

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0906237	(X3) Date Survey Completed 01/16/2019
Name of Provider or Supplier Cornerstone Women's Center Pllc	Street Address, City, State 8870 College St, Olive Branch, MS	
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
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>The 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on review of the personnel testing records on 1/16/19 (day of survey) and the lack of education documentation, the laboratory director did not ensure the testing personnel listed on the CMS (Centers for Medicare and Medicaid Services) 209 personnel form had the appropriate education to perform moderate complexity testing prior to testing patients. The testing personnel began moderate complexity testing on 10/7/18 according to QC (quality control) and personnel training records.</p>
D6041	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3)</p> <p>(b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory proficiency testing records, Centers of</p>

Medicare and Medicaid Services database proficiency testing report and confirmation by laboratory testing personnel at 1:30 pm 1/16/19 (day of survey), the technical consultant failed to ensure the laboratory was enrolled and participated in an HHS approved proficiency testing (PT) program for Group B Strep performed on the Gene Xpert-Cepheid analyzer for the third event of 2018.