

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0865334	(X3) Date Survey Completed 07/11/2018
Name of Provider or Supplier Valdosta State University- Student Health Center	Street Address, City, State 200 Georgia Avenue, Valdosta, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on July 11, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and the State Regulations, the laboratory is not in compliance with applicable State laboratory requirements Findings: 1. Interview with the Laboratory Manager by email on July 19, 2018 at 1:12pm, the Laboratory Manager stated that the facility did not have a state license as far as she new. 2. Review of the State Regulations for laboratories in the state of Georgia, the laboratory did not meet the Exemptions and should have applied for a state license. The exemptions are listed below. 111-8-10-.31 Exemptions. These rules and regulations shall not apply to: (a) Clinical laboratories operated by the Medical College of Georgia, the Emory University School of Medicine, Mercer University School of Medicine, Whorehouse School of Medicine, or any other medical schools in Georgia, or the United States Government; (b) Clinical laboratories operated and maintained exclusively for research and teaching purposes involving no patient or public health services; (c) Clinical laboratories operated by duly licensed physicians exclusively in connection with the diagnosis and treatment of their own patients; or (d) Pharmacists duly licensed in Georgia practicing in accordance with O.C.G.A. 26-4-4 as it pertains to the performing or capillary blood tests and the interpretation of the results of those tests as a means to screen for or monitor disease risk factors and facilitate patient education. The capillary blood tests allowed under this exemption shall be limited to</p>

those capillary blood tests available to and for use by the public without licensure of the user of the test. Authority: O.C.G.A. 26-4-4 and 31-22-9. 3. Further review and investigations of the laboratory ownership and operations it was determined on August 10, 2018, that the facility was not in compliance with state regulations, and did not hold a current Georgia Laboratory License.