

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0907841	<b>(X3) Date Survey Completed</b>  05/23/2019
<b>Name of Provider or Supplier</b>  Midwest Center For Reproductive Health	<b>Street Address, City, State</b>  12000 Elm Creek Blvd N Suite 350, Maple Grove, MN	
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>D6125</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(8)(v)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Based on document review and interview with laboratory personnel, the technical supervisor (TS) failed to ensure the 2017 and 2018 annual competency evaluation for 1 of 3 testing personnel included assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples for all testing performed by the laboratory. Findings are as follows: 1. The laboratory performed Chemistry and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:05 a.m. on 05/23/19. 2. Proficiency testing (PT) results for each of the following testing specialties /subspecialties and an inter-laboratory comparison were being used to evaluate testing personnel competency as indicated by the GS at 11:35 a.m on 05/23/19. Proficiency testing Specialty Instrument/test Chemistry Tosoh AIA 360 Hematology Semen Analysis Inter-laboratory comparison Specialty Instrument/test Hematology Semen Analysis 3. The laboratory's Employee Competency Evaluation procedure, located in the Andrology Competency manual, did not include a requirement to evaluate test performance using blind samples or proficiency testing results during annual competency assessments. This criteria was included on the competency form used by laboratory. 4. The PT and inter-laboratory comparison samples were not distributed in a manner to ensure TP2 performed blind sample testing for both specialties in 2017 and 2018 as indicated in the American Association of Bioanalysts Attestation Statements and inter-laboratory comparison documents. The laboratory was unable to provide additional documented evaluations of blind sample test performance upon</p>

request. See below where "x" indicates TP2 did not participate in proficiency testing or inter-laboratory comparisons. 2017 2018 Chemistry x x Hematology x 5. In an interview at 11:35 a.m. on 05/23/19, the GS confirmed the above finding.