

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D2031831	(X3) Date Survey Completed 06/11/2019
Name of Provider or Supplier Midwest Reproductive Center	Street Address, City, State 2750 Clay Edwards Drive Ste 604, North Kansas City, MO	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of procedure, chemistry quality control (QC) and interview with the technical supervisor, the laboratory failed to follow QC procedure for the analytes estradiol, progesterone and HCG. Findings: 1. Review of chemistry QC procedure states "BioRad Immunoassay Plus controls Levels 1, 2, and 3 are used". 2. Review of January 2019 estradiol QC showed on January 14 level 3 QC was not within laboratory's established acceptable QC range. January 23 level 2 QC was not within laboratory's established acceptable QC range. 3. Review of January 2019 progesterone QC showed on January 3 level 1 QC was not documented and level 2 was not within laboratory's established acceptable QC range. January 7, 22, 28, 29, 30 and 31, level 1 QC was not within laboratory's established acceptable QC range. 4. Review of January 2019 HCG QC showed on January 7 level 3 was not within laboratory's established acceptable QC range. January 23 level 2 QC was not within laboratory's established acceptable QC range. 5. Interview with the technical supervisor on June 11, 2019 at 2:00 PM confirmed the laboratory failed to follow chemistry QC procedure.</p>