

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0936920	(X3) Date Survey Completed 04/08/2021
Name of Provider or Supplier A Womans Choice Of Jacksonville	Street Address, City, State 4131 University Blvd S Ste 2, Jacksonville, 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	At the time of the announced, on-site recertificaton survey, A Woman's Choice of Jacksonville was found to NOT be in compliance with the CLIA laboratory requirements of 42 CFR 493. .
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 staff interview, the laboratory failed to rotate proficiency testing to include all testing personnel who perform patient testing for 3 of 3 testing events in 2020. The findings include: Review of the CMS 209 Testing Personnel sheet showed that 5 people performed patient testing (Testing Person #A, B, C, D, & E). Review of American Proficiency Institute (API) proficiency testing attestation statements showed that only Testing Person #D performed proficiency testing for the 1st, 2nd, and 3rd events of 2020. During an interview on 4/8/21 with Testing Person #E at 10:00 AM, it was confirmed that no other Testing Persons had performed proficiency testing. .</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p>

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to ensure that the semiannual performance evaluation was completed on three of three newly hired testing personnel in the laboratory (Testing personnel #A, B, & C). The findings include: Review of the laboratory's competency evaluation records for the three testing personnel hired in 2020 showed that the laboratory had documented the initial training performance evaluation for testing personnel #A on 8/5/20, testing personnel #B on 6/15/20, and testing personnel #C on 2/10/20. There was no semiannual performance evaluation performed after the initial assessment. During an interview on 4/8/21 at 10:00 AM, Testing Person #E confirmed that the semiannual assessments had not been performed. .

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the Technical Consultant did not document annual competency for three of three testing personnel. (Testing personnel #C, #D, & #E). Findings include: Review of personnel information and interview with Testing Person E at 10:00 a.m. on 4/8/21 revealed that there was no documentation to indicate that competency evaluations had been done annually for Testing Person C (hired 1/18/20), Testing Person D (hired 9/25/17), and Testing Person E (hired 2/14/17).