

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0716775	(X3) Date Survey Completed 02/28/2020
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
D0000	An announced CLIA recertification survey was conducted at All Women's Health Center of Sarasota Inc. on 02/28/2020. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5400 Analytic Systems 493.1250
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Administrator the laboratory failed to perform competency assessment for 3 out of 3 Testing Personnel. Findings Included: Review of the CMS 209 (signed and dated by the Laboratory Director on 02/26/2020) revealed that there were 3 Testing Personnel. Testing Person #A started 10/2018, Testing Person #B started 03/2019, and Testing Person #C started 02/2019. Review of Personnel files revealed no competency assessments for Testing Person #A, #B, or #C. Interview on 02/28/2020 at 2:15 PM with the Administrator confirmed that no competency assessments were performed on the Testing Personnel.</p>
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in</p>

493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on record review and interview with the Administrator the laboratory failed to perform preventative maintenance on the Rh view box since 03/22/2018 (See D5429).

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

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.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Administrator the laboratory failed to perform preventative maintenance on the Rh view box since 03/22/2018. This is a repeat deficiency from the recertification survey conducted 02/22/2018. Findings Included: Review of the preventative maintenance for the Rh view box revealed that the last time it was performed was 03/22/2018. The preventative maintenance was due 03/2019. Interview on 02/28/2019 at 1:00 PM with the Administrator confirmed that the preventative maintenance had not been performed. Review of the plan of correction (signed by the Laboratory Director on 03/14/2018) from the 02/22/2018 recertification survey stated, "We have contacted a vendor to perform preventative maintenance. They are scheduled to perform preventative maintenance on March 22, 2018 @ 8:30 AM. We will set up an annual contract with them to be certain this deficiency does not recur. The Administrator will monitor to ensure completed."