Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0970001	09/30/2024
Name of Provider or Supplier	**Street Address, City, State**	
Pedroso Pediatrics Pa	2647 Hollywood Blvd, Hollywood, 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 conducted from 09/25/2024 to 09/30/2024 found the PEDROSO PEDIATRICS PA clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have all testing personnel (TP) rotate through the testing of Proficiency Testing (PT) for Hematology specialty in one out of two years reviewed. Findings included: Review of FORM CMS-209 signed and dated by the Laboratory Director (LD) on 09/24/2024 revealed the laboratory had three TP listed (TP#A, TP# B and TP#C). -Review of personnel records revealed that TP#A, TP#B, TP#C had annual competencies during 2022 and 2023. -Review of College of American Pathologists (CAP) PT records for 2023 (first, second and third event) and 2024 (first and second event), revealed that TP#C had no PT participation during 2023 for Hematology specialty. During an interview on 09/25 /2024 at 11:30 AM, the Lead Technician confirmed that the laboratory failed to rotate the PT between all TP for the period of reference.
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended

	during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to participate in Proficiency Testing (PT) that resulted in a score of zero (0) percent for Hematology in first event of 2023. Findings included: -Review of College of American Pathologists (CAP) PT records for 2023 (first, second and third event) and 2024 (first event and second event), revealed that for the first event of 2023 for Hematology specialty the laboratory had a 0 score. -Review of instrument print outs revealed that the PT samples were tested on 02/21/2023 at 02:14 PM. - Review of CAP instructions revealed the following: "Results are due no latter than midnight, Central Time February 20, 2023" During an interview on 09/25/2024 at 11:30 AM, the Lead Technician confirmed that the laboratory failed to test the PT samples in time for the event of reference.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform at least two levels of quality control (QC) each day of patient testing on the Complete Blood Cell Counter (CBC) Medonic M Series for one out of three patients reviewed. Findings included: -Review Complete Blood Cell Count for three patients : Patient (P) #1 tested 04/11/2023, P#2 tested on 09/18/2023 and P#3 tested on 06/06/2024 -Review of QC records revealed that the laboratory failed to run quality control before patient testing on 09/18/2023, that day one patient was tested. During an interview on 09/25 /2024 at 11:35 AM, the Lead medical assistant confirmed that the laboratory failed to run QC before patient testing on the day of reference.
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 and staff interview, the Technical Consultant (TC) failed to perform the six-month Complete Blood Count (CBC) competency for one out of three

	Testing Personnel (TP) in 2023. Findings included: -Review of FORM-209 (01/2021) signed and dated by the Laboratory Director (LD) on 09/24/2024, revealed that the LD, Clinical Consultant (CC), and TC was the same person and there were three Testing Personnel (TP) (TP#1, TP#2 and TP#3) -Review of personnel records revealed that the TP#C had initial competency evaluation signed by the TC on 12/21 /2022 with a statement that said: 'Re Evaluation 6 months." No six-month competency found between the Initial and the annual on 12/19/2023. During an interview on 09/25 /2024 at 11:40 AM, the Lead Medical Assistant confirmed that the TC failed to document the six-month competency for TP#C.