

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2148953	(X3) Date Survey Completed 01/07/2021
Name of Provider or Supplier Aurora Fertility Services	Street Address, City, State 6815 118th Ave, Fertility Clinic, Kenosha, WI	
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 surveyor review of the American Association of Bioanalysts (AAB) proficiency testing (PT) reports and interview with the laboratory director and general supervisor, the laboratory did not review two of two ungraded "Sperm Cell ID" results from 2019 and 2020. Findings include: 1. Review of the AAB proficiency testing reports for 2019 and 2020 showed no evidence the laboratory evaluated the accuracy for two of two ungraded PT results for the "Sperm Cell ID" for events 2019-1, sample 5, and 2020-1, sample 5. The laboratory reported result for 2019-1 sample 5 was 'abnormal head'; the expected result was 'normal'. The laboratory reported result for 2020-1 sample 5 was 'normal'; the expected result was 'abnormal head'. 2. Interview with the laboratory director and general supervisor, Staff A, on January 7, 2021 at 10:16 AM, confirmed the laboratory did not review two of two ungraded "Sperm Cell ID" results to verify the accuracy in 2019 and 2020. This is a repeat deficiency from January 30, 2019.</p>
D6103	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to</p>

process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory procedures and interview with the laboratory director, the laboratory director did not establish a procedure for evaluating and maintaining competency of testing personnel. Findings include: 1. Review of the laboratory procedures showed the laboratory director did not have a written procedure for evaluating and maintaining competency of testing personnel. 2. Interview with the laboratory director on January 7, 2021 at 10:20 AM confirmed the laboratory director did not establish a procedure for evaluating and maintaining competency of testing personnel.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory records and interview with the laboratory director, the technical supervisor (who is also the laboratory director) did not document competency evaluation for two of two testing personnel in 2019 and 2020. Findings include: 1. Review of the laboratory records showed the technical supervisor (who is also the laboratory director) did not evaluate the competency of testing personnel in 2019 and 2020. 2. Interview with the laboratory director on January 7, 2021 at 8:29 AM confirmed the laboratory director did not evaluate competency for two of two testing personnel in 2019 and 2020.

D6177

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1495(b)(3)

Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory procedures and records and interview with the laboratory director and general supervisor, testing personnel did not perform internal proficiency testing monthly as required in the "Quality Control/Quality Assurance of Semen Analysis and the Andrology Laboratory" procedure for twenty of twenty-four months in 2019 and 2020. Findings include: 1. Review of the "Quality Control /Quality Assurance of Semen Analysis and the Andrology Laboratory" procedure stated, "Once a month, andrology technologists will engage in internal proficiency testing to examine intra- and inter-technologist variability". 2. Review of the internal

proficiency testing records showed the performance of the internal proficiency testing in January 2019, February 2019, April 2019 and May 2020. There is no evidence of monthly internal proficiency testing for other months in 2019 and 2020. 3. Interview with the laboratory director and general supervisor, Staff A, on January 7, 2021 at 10:25 AM confirmed testing personnel did not perform internal proficiency testing monthly as required for twenty of twenty-four months in 2019 and 2020.