

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2013309	(X3) Date Survey Completed 08/28/2018
Name of Provider or Supplier Advanced Reproductive Hlth Ctr - Chicago I V F	Street Address, City, State 28375 Davis Parkway, Ste 903, Warrenville, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, Laboratory Personnel Report (CLIA) (Form CMS 209), personnel records, direct observation, record review, and interview with the technical supervisor (personnel # 3 on Form CMS 209); PT samples were not examined by all personnel who routinely perform the testing in the laboratory. Findings include: 1. Review of laboratory policies and procedures revealed that the laboratory performed semen analysis (SA) and intrauterine insemination (IUI) which consists of the following: a. Specimen Collection b. Measure of Semen Volume c. Semen Appearance d. Semen Viscosity e. Total Sperm Count (using a makler chamber) f. Motility g. Progression h. Total Motile i. Sperm Agglutination 2. Four of six persons listed on Form CMS 209 were listed as testing personnel in the laboratory. 3. Review of PT records from the American Association of Bioanalysts (AAB) revealed that the laboratory performed twice yearly verification of Semen Analysis testing in 2016 and 2017 and once from January to August 2018. The Semen Analysis PT was broken down into the following 4 parts: a. Sperm Counts b. Sperm Morphology c. Sperm Motility d. Sperm Viability Attestation statements from PT records from the AAB show that only 2 of 4 testing personnel (testing persons # 2 and #3) performed all PT in 2016, 2017, and 2018. There was no documentation to show that testing person #4 and #5 were not included in the PT rotation in 2016, 2017, or 2018. 4. At 10:30 AM on 08/28/18, the surveyor observed a nurses (testing person # 5) performing a sperm count on a patient's specimen. 5. Review of laboratory worksheets and patients' reports revealed that testing person # 5 also performed and reported sperm counts on prewash and post wash patients' specimens on the following</p>

dates: a. 10/25/16 - patient 102516-227wv b. 12/13/17 - patient 121317-260wv 5. At 10:00 AM on 08/28/18, technical supervisor #3 stated that testing person #5 was not included in the rotation, because she only processed Intra-Uterine Insemination (IUI) specimens. When the surveyor asked technical supervisor # 3 what the "process was," it was revealed that part of the IUI process required a prewash sperm count and a post wash sperm count. 6. At 10:40: AM on 08/28/18, technical supervisor #3 confirmed the surveyor's findings.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies and procedures manual, Laboratory Personnel Report (Form CMS 209), personnel records, and interview with technical supervisor (personnel #3 on Form CMS 209); the laboratory failed to establish and follow written policies and procedures to assess employee and consultant competency. Findings include: 1. The laboratory's procedures manual lacked instructions for how it assessed the competency of persons who fulfil the responsibilities and duties of the following positions: a. Technical Supervisor b. Clinical Consultant c. General Supervisor d. All Testing Personnel performing any testing in the lab 2. Review of Form CMS 209 revealed that there is a total of 6 persons listed in positions for high complexity testing in the laboratory. The surveyor assigned numbers to high complexity testing personnel listed on Form CMS 209 as follows: a. The number 1 is assigned to personnel listed on Form CMS 209 as Laboratory Director (LD); Clinical Consultant (CC); and General Supervisor (GS). b. The number 2 is assigned to personnel listed on Form CMS 209 as Technical Supervisor (TS); General Supervisor (GS); and Testing Personnel (TP). c. The number 3 is assigned to personnel listed on Form CMS 209 as TS, GS, and TP. d. The number 4 is assigned to personnel listed on Form CMS 209 as TS and TP. e. The number 5 is assigned to personnel listed on Form CMS 209 as TP. f. The number 6 is assigned to personnel listed on Form CMS 209 3. Review of personnel records revealed that there was no documentation to show that a competency assessment based on the position responsibilities and duties was performed on 4 of 6 personnel listed on Form CMS 209 for the following positions: a. Technical Supervisor (personnel # 2 and # 3) b. Clinical Consultant (personnel # 6) c. General Supervisor (personnel # 2 and # 3) d. All Testing Personnel performing any testing in the lab (personnel # 5) 4. At 9:30 AM on 08/28/18, the technical supervisor (personnel # 3) confirmed the surveyor's findings.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of Laboratory Personnel Report (Form CMS 209), personnel records, laboratory policies and procedures manual, and interview with technical supervisor (personnel assigned the # 3 on Form CMS 209 by the surveyor), the laboratory director failed to specify in writing the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of each phase of testing, that identifies which examinations and procedures each individual is authorized to perform and whether supervision is required prior to reporting patient test results. Findings include: 1. Review of Form CMS 209 revealed that there is a total of 6 persons listed in positions for high complexity testing in the laboratory. The surveyor assigned numbers to high complexity testing personnel listed on Form CMS 209 as follows: a. The number 1 is assigned to personnel listed on Form CMS 209 as Laboratory Director (LD); Clinical Consultant (CC); and General Supervisor (GS). b. The number 2 is assigned to personnel listed on Form CMS 209 as Technical Supervisor (TS); General Supervisor (GS); and Testing Personnel (TP). c. The number 3 is assigned to personnel listed on Form CMS 209 as TS, GS, and TP. d. The number 4 is assigned to personnel listed on Form CMS 209 as TS and TP. e. The number 5 is assigned to personnel listed on Form CMS 209 as TP. f. The number 6 is assigned to personnel listed on Form CMS 209 2. Review of personnel records revealed that there was no documentation to show that the laboratory director assigned in writing persons to the following positions in the laboratory: a. TS b. CC c. GS d. TP and what tests they were authorized to perform. 3. Review of the laboratory's procedures manual revealed that there was no documentation to show who was assigned to the positions of TS, CC, GS, and TP in the laboratory. 4. Review of Form CMS 209 from the previous survey in 2016 revealed that personnel # 2 and personnel # 3 were previously listed as only testing personnel. When the surveyor asked when personnel # 2 and personnel # 3 were assigned to the positions of technical supervisor and general supervisor, the technical supervisor (personnel # 3) told the surveyor that the previous technical supervisor had assigned them to their positions before she left. 5. At 9:30 AM on 08/28/18, the technical supervisor (personnel # 3) confirmed the surveyor's findings.