Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2274159	02/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Vitas Fertility Holistic Ivf And Reproductive	1425 W Elliot Rd Ste 103, Gilbert, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 temperature and humidity documentation for review from 2024 and 2025 and interview with the Technical Consultant (TC-1), the laboratory failed to monitor and document the room temperature, refrigerator and ambient humidity that is essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting for testing performed on the TOSOH AIA-360 analyzer. Findings include: 1. The laboratory began performing patient testing on the TOSOH AIA-360 analyzer on 12/23/24 under the subspecialty of Endocrinology. The laboratory had performed testing on two patients by the time of the survey on 2/18 /25. 2. The laboratory failed to monitor and document the humidity of the room where patient testing occurred and testing reagents were stored from 12/24/24 through the survey date of 2/18/25. The manufacturer's ambient humidity requirement for the TOSOH AIA-360 analyzer is 40% - 80%. 3. The laboratory failed to monitor and document the room temperature where patient testing occurred and testing reagents were stored from 12/24/24 through the survey date of 2/18/25. The manufacturer's operating room temperature requirement for the TOSOH AIA-360 analyzer is 15C - 30 C. 4. The laboratory failed to monitor and document the temperature of the refrigerator where the TOSOH AIA-360 control materials were from 12/24/24

	through the survey date of: 2/18/25. The manufacturer's storage requirement for control materials is 2 - 10 C. 5. The TC-1 interviewed on 2/18/25 at 12:00 PM confirmed that the laboratory failed to produce evidence of temperature and humidity documentation from from 12/24/24 through the survey date of 2/18/25 for each day of patient testing.