method summary. Don't expect labs to hand you a copy of every SOP or method just because you call them. Remember, labs spend a great deal of money on method development and need some control over the use of proprietary technologies. However, there should be a balance in the handling of this information with prospective clients.

Ask whether the raw data will be available for review. This information may include chromatograms, data points and calculations. Most labs can provide a sample of a similar analysis they have done and explain the significance of the data. While it is not appropriate for labs to show work done for other clients if the lab follows a confidentiality protocol, the lab should at least be able to show a control sample or calibration chromatogram if not some work they have done on similar material. Labs charge a fee to run routine analysis and if they have to get too involved in an educational aspect of the analysis, they might need to be compensated. Taking up an hour of a lab person's time can consume all of a job's profit. In contrast, labs should be willing to spend some time with customers to ensure they understand the testing and answer basic questions.

Rating Customer Service

General impressions are important. When contacting a lab, start your determination of overall customer service. It is important to determine standard turn around time and any charges for rushed items. Find out whether they can provide an interpretative consultation of your test results for no extra charge. If you are planning a long-term project with a lab, it should be willing to spend time with you at no cost for a preliminary meeting. However, expect to pay consulting charges if you take up several hours of time from key personnel in the initial meeting or through the course of the project. Customer service is very important. Before you submit samples, make sure the lab has addressed your questions or concerns.

Discuss to what extent the lab stands behind its work. Will it hold up in court should that become necessary? If this a real concern, ask what steps the lab takes and whether it would appear to testify if asked (and appropriately compensated). If you do a site visit, note whether the lab appears to be well organized and whether the technicians appear to be paying careful attention to their work. Find out if they are trained for the work they are performing and if they are adequately supervised by more experienced personnel. It is extremely helpful if you have someone with adequate science training to interface with the lab. Don't expect a lab to teach you all the ins and outs of the field without paying for it. When shopping for technical services, it helps to have someone on your side with technical knowledge.

Other important considerations include the lab's experience with the sample matrix you are providing and whether it follows a chain of custody (COC). Labs should have some type of sample control and tracking, but strict COC is not well defined. There are different types of COC records a lab might use. The priority is whether the lab has records of the sample's travel and storage conditions, as well as records of who had custody of the sample, why they had it and for what period of time they had it. If you are providing a lab with methods and standards, ascertain whether they will be kept confidential and not used in other work that they may conduct.

Some labs may send samples out for analysis on testing they were contracted to conduct. This "subcontract testing" is sometimes unfairly frowned upon. The important point is to know you are dealing with people who can verify the testing results and that those results will be accurate and precise. A reputable lab will inform you in advance if any aspect of your project will be sent out to another lab. The originating lab should have some idea of the other lab's expertise either by an audit or check samples.

Laboratories should have security systems in place at several levels to prevent unauthorized access to equipment and data. This should include physical access control, network security and employee security policies. Ask the lab about these issues. Be sure the lab is taking precautions to protect data that may be mission critical to your company.

By knowing your needs and comparing them with the abilities of different labs, you are likely to find a match. Delving deeper into what a lab does and how it does it will make you an informed consumer who is more likely to be satisfied with services received than someone just shooting in the dark. ❑

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