Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0997031	(X3) Date Survey Completed 11/18/2021
Name of Provider or Supplier Sacred Heart Health System Inc	**Street Address, City, State** 12385 Sorrento Rd Ste C4, Pensacola, FL	

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	A recertification survey was conducted on November 18, 2021. A special Coronavirus Disease 2019 (COVID-19) reporting survey was performed in conjunction. Pediatric Associates PA clinical laboratory was not in compliance with 42 CFR 493, Requirements for Clinical Laboratories.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on record review and interview with lab employee #A, the laboratory failed to report both positive and negative Coronavirus Disease 2019 (COVID-19) test results to the Department of Health from March 25, 2021 to November 18, 2021 within the required time frame of 24 hours, for a total of two hundred and sixteen Quidel Sofia 2 SARS Covid 19 Antigen tests. The findings include: Record review revealed the laboratory was not sending negative COVID-19 results to the Florida Department of Health, and COVID-19 positive results were being sent weekly. Review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116) signed by the Laboratory Director on Novemebr 17, 2021, revealed

	that the laboratory performed Quidel Sofia 2 SARS Covid 19 Antigen testing. During interview with lab employee #A, it was confirmed that the lab was not aware of the reporting requirements for COVID-19 until the day of survey.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review of employee competencies and interview with lab staff #A, the Technical Consultant, the lab failed to include the minimal six (6) competency assessment criteria in their personnel competencies for seven (7) out of 7 testing personnel (TP) in 2019, 2020 and 2021. The findings include: Record review of employee competencies revealed a statement that testing staff "have been observed and are considered proficient" without any more details as to how they arrived at that conclusion. The minimal 6 competency assessment criteria were not included in evaluations for 7 out of 7 testing personnel. The following competency assessment criteria were missing from the evaluations: 1) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing 2) Monitoring the recording and reporting of test results 3) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records 4) Direct observation of performance of instrument maintenance and function checks 5) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples 6) Assessment of problem solving skills Interview with lab staff #A on 11/18/2021 at 1130 am, confirmed that is all the documentation they had for the 7 testing personnel competencies.