Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D2006893	09/15/2020
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Reproductive Health Centers Chicago Ivf	8840 Calumet Ave Suite 201, Munster, IN	

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
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on document review and interview, the laboratory director failed to: 1) evaluate the laboratory's proficiency testing (PT) performance for two of three analytes (sperm viability and sperm morphology) during 2018 and 2019 (refer to D6091); 2) establish a corrective action plan for unacceptable proficiency testing (PT) results for two of three analytes (sperm viability and sperm morphology) during 2018 and 2019 (refer to D6092); 3) ensure the quality control (QC) was performed during one of five patient testing dates (4-3-2020) reviewed (refer to D6093); and 4) establish competency policies and procedures for two of two testing persons reviewed (SP1 and SP3) (refer to D6103).
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory director failed to evaluate the laboratory's proficiency testing (PT) performance for two of three analytes (sperm viability and sperm morphology) reviewed during 2018 and 2019. Findings included:

	1. Review of proficiency testing (PT) documentation indicated the following: a. The laboratory used American Association of Bioanalysts (AAB) for sperm viability, sperm morphology, and sperm count PT. b. AAB provided the laboratory with two PT events for each of the above analytes in 2018 and 2019. c. During PT event 2, 2018, the laboratory received a score of 50% for sperm viability. d. During PT event 2, 2019, the laboratory received a score of 50% for sperm morphology. e. There was no documentation of a review of PT results during event 2, 2018 and event 2, 2019. 2. Review of policies and procedures indicated the laboratory did not have policies /procedures for proficiency testing of sperm viability, sperm morphology, and sperm count tests. 3. In interview on 9-15-2020 at 12:04 PM, SP1, Lab Tech, acknowledged the laboratory received a 50% during PT event 2, 2018 for sperm viability and a 50% during PT event 2, 2019 for sperm morphology. SP1 indicated the laboratory director should have reviewed the PT results for event 2, 2018 and event 2, 2019, but was unsure where to locate documentation of such a review. 4. Review of "Test Methodology and Annual Test Volume Log" (Enclosure I) indicated the laboratory performed less than 20 semen analysis tests per year, which included sperm viability and sperm morphology.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory director failed to establish a corrective action plan for unacceptable proficiency testing (PT) results for two of three analytes (sperm viability and sperm morphology) during 2018 and 2019. Findings included: 1. Review of proficiency testing (PT) documentation indicated the following: a. During PT event 2, 2018, the laboratory received a score of 50% for sperm viability. b. During PT event 2, 2019, the laboratory received a score of 50% for sperm morphology. e. There was no documentation of a corrective action plan for the above unacceptable PT results. 2. Review of policies and procedures indicated the laboratory did not have policies/procedures for unacceptable PT results. 3. In interview on 9-15-2020 at 12:04 PM, SP1, Lab Tech, acknowledged the laboratory received a 50% during PT event 2, 2018 for sperm viability and a 50% during PT event 2, 2019 for sperm morphology. SP1 acknowledged there was no documentation of corrective action for the above unacceptable PT results. 4. Review of "Test Methodology and Annual Test Volume Log" (Enclosure I) indicated the laboratory performed less than 20 semen analysis tests per year, which included sperm viability and sperm morphology.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory director failed to ensure the

	quality control (QC) was performed during one of five patient testing dates (4-3-2020) reviewed. Findings included: 1. Review of "General Policies For Andrology Section (V.12.19.2)," approved by the laboratory director on 1-4-2020 did not indicate quality control for sperm count testing would be performed each day of patient testing. 2. Review of quality control documentation indicated the following: a. QC was to be performed on "days when andrological testing is conducted." a. The sperm count QC acceptable range for the low control was 18 plus or minus 2.5 million per milliliter. b. The sperm count QC acceptable range for the high control was 35 plus or minus 5 million per milliliter. c. On 4-3-2020, the sperm count QC low control was counted in duplicate with results of 25 and 23, respectively. The high control was counted in duplicate with results of 45 and 47, respectively. There was no documented remedial action. 3. Review of patient test reports indicated the following patients had sperm count testing performed on 4-3-2020, when the QC was not within an acceptable range: Patient #7, Patient #8, Patient #9, and Patient #10. 4. In interview on 9-15-2020 at 1:27 PM, SP1, Lab Tech, acknowledged sperm count QC was not performed on 4-3-2020, when patients #7 though #10 had sperm count testing performed. 4. Review of "Test Methodology and Annual Test Volume Log" (Enclosure I) indicated the laboratory performed less than 20 semen analysis tests per year, which included a sperm count.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) 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 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 document review and interview, the laboratory director failed to establish competency policies and procedures for two of two testing persons reviewed (SP1 and SP3). Findings included: 1. Review of policies and procedures indicated the following: a. A policy/procedure titled "Andrology Employee Training Protocol (v. 12.19.2)," approved by the laboratory director on 1-2-2020, indicated testing personnel will have two competency assessments in the first year and one annually thereafter. The policy did not indicate what was included in a competency assessment. b. There was no policy which indicated what was included in a competency assessment. 2. Review of personnel records indicated the following: a. SP1, lab tech, hire date 10-11-2019, had an "Employee Competency Checklist" completed on 10-4-2019 by the previous General Supervisor. SP1 had a second "Employee Competency Checklist" signed by the laboratory director on 5-21-2020. The "Employee Competency Checklist" did not include direct observation of routine test performance, nor did it include an assessment of problem solving skills. b. SP3, testing person, hire date 12-16-2019, had an "Employee Competency Checklist" completed on 6-25-2020 by the laboratory director. The "Employee Competency Checklist" did not include direct observation of routine test performance, nor did it include an assessment of problem solving skills. 3. Review of patient test reports indicated SP1 had performed semen analysis testing for the following patients: Patient #6 (10-18-2019); Patient #7 (4-3-2020); Patient #8 (4-3-2020); Patient #9 (4-3-2020); and Patient #10 (4-3-2020). 4. In interview on 9-15-2020 at 11:25 AM, SP1 indicated blank competency

	assessment forms are given to the employee to sign. The employee signs the blank form, then the form is given to the laboratory director. The laboratory director checks off the boxes on the competency form and signs the form. SP1 acknowledged the competency assessment form did not include a direct observation of routine test performance, nor did it include an assessment of problem solving skills. SP1 indicated the laboratory director was not present in the laboratory during the competency assessment to perform direct observation of routine test performance. SP1 also indicated they were unsure how the laboratory director performed an assessment of the testing person's problem solving skills during the competency assessment.