

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D1082776	(X3) Date Survey Completed 01/03/2018
Name of Provider or Supplier Women's Health Center Of Saginaw	Street Address, City, State 3141 S Cabaret Trail Suite 100, Saginaw, MI	
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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to test the American Association of Bioanalysts (AAB) D (Rho) typing proficiency testing samples the same number of times that it routinely tests patient samples for one (AAB, 3rd event of 2017) of six events in 2016 and 2017. Findings include: 1. On January 3, 2018 at 10:56 a.m., record review of the AAB D (Rho) Typing proficiency testing reports revealed for one (3rd event of 2017) of six events in 2016 and 2017 reviewed two sets of sample testing documents for the testing event. 2. On January 3, 2018, at 11:16 a. m., the "Checklist for proficiency testing success" procedure revealed "do not test PT samples more than once unless it is your regular laboratory procedure for testing patient samples" 3. During the interview on January 3, 2017 at 10:56 a.m., testing personnel #1 as listed on the CMS-209 confirmed the event samples were run multiple times.</p>
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, the laboratory failed to ensure written</p>

competency policies were established and implemented for one (clinical consultant and technical consultant) of one non-testing technical personnel based on their federal regulatory responsibilities for 2016 and 2017. Findings include: 1. On January 3, 2018 at 11:01 a.m., record review revealed the laboratory did not establish or implement a written competency policy that covered the federal regularity responsibilities for one of one non-testing technical personnel. 2. On January 3, 2018 at 11:01 a.m., during the interview, testing personnel #1 as listed on the CMS-209 confirmed a competency policy was not established and implemented in 2016 and 2017 for the non-testing personnel based on the federal regulatory responsibilities.