Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2119463	04/20/2018
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	The laboratory was surveyed on April 20, 2018 and found to be in compliance with the CLIA regulations.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of twice annual accuracy assessment for semen analysis. The findings were: 1. A review of the laboratory's test menu revealed the laboratory performed 100 semen analysis tests in 2017. 2. A review of the laboratory's records revealed the laboratory performed an accuracy assessment once in 2017. 3. The laboratory was asked to provide documentation performing twice annual accuracy assessments for semen analysis twice in 2017. No documentation was provided. 4. An interview with the technical supervisor on 04/20/2018 at 1015 hours in the break room confirmed the findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by:

	Based on review of laboratory policy, review of quality control records, review of patient results, and confirmed in interview of facility personnel, the laboratory failed to follow its own policy for evaluating threshold limits for its quality control testing. The findings were: 1. The laboratory's quality control policy stated, "Threshold Limits: All embryologists should be within 10% of the mean." 2. Review of the manufacturer's established quality control ranges located on the outside of the packaging listed the following means and ranges: Level 1 Lot # 260218001 Mean: 48 (+/- 12.0) Level 2 Lot # 260218002 Mean: 26 (+/- 6.5) Level 3 Lot # 260218003 Mean: 0.0 3. Review of the laboratory's quality control records revealed the laboratory had established the following ranges: Level 1 (high) Lot # 260218001 36 - 58 Level 2 (low) Lot # 260218002 20 - 32 Level 3 (negative) Lot # 260218003 0 4. Review of the laboratory's quality control records from October 2016 to April 2018 revealed the laboratory ran each level of control in duplicate but failed to calculate the percent difference to determine if the quality control was acceptable prior to patient testing. 5. An interview with the technical supervisor on 04/20/2018 at 1045 hours in the hallway confirmed the findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observations, review of manufacturer's instructions, and interview will facility personnel, the laboratory failed to ensure expired reagents and solutions were not available for use in patient testing. The findings included: 1. At 1030 hours on April 20, 2018 in the laboratory, the surveyor observed the following expired quality control material: wik heck beads Lot #260218001 (opened: 10-05-2016) Lot #260218002 (opened: 10-05-2016) Lot #260218003 (opened: 10-05-2016) 2. Review of the manufacturer's instructions for the wik heck beads (Rev. 22_NOV_2017) under, "For in-vitro use only" stated, "Open vial shelf life is 90 days." 3. Review of the laboratory's "Semen Log Sheet" revealed the laboratory performed 100 semen analysis tests annually. 4. In an interview at 1200 hours on 04/20/2018 in the break room, the technical supervisor confirmed that the quality control materials were expired.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review the laboratory's environmental logs, and confirmed in interview of facility personnel, the laboratory failed to perform corrective action for dates when the room temperature and the refrigerator in the laboratory were documented out of range. The findings were: 1. Review of the laboratory's "Temperature Log" revealed the laboratory had a defined room temperature range of 20-25 degrees Celsius. 2. Review

	of temperature records from October 2016 to March 2018 revealed the following dates when the temperature for the room was documented out of range: 09-18-2017 28.1 degrees Celsius 10-19-2017 19.8 degrees Celsius 11-16-2017 25.2 degrees Celsius 03-29-2018 19.9 degrees Celsius 3. Review of the laboratory's environmental records revealed the laboratory had a defined refrigerator temperature of 2-7 degrees Celsius. 4. Review of temperature records from October 2016 to March 2018 revealed the following dates when the temperature of the refrigerator was documented out of range: 10-05-2016 9 degrees Celsius 11-16-2017 9 degrees Celsius 12-06-2017 9 degrees Celsius 12-18-2017 9 degrees Celsius 01-16-2018 8 degrees Celsius 01-17-2018 8 degrees Celsius 01-18-2018 8 degrees Celsius 5. The laboratory was asked to provide documentation of performing corrective action when the temperature for the room and refrigerator were documented out of range. No documentation was provided. 6. An interview with the technical supervisor on 04/202018 at 1100 hours in the conference room confirmed the findings.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the laboratory's submitted Form CMS-209, and confirmed in interview of facility personnel, the laboratory director failed to ensure each testing person had the appropriate training prior to patient testing in October 2016. The findings were: 1. Review of the laboratory's policy for "Personnel Assessment" stated, "...Each embryologist personnel file should contain at least: summary of training and experience." 2. Review of the laboratory's submitted Form CMS-209 revealed the laboratory identified 1 testing person. 3. Review of the personnel records for Testing Person 1 revealed no documentation of training was available for review. 4. The laboratory was asked to provide the missing documentation. No documentation was provided. 5. An interview with the technical supervisor on 04/30/2018 at 1100 hours in the conference room confirmed the findings. He confirmed that he called the office at another location and the records were not available. Key: CMS - Centers for Medicare and Medicaid Services