



Guidance for Holistic Practitioners The Use of Laboratory Testing

For decades the world of laboratory testing was reserved for only licensed medical providers, hospitals, and laboratories. In just the past few years, there has been a fundamental shift in the marketplace. Access to new innovative health and wellness laboratory testing is now available to holistic practitioners and the public.

Though it is called many things, the core concept is the same; rather than a licensed physician ordering a test for a patient; holistic practitioners and consumers can purchase a laboratory test directly from a digital health, or online lab company (or company representative/affiliate). Consumers pay for the test up-front and receive the results directly. This new model is in stark contrast to the healthcare processes and systems that have been in place for decades.

There are several reasons for the increased use and popularity of direct-to-consumer testing. A combination of new commercially available laboratory tests, reduction of laboratory testing costs, and marketplace/consumer friendly regulations have made the world of health and wellness laboratory testing available to more people.

Although, there is increased marketplace availability there are still critical safeguards, and practices practitioners need to incorporate to reduce a variety of risks to them and their businesses.

Practitioner Guidance:

- The Holistic Council is not aware of any regulations that prohibit holistic practitioners from engaging in the use and utilization of consumer-initiated lab testing.
- The FDA, FTC, and state regulators *will* consider even low-risk general wellness tests to be medical devices and the practice of medicine if the test or practitioner claims to, treat, cure, or mitigate, or diagnose diseases.
- Regulators consider *claims* to be any content posted to websites, social media, or in marketing materials. Note: Even comments left on social media by clients can be considered a “claim.” Be mindful and be sure moderate social media postings.
- Practitioners need to ensure their clients understand that holistic practitioners/practices/and even the use of testing is not medical treatment, and that holistic practitioners are not licensed medical providers. Utilize the disclaimer language often provided by your educational program, testing companies, and recommended by the support services available to the holistic community. Generally, disclaimer language consists of these elements.

- The information (the test/company provides) is for educational and informational use only.
 - The information is not intended to be used by the customer for any diagnostic purpose and is not a substitute for professional medical advice.
 - Customers should always seek the advice of their physician or other healthcare providers with any questions they may have regarding the diagnosis, cure, treatment, mitigation, or prevention of any disease or other medical condition or impairment or the status of their health.
 - The services and guidance provided by the holistic practitioner is not medical treatment.
- Practitioners *can provide* education and guidance on laboratory company provided materials regarding the proper use of the tests. Practitioners *should not* engage in the collecting, handling, or shipping of client specimens needed for laboratory tests.
 - So as long as, tests are widely available for purchase by the public, we are not aware of any regulations that limit a practitioner's ability to resell tests or purchase tests on behalf of a client. It is advisable to be aware of and follow the testing company's affiliate policies and procedures.
 - When working with clients and lab testing, practitioners *should use* wellness focused terms such as support, guidance, coaching, education, improving health and providing insights and information. Practitioners *should not* use terms generally reserved for medical professionals such as "run tests", "order tests", "interpret test results", "diagnostic test", "patient."
 - Generally, the advertisement, recommendation, education, and marketing of commercially/publicly available laboratory tests is not prohibited. Practitioners should be mindful and utilize the language and materials approved by the testing company.
 - Direct-to-consumer testing is largely not available for purchase in New York. Some testing companies may have limited availability in certain states. Check with individual the testing company for more information.
 - Holistic practitioners and their clients should seek lab services that are available to the public and with lab companies familiar with non-licensed practitioners.
 - It is important for practitioners to develop privacy and record keeping procedures to ensure their clients' information is safe.
 - Whether working in a medical practice, employee wellness capacity, running their own health coaching or nutrition business, practitioners can provide crucial education, information, guidance, and recommendations to their clients about lab testing.
 - Consumer initiated lab testing provides meaningful information that empowers the individual to make positive lifestyle changes. Holistic practitioners can help guide that revolutionary process.