Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1076391	10/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Department Of Obstetrics & Gyne Andrology Lab	751 N Rutledge St, Rm 0100, Springfield, IL	

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	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) 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). This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to verify the accuracy of ungraded proficiency testing (PT) analyte performance for sperm morphology for 2 of 5 PT events reviewed in 2018 through 2019. Findings Include: 1. American Proficiency Institute (API) PT documentation was reviewed for 2018 through 2019. 2. Review of API Hematology /Coagulation PT documentation revealed for event 3 of 2018 and event 1 of 2019 the laboratory failed to evaluate the performance of sperm morphology due to non-graded sperm morphology samples: 2018 Event 3 Reported Result Expected Result SCL-13 Abnormal Normal SCL-17 Normal Normal SCL-20 Normal Abnormal/Borderline 2019 Event1 Reported Result Expected Result SCL-04 Abnormal Normal SCL-05 Abnormal Normal SCL-07 Abnormal Normal SCL-08 Abnormal Normal SM-01 7 see Data Summary 3. Review of the laboratory's PT policy, "Proficiency Testing (SIU-2016-021)", explained on page 3 that an incident report should be completed to document an investigation and plan of correction for ungraded PT samples. 4. Review of PT incident reports revealed the laboratory failed to document incident reports for the non-graded PT samples identified in event 3 of 2018 and event 1 of 2019 for sperm morphology. 5. On survey date 10-17-2019, at 1:00 pm, the LD confirmed that non-graded sperm morphology PT were not evaluated for event 3 in 2018 and event 1 in 2019.

D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to ensure two levels of quality control (QC) materials were ran each day of testing before reporting semen analysis patient test results for 2 of 9 patient testing dates reviewed. Findings Include: 1. Review of the laboratory procedure, "Semen Analysis 007", indicated on page 13 that 3 levels of QwikCheck quality control beads are performed and documented each day of patient testing for semen analysis. 2. Review of patient testing for semen analysis revealed for 2 of 9 patient testing dates reviewed the laboratory failed to document quality control QwikCheck bead results for sperm counts on the "Andrology Lab Bead QC-Qwik-Check" log. Patient Identification Test Date A2 10-30-2018 A8 11-16-2018 3. Interview with the LD on 10-17-2019, at 1:00 pm, confirmed no quality control results were performed or documented for 2 of 9 patient testing dates reviewed for semen analysis, sperm counts.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to test staining material for intended reactivity each day of use for semen analysis sperm morphology testing for 1 of 9 patient test dates reviewed. Findings Include: 1. Review of the laboratory procedure, "Semen Analysis 007", indicated on page 14 that Diff-Quick Stain will be evaluated each day of testing and documented on the Diff-Quik stain quality control log. 2. Review of patient testing for semen analysis revealed for 1 of 9 patient testing dates reviewed the laboratory failed to document quality control for Diff-Quik staining on the Diff-Quik quality control log. Patient Identification Test Date A3 05-25-2018 3. Interview with the LD on 10-17-2019, at 1:00 pm, confirmed Diff-Quik staining was not performed or documented for 1 of 9 patient testing dates reviewed for semen analysis, morphology.