Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2119463	03/03/2021
Name of Provider or Supplier	**Street Address, City, State**	
Aspire Fertility Institute - Smart Ivf	4300 N Mccoll #200, Mcallen, 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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 the laboratory's quality control records for Qwik-Check Beads, and confirmed in interview of facility personnel, the laboratory failed to verify new lot numbers of external quality control for semen analysis before placing them into use. The findings included: 1. Based on review of the laboratory's quality control records for Qwik-Check Beads from April 2020 to February 2021 revealed there was no documentation available for review that the laboratory had performed lot to lot verifications for the following lot numbers of external quality control materials: Low Control Lot # 051020002 Expiration Date: 05-01-2021 High Control Lot # 051020001 Expiration Date: 05-01-2021 Negative Control Lot # 051020003 Expiration Date: 05-01-2021 Low Control Lot # 290720002 Expiration Date: 02-02-2021 High Control Lot # 290720001 Expiration Date: 02-02-2021 Negative Control Lot # 290720003 Expiration Date: 02-02-2021 Low Control Lot # 240220001 Expiration Date: 08-21-2020 High Control Lot # 240220002 Expiration Date: 08-21-2020 Negative Control Lot # 240220002 Expiration Date: 08-21-2020 2. The laboratory was asked to provide documentation of verifying new lot numbers of Qwik-Check Beads prior to placing them into use. No documentation was provided. 3. An interview with the testing person on March 3, 2021 at 11:00 hours in her office confirmed the findings.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of patient reports and confirmed in interview of facility personnel, it was revealed the laboratory failed to have documentation of verifying calculations for 2019 and 2020. The findings were: 1. Review of patient final reports found the laboratory's electronic records system performs the following calculation: Total Motility 2. The laboratory was asked to provide documentation of manually verifying the calculation in 2019 and 2020 to ensure the system is performing the calculation correctly. No documentation was provided. 3. An interview with the Technical Supervisor in the break room at 11:30 hours on March 3, 2021 confirmed the findings.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) 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 laboratory policies, and confirmed in interview of facility personnel, the laboratory director failed to ensure a procedure manual is available to all testing personnel. The findings were: 1. Review of the laboratory's procedure manual found it was not approved by the current laboratory director. 2. Interview with the Technical Supervisor on March 3, 2021 at 11:30 hours in the break room confirmed the findings.