

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0272938	<b>(X3) Date Survey Completed</b>  02/22/2019
<b>Name of Provider or Supplier</b>  Regional General Hospital Williston	<b>Street Address, City, State</b>  125 Sw 7th St, Williston, FL	
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>	A complaint survey was conducted on February 22, 2019. Regional General Hospital Williston was found to be in non-compliance with the CLIA laboratory regulatory requirements of 42 CFR 493. One CLIA Condition was not met, at the Condition level : 42 CFR 493.1441, Laboratory Director for High Complexity Testing.
<b>D6076</b>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on patient record review, and staff interview, the facility failed to ensure compliance with the requirement to have a qualified laboratory director who will perform the overall management and direction of the laboratory. Refer to D6078.</p>
<b>D6078</b>	<p>LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443</p> <p>The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director 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) Be a</p>

doctor of medicine, a 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)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory did not have a qualified laboratory director to perform the overall management of the laboratory from 1/1/19 through 1/31/19. Findings included: Review of the documents revealed that the laboratory director ceased duties and responsibilities to manage the laboratory on 1/1/19 and a new laboratory director position was not filled by the hospital until 2/1/19. Review of 5 out of 5 test reports showed that the laboratory tested patient samples for CBC ( Complete Blood Count ) in Hematology and CMP ( Complete Metabolic Panel ) in Chemistry from 1/1/19 through 1/31/19 without a qualified laboratory director. Interview at 10:00 AM on 2/22/19 with the hospital CEO ( Chief Executive Officer ) confirmed that there was a new qualified laboratory director but did not provide direction of the laboratory until 2/1/19.