

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 51D0707042	<b>(X3) Date Survey Completed</b> 06/29/2023
<b>Name of Provider or Supplier</b> Grant Memorial Hospital Respiratory	<b>Street Address, City, State</b> 117 Hospital Drive, Petersburg, WV	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced, on site, routine recertification survey was conducted at Grant Memorial Hospital on June 29, 2023, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies cited are explained below.
<b>D6000</b>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview the laboratory failed to ensure the acting laboratory director (LD) is qualified to fill the position. Findings: 1. Review of current personnel form CMS 209 identified a change in laboratory director. 2. The laboratory failure to notify the WV CLIA office of the laboratory director change resulted in no qualification process of the LD position for the laboratory until the date of survey. 3. Review of WV Board of Osteopathic Medicine primary verification identified the LD has a current medical license (DO). No documented training or experience in directing a laboratory or in supervising non-waived testing could be located. 4. An interview with the laboratory manager and the acting LD, 6/29/23 at approximately 8:35 AM, confirmed the lack of training and documented experience in directing a laboratory or supervising non-waived testing to meet the required qualifications.</p>
<b>D6035</b>	<p><b>TECHNICAL CONSULTANT QUALIFICATIONS</b> CFR(s): 493.1411</p> <p>(a) The technical consultant must be qualified and must possess a current license</p>

issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Based on record review and interview the laboratory failed to ensure the acting technical consultant (TC) for the laboratory is qualified to fill the position. Findings: 1. Review of current CMS 209 personnel form identified a change in the TC. 2. Review of WV Board of Osteopathic Medicine primary source verification identified the TC has a current medical license (DO). No documented training or experience in directing a laboratory or in supervising non-waived testing could be located. 4. An interview with the laboratory manager and the acting TC, 6/29/23 at approximately 8:35 AM, confirmed the lack of training and documented experience in directing a laboratory or in supervising non-waived testing to meet the qualification requirements for the position.