Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0692832	11/16/2023
Name of Provider or Supplier	**Street Address, City, State**	
Fertility Treatment Center	2155 E Conference Dr, Suite 115, Tempe, AZ	

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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on lack of established policies and procedures for review and interview with the technical supervisor (TS-1), the laboratory failed to establish policies and procedures related to the accuracy verification process for semen morphology analysis. Findings include: 1. The laboratory performs semen morphology analysis under the speciality of Hematology with an annual test volume of 2,050. 2. No documentation was presented for review during the survey to indicate the laboratory established policies and procedures related to the verification of accuracy process for semen morphology analysis. 3. The TS-1 interviewed during the survey on 11/16/23 at 2:25 PM confirmed that the laboratory failed establish a written policy and procedure specific to the verification of accuracy process for semen morphology analysis.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in

	electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on lack of humidity records for review from 2021, 2022 and 2023, review of the manufacturer's specifications for the Tosoh AIA-900 analyzer, and interview with the technical supervisor (TS-1), the laboratory failed to monitor and document the humidity of the room where the Tosoh AIA-900 is utilized. Findings include: 1. The laboratory utilizes the Tosoh AIA-900 for performing testing under the subspecialty of Endocrinology. The laboratory's reported annual test volume in the subspecialty of Endocrinology is 10,000. 2. The manufacturer's specifications for the Tosoh AIA-900 reviewed during the survey listed an operating relative humidity range of 40% - 80%. 3. On the survey date of 11/16/2023, no documentation was provided for review to indicate the laboratory monitored and documented the humidity of the room where the Tosoh AIA-900 is utilized on each day of patient testing during 2021, 2022 and 2023, through the date of the survey. 4. The TS-1 interviewed on 11/16/2023 at 2:25 PM confirmed the laboratory failed to monitor and document the ambient humidity as indicated above.