

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0873828	(X3) Date Survey Completed 09/18/2019
Name of Provider or Supplier Mid Iowa Fertility, Pc	Street Address, City, State 1371 Nw 121st Street, Clive, IA	
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
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 2:30 pm on 09/18/2019, the laboratory failed to perform a self evaluation when it received a score of zero for one out of three testing events (2018 event 1) in 2018 and 2019. The findings include: 1. For 2018 testing event 1, the laboratory received a score of zero for failure to submit PT results before the submission deadline for the following analytes: sperm count, sperm morphology, sperm cell identification, and sperm motility. 2. At the time of the survey, the laboratory did not have records indicating that it performed a self-evaluation for the failed PT scores.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Laboratory Test List & Annual Volume form, lack of proficiency testing (PT) records and confirmed by laboratory personnel identifier #2</p>

(refer to the Laboratory Personnel Report) at approximately 2:30 pm on 09/18/2019, the laboratory failed to verify the accuracy of the analyte, thyroid peroxidase (TPO), at least twice annually for two out of two time periods from January 2018- December 2018. The findings include: 1. The laboratory listed TPO testing on the Laboratory Test List & Annual Volume form. 2. Personnel identifier #2 confirmed that the laboratory did not enroll in PT for the analyte, TPO, in 2018. 3. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not have additional records indicating the verification of accuracy for the analyte, TPO, in 2018.

D5219

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(2)

At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:
Based on review of the Laboratory Test List & Annual Volume form, lack of proficiency testing records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 2:30 pm on 09/18/2019, the laboratory failed to verify the accuracy of the analyte, anti mullerian hormone (AMH), at least twice annually for two out of two time periods from January 2018- December 2018. The findings include: 1. The laboratory listed AMH testing on the Laboratory Test List & Annual Volume form. 2. Personnel identifier #2 confirmed that proficiency testing samples are not available for AMH testing. 3. At the time of the survey, the laboratory did not have additional records indicating verification of accuracy for the analyte, AMH, in 2018.

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 review of Access 2 maintenance records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 3:30 pm on 09/18/2019, the laboratory failed to perform and document weekly maintenance as defined by the manufacturer on the Access 2 instrument for four out of four weeks in March 2019. The findings include: 1. The Access 2 maintenance log indicates the following tasks are to be performed and documented weekly: *Clean Instrument Exterior *Inspect Liquid Waste Bottle *Check Waste Filter Bottle *Inspect /Clean Primary Probe *Replace/Clean Aspirate Probes *Run Daily Maintenance *Run System Check 2. The following statement is located in the weekly maintenance section of the log: "Perform the tasks listed at the left and draw a check in the accompanying box on the right. Initial the tech initials box." 3. In the weekly maintenance section of the log, the laboratory listed the beginning date of each week in March (03/04/2019, 03/11/2019, 03/18/2019, and 03/25/2019) but did not draw checks in each of the accompanying boxes to the right of each task. 4. At the time of the survey, the laboratory did not have additional documentation showing that each

	<p>weekly maintenance task was performed and documented for the weeks of 03/04/2019, 03/11/2019, 03/18/2019, and 03/25/2019.</p>
<p>D6054</p>	<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 annually, after the first year.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 09/18/2019, the technical consultant failed to assess and document the competency of individuals performing moderate complexity testing at least annually for three out of five testing personnel (laboratory personnel identifiers #2, #3, and #5) in 2017 and 2018.</p>
<p>D6128</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 09/18/2019, the technical supervisor failed to assess and document the competency of individuals performing high complexity testing at least annually for one out of four testing personnel (personnel identifier #2) in 2017 and two out of four testing personnel (personnel identifiers #2 and #3) in 2018.</p>