Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0914265	02/24/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pensacola Pediatrics Pa - Tiger Point	1368 Country Club Rd, Gulf Breeze, 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	On 2/16/2022, a recertification survey was conducted at Pensacola Pediatrics PA - Tiger Point. The survey continued through 2/24/2022 to gather additional information. Pensacola Pediatrics PA - Tiger Point clinical laboratory was not in compliance with 42 CFR 493, Requirements for Laboratories.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review of College of American Pathologist (CAP) proficiency testing documents, and interview with lab staff, the Laboratory Director (or designee) and testing personnel failed to sign attestation forms or sign correctly for testing events for the years 2020 and 2021. The findings included: Review of CAP Hematology proficiency testing attestation forms revealed that they had not been signed for three testing events in 2020 and one testing event in 2021. Review of CAP Routine Microbiology testing events in 2020 revealed two attestation forms had typed initials where signatures should be and one attestation sheet had the Laboratory Director's signature, but was missing the testing personnel's signature. Attestation forms for Microbiology in 2021 revealed one testing event had not been signed and one event's

	attestation form had typed initials where signatures should be. Interview with lab staff on 2/16/22 at 1600, confirmed that the attestation forms had not been signed or had been signed incorrectly.
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 record review and interview with lab staff, the laboratory failed to document a temperature range for the incubator for all of 2020, 2021, and the first two months of 2022. Findings included: Record review of the laboratory's Incubator Temperature Log revealed no temperature range had been documented for the years 2020, 2021, and the first two months of 2022. Interview with lab staff on 2/16/22 at approximately 1600, confirmed the temperature ranges for the incubator were missing from the log sheets.