

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0914104	(X3) Date Survey Completed 12/11/2023
Name of Provider or Supplier American Women's Services	Street Address, City, State 157 South Main St, Phillipsburg, NJ	
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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on an office review of the CASPER reports 153 and 155 and proficiency testing provider reports, the laboratory failed to achieve 80% or more in two out of three events for ABO and Rh Factor testing with the American Association of Bioanalysts.</p>
D2153	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(a)</p> <p>Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the</p>

	<p>testing event.</p> <p>This STANDARD is not met as evidenced by: Based on an office review of the CASPER reports 153 and 155 and Proficiency Testing (PT) provider reports, the laboratory failed to attain an overall testing event score of at least 100 percent for D (Rho) typing with the American Association of Bioanalysts PT in the Sewcond and third event of 2023. The finding includes: 1. The laboratory scored 0 % for ABO Group and D (Rho) Typing in the second and third events of 2023</p>
<p>D2154</p>	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(b)</p> <p>Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on an office review of the CASPER reports 153 and 155 and Proficiency Testing (PT) provider reports, the laboratory failed to attain an overall testing event score of at least 100 percent for D (Rho) typing prformed the findings include. 1. The laboratory scored 0% for D (Rho) Typing and ABO Group event 2, 2023 with American Association of Bioanalysts (AAB). 2. The laboratory scored 0% for D (Rho) Typing and ABO Group event 3, 2023 with AAB.</p>
<p>D2155</p>	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and review of CASPER reports 153 and 155, the laboratory failed to submit ABO Group and D (Rho) Typing results to the American Association of Bioanalysts in events 2 and 3 in 2023.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p>

This CONDITION is not met as evidenced by:
Based on an office review of the laboratory's performance in Proficiency Testing (PT) surveys, the laboratory director failed to provide appropriate direction to the laboratory personnel to ensure that the PT surveys are performed satisfactorily and compliance with the CLIA regulations are maintained.