Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2137456	12/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Fertlity Specialists Medical Group	6125 Paseo Del Norte, Ste 120, Carlsbad, CA	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on observation of the TOSOH AIA 360 chemistry analyzer, review of laboratory records, and interview with Testing personnel, the laboratory failed to incorporate proficiency test (PT) samples into the regular workload for testing by personnel routinely testing patients specimen. Findings included: 1. The laboratory routinely tested patients specimen for bHCG (pregnancy test), E2 (Estradiol), and P2 (Progesterone) using the TOSOH AIA 360 analyzer (serial number 27197703). 2. Persons routinely testing patients specimen were Lisa in 2021, Shelby in 2022, and KR in 2023. 3. Laboratory proficiency test Attestation documents for 2021-2023 recorded BG and DC as the testing persons. 4. Testing person-KP affirmed (12/13/23 at 1:30 PM) that the PT samples were not tested by the persons routinely testing patients specimen. 5. The reliability and quality of results reported for patients could not be assured when none of the routine testing personnel tested PT samples. Annual number of patients results reported: 1,244 (CMS116, 12/07/23). .
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel

	who performed the test(s). This STANDARD is not met as evidenced by: Based on observation of patients specimen, review of laboratory test records, and interview with laboratory testing personnel, the laboratory failed to maintain positive identification of specimens during testing. Findings included: 1. Patients serum specimen were uniquely accessioned and affixed with bar-coded labels for testing using the TOSOH chemistry analyzer. 2. The TOSOH results printouts failed to record accession numbers and thus, failed to provide positive identification of results to the specimen, as follows: Number of Sample IDs specimens without Accession Date tested number 2/04/22 14 9 out of 14 Sample IDs 1/23/23 11 9 out of 16 6/07/23 3 2 out of 3 9/25/23 6 4 out of 7 12/11/23 6 5 out of 6 3. Laboratory personnel affirmed (12/13/23 at 2:00 PM) the aforementioned findings and that positive identification of specimen tested was not maintained. 4. The reliability and quality of reporting results accurately could not be assured when positive specimen identification failed. .
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on survey findings and interview with laboratory personnel, the laboratory failed to establish and maintain an ongoing process to monitor, assess, and correct problems with the TOSOH barcode reader. Findings included: 1. TOSOH printouts of results erratically failed to record specimen Accession numbers in the Sample ID field. [Refer to D5787] 2. The errors extended throughout the timeframe under review for this survey: 2021-2023. 3. Laboratory personnel affirmed (12/13/23 at 2:00PM) knowing that the TOSOH bar code scanner malfunctioned, and that there had been no actions taken to correct it. 4. The laboratory failed to establish an ongoing process to assess all aspects of testing and correct problems as they arise.