Department Of Health
Health Systems Quality Assurance Division
Washington State Board of Naturopathy
Policy Statement

Title:	Laboratory Medical Tests in Naturopathic Practice – Specifically the Bolen Blood Procedure and the Carroll Food Intolerance Evaluation	Number: BON 14-01
Reference:		
Contact:	Susan Gragg, Program Manager	
Effective Date:	February 28, 2014	
Supersedes	N/A	
Approved	(signature on file)	
	Mark Monwai, ND, Chair, Board of Naturopathy	

PURPOSE

To clarify the enforcement and regulatory boundaries related to licensed naturopathic physicians and licensed clinical laboratory medical test sites.

BACKGROUND

In 2011, the Washington State Office of Laboratory Quality Assurance (LQA) cited a naturopathic clinic in Spokane for conducting live blood cell analysis for which it was not licensed. The specific procedures identified were the Bolen Blood Procedure[1] and the Carroll Food Intolerance Evaluation[2], which are not considered by this board as live blood cell analysis.

The clinic director, who is a licensed naturopathic physician, appeared at the November 4, 2011, Board of Naturopathy (board) meeting to ask the board about proper jurisdiction in prohibiting statutorily designated naturopathic scope of practice, specifically "common diagnostic

[1] The Bolen Blood Procedure uses a finger lancet and five to six drops of blood are placed on a clean slide to dry (no reagents are used in the slide preparation). When dry, the slide is then observed under a microscope to detect blood vitality.
[2] The Carroll Food Intolerance Evaluation uses a finger lancet to collect a dime-size circle of blood on a piece of absorbent paper, which is put into a small envelope and placed upon the patient's forehead. A glass rod is used to locate acupuncture point "Stomach 25" on the abdomen, which then interacts with skin current to produce a "tug" (an electro-magnetic response, a normal "positive"). Food samples in glass containers are then placed on top of the envelope and if the food is incompatible to the patient, a negative skin response occurs (no "tug" effect).

procedures" (RCW 18.36A.040[3] and 18.36A.020(2)[4]). The LQA Program Manager attended the May 11, 2012, meeting to provide the board and the clinic director with information on federal requirements for performing in-office blood tests.

ANALYSIS

The federal Food and Drug Administration (FDA), through the Clinical Laboratory Improvement Amendments (CLIA) regulate laboratory testing. Washington State has been granted approval as a laboratory licensure program because it meets or exceeds the federal requirements. The exemption allows LQA to respond locally to questions and provide training and technical assistance to new and existing laboratories; something the federal program is not able to provide.

Washington's LQA monitors and evaluates medical test sites for compliance with minimum standards of quality assurance for clinical laboratory testing. LQA regulates all clinical laboratory services in Washington through their Medical Test Site licensure program. Being an approved program allows laboratories in Washington State to be free from CLIA oversight, so long as LQA continues to meet or exceed federal guidelines.

There are certain areas, however, that LQA does not have jurisdiction. One of those areas is the categorization of medical tests. This rests with the FDA and the Centers for Medicare and Medicaid Services (CMS). Laboratory medical tests are categorized as one of three designations: waived[5]; moderate complexity[6]; and high complexity[7]. If a specific test has not been specifically designated as waived or moderate complexity, it is automatically considered high complexity. The federal citation about the categorization process and the FDA responsibility can be found at CFR 493-17[8].

The Bolen Blood Procedure is used as a screening tool, not as a diagnostic test. The blood collected for the Carroll Food Intolerance Evaluation is not looked at under a microscope. However, whenever an analysis is performed that uses a specimen obtained from the human body, it falls under CLIA regulations and is subject to clinical laboratory licensure.

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[3] RCW 18.36A.040 – Scope of Practice. The practice of naturopathic medicine includes manual manipulation (mechanotherapy), the prescription, administration, dispensing, and use, except for the treatment of malignancies, of nutrition and food science, physical modalities, minor office procedures, homeopathy, naturopathic medicines, hygiene and immunization, contraceptive devices, common diagnostic procedures, and suggestion; however, nothing in this chapter shall prohibit consultation and treatment of a patient in concert with a practitioner licensed under chapter 18.57 or 18.71 RCW. No person licensed under this chapter may employ the term "chiropractic" to describe any services provided by a naturopath under this chapter.

[4] RCW 18.36A.020(2) "Common diagnostic procedures" means the use of venipuncture consistent with the practice of naturopathic medicine, commonly used diagnostic modalities consistent with naturopathic practice, health history taking, physical examination, radiography, examination of body orifices excluding endoscopy, laboratory medicine, and obtaining samples of human tissues, but excluding incision or excision beyond that which is authorized as a minor office procedure.

[5] Waived tests pose no reasonable risk of harm if performed incorrectly, employ methodologies so simple and accurate as to render the likelihood of error negligible, and are cleared for home use.

[6] Moderate complexity tests have 2 categories: 1) Provider Performed Microscopy are tests performed by a physician or mid-level practitioner during the patient visit, have been designated moderately complex, use a microscope, and have limited specimen handling; and 2) most automated tests that don't meet the waiver criteria.

[7] High complexity tests are non-automated tests, nontraditional tests, or any test not otherwise designated (i.e. if a test has not been designated waived or moderate complexity, it automatically becomes a high complexity test).

[8] Full web address is: https://www.federalregister.gov/articles/1995/05/15/95-11653/specific-list-for-categorization-of-laboratory-test-systems-assays-and-examinations-by-complexity

Under the LQA licensure program, medical test sites are either issued a certificate of waiver, which allows them to perform all waived tests, or issued a license to perform either moderate complexity tests or high complexity tests.

A person using a finger lancet in a home setting (such as blood glucose levels) would not fall within the CLIA regulations; a health care professional collecting blood, in any manner, in an office setting does. The person in a home setting is performing self-monitoring activities. With a health care professional, there is an expectation of an evaluation, assessment, or analysis, which falls under the CLIA regulations.

Washington's LQA contacted representatives from the FDA and the national director of the federal CLIA program, who stated that the Bolen Blood Procedure and the Carroll Food Intolerance Evaluation are considered highly complex and as such, are subject to all high complexity regulations of test validation, personnel, inspection, and proficiency testing.

The process for how testing can be reviewed and added to the list of approved in-office testing procedures involves submitting the test to the FDA for a 510K review and CLIA test categorization. Information on this process can be found on the FDA website[9].

CONCLUSION

The board recognizes the confusion and it is the board's goal to provide, through this policy statement, clarification to practitioners on the jurisdiction authority between naturopathic scope of practice and clinical laboratory medical tests.

The Washington State Legislature has granted the Board of Naturopathy (board) the authority to protect public health and safety by regulating the competency and quality of licensed naturopathic physicians. The board establishes and enforces qualifications for licensure and consistent standards of practice.

The Washington State Legislature has granted the Office of Laboratory Quality Assurance (LQA) the authority to monitor and evaluate medical test sites for compliance with minimum standards of quality assurance for clinical laboratory testing.

The board governs what naturopathic physicians can do (to include performing laboratory tests) and, as an approved program, LQA governs how those laboratory tests are done based on federal CLIA laws.

The board considers the Bolen Blood Procedure and the Carroll Food Intolerance Evaluation to be fully within the scope of practice for naturopathic physicians. However, the board recognizes the LQA's authority with regard to how those tests are performed in a health care setting.

[9] Full web address is: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070762.htm