Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2183334	02/01/2023
Name of Provider or Supplier	**Street Address, City, State**	
Vincere Molecular & Pathology Lab	7469 E Monte Cristo Ave Ste 100, Scottsdale, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records from 2021 for testing performed by the laboratory and interview with the facility personnel, the testing personnel failed to sign the PT attestation statements. Findings include: 1. The laboratory performs SARS-CoV-2 (COVID-19) testing using a PCR test that is authorized for use by the FDA under an Emergency Use Authorization (EUA), with an approximate annual test volume of 100. The laboratory participates in three PT events annually. 2. The PT attestation statements presented for review for the first, second and third events of 2021 lacked the testing personnel's signature. 3. The facility personnel interviewed on 2/01/23 at 1:40pm confirmed that the PT attestation statements indicated above were not signed by the testing personnel.
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 documentation for review and interview with the laboratory director, the laboratory failed to monitor and document the ambient humidity that is essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. Findings include: 1. The laboratory performs testing under the sub-specialties of Virology and Routine Chemistry, with an approximate annual test volume of 1,600. The laboratory began PSA testing on the Frend analyzer in October 2022 and began SARS-CoV-2 (COVID-19) testing on the QuantStudio 7 analyzer in February 2021. 2. No documentation was presented for review during the survey conducted on February 1, 2023 to indicate the laboratory monitored and documented the humidity of the room where the PSA testing occurs. The manufacturer's ambient humidity requirement for the Frend analyzer is 10-80%. 3. No documentation was presented for review during the survey conducted on February 1, 2023 to indicate the laboratory monitored and documented the humidity of the room where the COVID-19 testing occurs. The manufacturer's ambient humidity requirement for the QuantStudio 7 analyzer is 15-85%. 4. The laboratory director interviewed on 2/01/23 at 4:10pm confirmed that the laboratory failed to monitor and document the ambient humidity of the rooms where testing occurs, as indicated above.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of patient test reports and interview with the laboratory director, the laboratory failed to have a system in place to ensure the accuracy of test results that are manually entered into the Laboratory Information System (LIS). Findings include: 1. The laboratory began testing for PSA (Prostrate Specific Antigen) on the Frend analyzer in the specialty of Chemistry in October 2022, with an approximate annual test volume of 1,500. 2. The PSA test results are manually entered by testing personnel into the laboratory's LIS. 3. No documentation was presented for review during the survey conducted on February 1, 2023 to indicate the laboratory has a system in place to ensure the accuracy of patient test results that are manually entered from the analyzer to the LIS. 4. The laboratory director interviewed on 2/01/23 at 3: 20pm confirmed that the laboratory did not have a system in place to verify the accuracy of the patient test results that are manually entered from the analyzer to the LIS.