

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D2032083	<b>(X3) Date Survey Completed</b> 11/29/2022
<b>Name of Provider or Supplier</b> Princeton Women's Services	<b>Street Address, City, State</b> 1345 Kuser Road, Hamilton, NJ	
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>D3009</b>	<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: a) Based on an in-office review of the laboratory's requirements for a New Jersey State Clinical Laboratory License (NJCLL) under New Jersey Statutes Annotated: N.J. S.A. 45:9-42.28. License; necessity; categories, the laboratory failed to obtain a NJCLL before the laboratory started patient testing. The Supervisor for the Clinical Laboratory Improvement Services (CLIS) confirmed on 11/28/22 that the laboratory did not obtain its NJCLL license before the laboratory started testing. b) Based on interview with the office manager, and an in-office interview with Supervisor for the CLIS both confirmed on 11/30/22 that Laboratory Director (LD) did not hold a license for bioanalytical laboratory director under New Jersey State Administrative Code: N.J.A.C. 8:44-2.3. The the LD listed on the CMS 209 form is not a qualified LD as stated above.</p>
<b>D5221</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Office Manager (OM) the laboratory failed to review and evaluate results when they received an unacceptable score in ASBO and RHo(D) Group tests performed with the American Association of Bioanalysts (AAB), for event S1-2021. The</p>

findings include: 1. The laboratory received an 0% grade for D(Rho) Typing. 2. There was no documented evidence that the laboratory ran the PT samples and compared them with AAB PT results. 3. The OM confirmed on 11/26/22 at 10:45 am that the laboratory did not review and document an evaluation of unacceptable PT results.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

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.

This CONDITION is not met as evidenced by:  
Based interview with the Office Manager (OM) and in-office interview with the Supervisor for the Clinical Laboratory Improvement Services (CLIS) The laboratory failed have a a qualified Laboratory Director (LD) an the date of survey. Cross refer 3009