

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0716773	<b>(X3) Date Survey Completed</b>  10/20/2020
<b>Name of Provider or Supplier</b>  All Womens Health Center Inc	<b>Street Address, City, State</b>  4131 Central Ave, Saint Petersburg, FL	
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>	An announced CLIA recertification survey was conducted at All Women's Health Center, Inc. on 10/20/20. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
<b>D6029</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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 record review and interview with the Administrator (Testing Personnel #B), the Laboratory Director failed to ensure that the laboratory documented the training of individuals that performed specialty testing of immunohematology (rH testing non-transfusion) on patient specimens. Findings included: 1. Record review of training and competency records revealed that Testing Personnel #B, who had a start date of 05/28 /20, did not have rH testing training records. 2. Interview on 10/20/20 at 11:10 AM with the Administrator (Testing Personnel #B) confirmed her start date of 05/28/20 and reported being trained on rH testing, however, the laboratory had not documented the training.</p>