ChromaDex®

Tech Tip 0007

Does Your Contract Testing Lab Pass the Test?

There are many contract testing labs competing for your business. How can you be confident that the data you pay for is accurate, precise, and meets cGMP requirements? If your contract manufacturer is performing tests on your product, you will need to ensure the quality and cGMP compliance of their lab as well.

It is up to you to put your contract lab to the test. Here are some key questions you should ask:

Q. Do they offer full method and data disclosure for the analysis of your sample?

A. Transparency of analytical test methods is important in establishing the scientific validity of analytical data as required by the Dietary Supplement cGMPs (21 CFR Part 111). Access to full method and data details are critical in complying with cGMPs and in resolving out of specification test results with raw material vendors. ChromaDex® offers an Analytical Test Report (ATR) which details the full sample preparation procedure, analytical testing method, data, and results. HPLC and GC ATRs include the chromatograms while HP-TLC ATRs include the plate images. Alternately, the basic Analysis Results Sheet (ARS) is also available for routine testing. Complete documentation of the test method used for a given analysis is a crucial part of your quality system files.

Q. Have you sent them dummy test samples to check their results?

A. One way to double check your contract lab is to send them dummy test samples. We suggest that you send dummy samples with either no stated specification or a purposefully misstated specification to check their results on an occasional basis. This will let you verify the validity of the data they are reporting and it's a straight forward way to detect fabricated results often called dry-labbing. ChromaDex welcomes our clients to send us such dummy samples. Although we ask clients to indicate an expected range of results to aid our sample preparation process, specifications are not required.

Q. Is your testing lab ISO 17025 accredited?

A. ISO is the International Organization for Standardization that develops and publishes International Standards. ISO/IEC 17025 is their general requirements for the competence of testing and calibration laboratories. Such accreditation recognizes the laboratory's ability to perform the test method specified and care should be taken to check the test method details regarding any laboratory's ISO 17025 accreditation as it is method specific. One very important aspect of an ISO 17025 registration is it demonstrates that the accredited laboratory has a full functioning quality system in place. ChromaDex received ISO 17025 Accreditation per ACLASS certificate # AT-1816 in October 2013.

Q. Do they have the appropriate testing equipment required for your analysis?

A. Certain assays require very specific equipment for proper data confirmation. For instance, P57 in Hoodia requires HPLC analysis with MS detection for identity confirmation. ChromaDex is equipped with HPLC, GC, MS, UV, IR, NMR, and HP-TLC testing capabilities. The equipment is maintained and calibrated regularly to ensure the accuracy of your data. For more details on our equipment capabilities please see our Laboratory Versatility flyer.

Q. Do they use fully characterized reference standards?

A. The accuracy of HPLC and GC purity analysis is only as good as the reference standard used to quantify the test sample against. ChromaDex reference standards are

Does Your Contract Testing Lab Pass the Test?

characterized by a series of analytical techniques that determine chromatographic purity, water and residual solvent content, along with mass (MS) and structure (NMR) confirmation. These analytical techniques provide the essential data needed to accurately determine reference standard identity and adjusted purity. Reagent grade chemicals and fine chemicals are not reference standards and are not suitable for quantitative purity and potency analysis without further testing. If your contract lab uses inappropriate reference standards, your results could be inaccurate by 20% or more regardless of other sources of analytical error. ChromaDex is the leading provider of reference standards in the industry and we use only properly qualified reference standards in analysis.

Q. Do they use Laboratory Control Standards?

A. Laboratory Control Standards are an important quality tool that helps ensure method stability and reproducibility. ChromaDex tests a Laboratory Control Standard alongside all samples being analyzed to ensure the method is performing properly and the results are accurate. The Laboratory Control Standard results are placed on control charts to insure method consistency. Your contract laboratory should be able to outline their systems for quality assurance of analytical methods.

Q. Do they use appropriate reference materials for botanical identity testing?

A. 21 CFR Part 111 requires that all components used in the production process must have their identity verified. Botanical identity verification is often performed via HP-TLC analysis in which case an appropriate method and reference material must be used. ChromaDex is a leader in the development and supply of Botanical Reference Materials (BRM) and we ensure that all tested samples are compared to both the appropriate BRM and reference standard/s and also use state-of-the-art HP-TLC equipment and techniques. Additionally, ChromaDex offers a full line of verified BRMs along with our analytical Reference Standards for your in-house testing needs.

Q. Have you visited their facility? What did you see?

A. Running an analytical testing lab takes resources, equipment and skilled personnel. From sample receiving to sample preparation to performing the analysis itself, analytical labs should have documented procedures with a number of qualified people involved. Your lab should welcome you for a visit and quality audit of their systems. Key points to observe are the number of employees, suitability and age of their testing equipment, calibration and maintenance procedures, and established quality assurance procedures. If equipment is not plugged in and running or there are only a few personnel working, it should raise a red flag. ChromaDex welcomes all of our clients for a quality audit at our Boulder, Colorado site.

Q. Are you assigned a dedicated technical account manager?

A. Having a single point of contact for technical questions and sample submission will make your job easier. ChromaDex employs a staff of specialized Technical Sales Representatives all of whom have science backgrounds and have completed an extensive internal training program. Your Technical Sales Representative will be your key contact, assist you in completing and reviewing all sample submission paperwork, and be able to help you choose the appropriate testing for your needs.

Q. Do they provide extended custom services beyond contract testing?

A. Choosing a full service lab capable of method development and validation services can be an important advantage. ChromaDex is a full service provider of contract testing services, bioassays, reference standards and botanical materials, custom chemical isolation, test method development and validation, label claim review and quality system consulting. We can assist you every step of the way from performing your testing to helping you bring your testing in-house.

Q. Do they carry professional liability insurance?

A. ChromaDex is fully insured with Professional Liability Error and Omissions insurance of $2MM as well as product insurance of $5MM. This is a key feature that helps to protect your company in the case of errors, omissions, etc. especially useful if you face litigation from your customer.

10005 Muirlands Blvd., Suite G • Irvine, CA 92618 • Ph: +1-949-419-0288 • Fx: +1-949-419-0294
Em: sales@chromadex.com • www.chromadex.com