Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1066816	10/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Aspire Fertility San Antonio	150 E Sonterra Blvd #220, San Antonio, 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.
D6050	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the facility failed to have documentation of training for 3 of 4 personnel who performed moderate complexity testing on the Immulite 1000 analyzer. The findings were: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 4 testing personnel who performed testing on the Immulite 1000 analyzer. They were (as listed on Form CMS 209): Testing personnel #1 Testing personnel #2 Testing personnel #3 Testing personnel #4 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of training for 3 of 4 personnel. The testing

	personnel without documentation of training were: Testing personnel #2 Testing personnel #3 Testing personnel #4 3. The laboratory was asked to provide documentation of training on the Immulite 1000 analyzer. No documentation was provided. 4. A interview with the technical supervisor on 10/21/2019 at 1130 hours in the break room - after his review of the records - confirmed the findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, and staff interview, it was revealed the technical consultant failed to include the observation of the performance of maintenance procedures as part of competency assessments for of 3 testing personnel performed in 2019. The findings were: 1. A review of the laboratory's personnel records revealed the technical consultant did not include the observation of the performance of maintenance procedures on the Immulite 1000 analyzer as part of the competency assessments performed in 2019 on 3 of 3 test personnel. They were (as listed on Form CMS 209): Testing personnel #1 Testing personnel #2 Testing personnel #3 2. An interview with the technical supervisor on 10/21/2019 at 1130 hours in the break room - after his review of the records- confirmed the findings.