Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2068321	06/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Aspire Fertility Institute	911 W 38th St Ste 402, Austin, TX	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based upon a review of proficiency testing records for program years 2018 and 2019 and staff interview, the laboratory failed to ensure that the attestation statements for Andrology were signed by testing personnel and the laboratory director or designee in three of three events reviewed. Findings included: 1. Review of proficiency test records from the American Association of Bioanalysts (AAB) proficiency testing program revealed that Testing personnel and the Laboratory director or designee failed to physically sign attestation statements in three of three events between the first testing event of 2018 and the first testing event of 2019 (2 testing events per year). 2. Interview of the Embryology Laboratory Director conducted on June 4, 2019 at 10:32 AM confirmed the above findings.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on a review of proficiency testing records, test records, review of policies and procedures and interview with facility personnel, the laboratory failed to test proficiency samples the same number of times that it routinely tests patient samples.

	The findings included: 1. A review of the American Association of Bioanalysts (AAB) proficiency testing records from 2018 and 2019 (two events per year) revealed proficiency samples from each testing event were tested by all testing personnel. Each testing person would document their results for two of two specimens received on a separate page. 2. Review of the facility procedure titled Proficiency Testing (External Audit System) found on page 6: " The laboratory assures that all proficiency testing specimens are tested in the same manner as patient specimens. " 3. Interview of the Embryology Laboratory director conducted on June 4, 2019 at 10:27 AM confirmed that the proficiency testing samples were tested by all testing personnel, but patient specimens were only tested once.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, and staff interview, it was found that the laboratory director failed to document the approval of procedures available to testing personnel. The findings included: 1. A review of the policies and procedures found no documentation of the laboratory director's approval for procedures available to testing personnel performing Sperm Counts. The procedures titled Sperm Count Daily QC and Proficiency Testing (External Audit System) dated 2019, had no documentation of Laboratory Director approval. 2. Interview with the Embryology Laboratory director conducted on June 4, 2019 at 9:58 AM confirmed that the procedures provided were the procedures currently in use and they had not been approved by the laboratory director.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Observations,and interview of facility personnel found that the laboratory failed to ensure that all reagents and solutions were labeled with the preparation expiration dates, lot numbers and storage requirements for all reagents and controls stored in the laboratory. Findings included: 1. Observations made during the survey conducted on June 4, 2019 found three unlabeled conical tubes in a styrofoam rack located on the laboratory bench. The tubes contained aliquots of colored liquids that were not labeled with the preparation expiration dates, lot numbers and storage requirements. 2. Interview of the Embryology Laboratory Director and testing person two conducted on June 4, 2019 at 11:41 AM found that the liquids in the unlabeled conical tubes were aliquots of the pH standards used as controls.
D5469	CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of Bio-Rad Lyphochek Immunoassay Plus control instructions for use, laboratory policies and procedures, laboratory quality control records from May 3, 2019 through June 4, 2019, and interview with the Technical Supervisor, the laboratory failed to establish acceptability criteria for 3 of 3 lots of control materials. The findings included: 1. Based on review of the Bio-Rad Lyphochek Immunoassay Plus control instructions for use (Ref 370), under Assignment of Values, the instructions for use state the following: "The mean values and corresponding plus /minus 3 standard deviation (SD) ranges in the Assignment of Values Data Charts were derived from replicate analysis and are specific for this lot of product." And; "It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." And; "Laboratory established ranges may vary from those listed during the life of this control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications." 2. Based on surveyor observations of the quality control screen on the Siemens Immulite 1000 analyzer, the laboratory had established means for lots 40371, 40372, and 40373 but had not established acceptability criteria. Examples: Level 1 - 40371 Progesterone Lab Mean: 0.77 Bio-Rad expected Mean: 0.75 Bio-Rad Expected Range: 0.459 - 1.04 The expected ranges provided are plus/minus 3 SD levels. To find the Bio-Rad 1SD: 1.04 - 0.75 = 0.29 0.29 /3 = 0.096 The laboratory was using 0.145 as an expected SD. This was calculated by dividing Bio-Rad's plus/minus 3SD range by 2: 1.04 - 0.75 = 0.29 0.29/2 = .145 Other examples: Level 2 - 40372 Progesterone Lab Mean: 9.44 Bio-Rad expected Mean: 9.36 Bio-Rad Expected Range: 6.32 - 12.4 The expected ranges provided are plus /minus 3 SD levels. To find the Bio-Rad 1SD: 12.4 - 9.36 = 3.04 3.04/3 = 1.013 The laboratory was using 1.52 as an expected SD. This was calculated by dividing Bio-Rad's plus/minus 3SD range by 2: 12.4 - 9.36 = 3.04 3.04/2 = 1.52 Level 3 - 40373 TSH Lab Mean 34.8 Bio-Rad expected Mean: 36.7 Bio-Rad Expected Range: 26.7 - 46.7 The expected ranges provided are plus/minus 3 SD levels. To find the Bio-Rad 1SD: 46.7-36.7 = 10 10/3 = 3.333 The laboratory was using 5.0 as an expected SD. This was calculated by dividing Bio-Rad's plus/minus 3SD range by 2: 46.7-36.7 = 10 10/2 = 5 3. In an interview at 12:40 hours on 6/4/2019 in the laboratory, when asked if the laboratory had a quality control procedure that included step by step instructions for establishing means and limits for quality control materials, the Laboratory Manager stated the laboratory used the Immulite 1000 operator's manual. Based on review of the Siemens Immulite 1000 operator's manual, on pages 7-6 and 7-7, the manual describes how to edit a control, including editing the mean, SD, and SD

	Multiplier fields. The operator's manual does not describe how to establish means and limits for Bio-Rad Lyphochek Immunoassay Plus controls. 4. In an interview at 13:00 hours on 6/4/2019 in the laboratory, the Technical Supervisor stated the laboratory performed a lot-to-lot rollover in May 2019 where the laboratory recorded at least 10 runs of each quality control and calculated a target mean based on those runs. When asked how the laboratory established the acceptability criteria, the Technical Supervisor stated she set the target SD's based on advice from the supervisor at a sister facility. When asked if the laboratory had a procedure that described how to establish means and limits for quality control materials, the Laboratory manager stated the laboratory did not have a procedure that described quality control procedures step by step outside of the operator's manual.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Review of proficiency testing records and interview of facility personnel found that the laboratory director failed to ensure that the proficiency samples were tested in the same manner as patient samples. (See D 2009 and D 2010)
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of the laboratory's written polices and procedures, and staff interview, revealed the laboratory director failed to ensure an approved procedure manual was available to testing personnel for performing semen analysis. (see D5407)