

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0716775	(X3) Date Survey Completed 02/22/2018
Name of Provider or Supplier All Womens Health Center Of Sarasota Inc	Street Address, City, State 2700 S Tamiami Trail Ste 5, Sarasota, FL	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Manager, the laboratory failed to rotate proficiency testing to include all testing personnel who perform patient testing for 2 out of 2 years (2016-2017) reviewed. Findings Included: Review of the Testing Personnel sheet revealed that 4 people performed patient testing (Testing Person #A, B, C, and D). Review of American Proficiency Institute (API) proficiency testing attestation statements revealed that Testing Person #A performed proficiency testing 5 (1st, 2nd, 3rd 2016 and 1st and 2nd 2017) out of 6 (1st, 2nd, 3rd testing events in 2016 and 2017) testing events and Testing Person #C performed testing for testing event 3 in 2017. During an interview on 02/22/18 at 10:00 AM the Laboratory Manager confirmed that proficiency testing was not rotated among all staff who performed patient testing.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Manager, the laboratory</p>

failed to perform preventative maintenance on the Rh view box for 2 out of 2 years (2016-2017) reviewed. Findings Included: Review of laboratory preventative maintenance revealed no preventative maintenance documentation for the Rh view box. During an interview on 02/22/18 at 10:40 AM the Laboratory Manager confirmed that there had been no preventative maintenance performed on the Rh view box.