Assistant Lab Director, CLIA, Clinical Chemistry Certification – TX

Overview:
The CLIA Laboratory Director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations.

Technical Supervision Responsibilities

1. Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed
2. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing
3. Monitoring the recording and reporting of test results
4. Direct observation of performance of instrument maintenance and function checks
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples
6. Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens

General Supervisor Responsibilities

1. Must be accessible to test personnel at all times. Testing is performed to provide on-site, telephone or electronic consultation to resolve technical problems in accordance with policies and procedures established either by the laboratory director or technical supervisor
2. Is responsible for providing day-to-day supervision of high complexity test performance by a testing personnel qualified
3. Is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained
4. Oversees the quality system and quality management program with the direction of the quality affairs director

Requirements

1. Is available to provide consultation to the laboratory's clients
2. Is available to assist the laboratory's clients in ensuring that the ordered tests are appropriate to meet the clinical expectations
3. Is available for consultation and communication with the laboratory's clients on matters related to the quality of reported test results and their interpretation concerning specific patient conditions
4. Ensures that reports of test results include pertinent information required for specific patient interpretation
5. Proficient in CLIA and CAP regulatory requirements
6. Minimum of 5 years acting as an assistant laboratory director
7. Experience in test assay development and validation following CLIA and CAP LDT guidelines
8. Experience, not mandatory, with FDA test validation

Qualifications

The laboratory director must hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution and be certified and continue to be certified by a board approved by HHS.

1. The current approved boards are the following:
2. ABB – American Board of Bioanalysis
3. ABB public health microbiology certification
4. ABCC – American Board of Clinical Chemistry
5. ABFT – American Board of Forensic Toxicology (limited to individuals with a doctoral degree with Fellow status)*
6. ABHI – American Board of Histocompatibility and Immunogenetics
7. ABMGG – American Board of Medical Genetics and Genomics (formerly known as American Board of Medical Genetics (ABMG))
8. ABMLI – American Board of Medical Laboratory Immunology
9. ABMM – American Board of Medical Microbiology
10. NRCC – National Registry of Certified Chemists (limited to individuals with a doctoral degree)*

About Aspira Women's Health Inc.

Aspira Women's Health, Inc. (formerly known as, Vermillion inc., Nasdaq: VRML) is transforming women's health with the discovery, development, and commercialization of innovative testing options and bio-analytical solutions that help physicians assess risk, optimize patient management and improve gynecologic health outcomes for women. ASPIRA is particularly focused on closing the ethnic disparity gap in ovarian cancer risk assessment and developing solutions for pelvic diseases such as pelvic mass risk assessment and endometriosis. OVA1® plus includes our FDA-cleared products, OVA1® , and OVERA® to detect risk of ovarian malignancy in women with adnexal masses. ASPIRA GenetiX™ testing offers both targeted and comprehensive genetic testing options with a gynecologic focus. With over 10 years of expertise in ovarian cancer risk assessment, ASPIRA is delivering a portfolio of pelvic mass products over a patient's lifetime with our cutting-edge research. The next generation of products in development are OVANEX™ and EndoCheck™. Visit our website for more information at www.aspirawh.com.