

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D2087106	<b>(X3) Date Survey Completed</b>  07/22/2024
<b>Name of Provider or Supplier</b>  Jill Gibson Md, Llc	<b>Street Address, City, State</b>  106 Highland Park Plaza, Covington, LA	
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 Recertification survey was performed at Jill Gibson, MD, LLC, CLIA ID 19D2087106, on July 22, 2024. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the manufacturers' storage requirements, and interview with personnel, the laboratory failed to monitor the room temperature of areas where laboratory supplies and test kits were stored. Findings: 1. Observation by surveyor during the laboratory tour on July 22, 2024 at 9:42 am revealed the following items stored without temperature monitoring: a) Receptionist area: Aptima urine specimen collection kits and Consult Diagnostics 10 SG urine reagent strips b) Hallway: Consult Diagnostics hCG Urine test cassettes 2. Review of the manufacturers' storage requirements revealed the following: a) Aptima urine specimen collection kits: storage temperature 15-30 degrees Celsius b) Consult Diagnostics urine reagent strips: storage requirement 2-30 degrees Celsius b) Consult hCG urine test cassettes: storage temperature 2-30 degrees Celsius 3. In interview on July 22, 2024 at 12:00 pm, the Office Manager stated the room temperature was not monitored in the areas where the supplies and test kits were stored.</p>

<p><b>D6014</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(3)(iii)</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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the manufacturers' storage requirements, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5413.</p>
<p><b>D6030</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(12)</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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6050.</p>
<p><b>D6050</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)(iv)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 form, competency assessments, and interview with personnel, the Technical Consultant failed to perform a direct observation of instrument maintenance and function checks as a part of competency assessment in 2023 and 2024 for one (1) of two (2) Testing Personnel reviewed. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the Laboratory Director and Testing Personnel 1 serve as testing personnel. 2. Review of Testing Personnel 1's competency assessments for 2023 and 2024 revealed the Laboratory Director, who also serves as the Technical Consultant, did not</p>

perform a direct observation of instrument maintenance and function checks. The competency was signed as completed on January 31, 2023 for the BD Max and Affirm instruments and January 31, 2024 for the BD Max instrument. 3. In interview on July 22, 2024 at 12:30 pm, the Laboratory Director confirmed she did not document a direct observation of instrument maintenance for Testing Personnel 1's annual competency assessment for 2023 and 2024.