Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1043309	05/06/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pedroso Pediatrics Pa-#2	4302 Alton Road - 450, Miami Beach, 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 on 05/06/2021 found that the clinical laboratory PEDROSO PEDIATRICS PA-# 2 was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2127	HEMATOLOGY CFR(s): 493.851(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on record review of College of American Pathologists (CAP) Hematology proficiency testing (PT) results and interview with testing personnel (TP) A, the laboratory failed to submit PT results in the specified timeframe for 2nd event of 2019 for the specialty of Hematology resulting in a score of 0% for all hematology analytes. Findings include: Review of CAP Hematology PT records revealed that the laboratory failed to submit the results for the second event of 2020 on time resulting in a score of 0 % scores for Hematology, Cell Identification or White Blood Differential, Red Blood Cell, Hematocrit, Hemoglobin, White Blood Cells and Platelets. During an interview on 06/06/2021 at 10:00 AM, the TP A confirmed that the laboratory failed to submit timely results for the 2nd event of 2020.
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 Hematology analyzer Medonic M series user manual review and interview with testing personnel (TP) A, the laboratory failed to document room temperature and humidity requirement to assure optimal operation of the analyzer during 2020 and 2021. Findings include: Review of the Medonic M series manual indicates that the operation temperature range is 18 to 32 degrees celsius and humidity below 80 %. Review of the temperature and humidity log revealed that there was no record of the daily temperature and humidity of the laboratory room in May 2021. The laboratory could not provide temperature log for 2020 and 2021. During an interview on 5/06 /2021 at 10:30 a.m., the TP A confirmed that there was no documentation of room and humidity control check.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on Medonic M Series maintenance records and testing personnel (TP) A interview, the laboratory failed to document all required maintenance performed for 2019 and 2020. Findings include: Based on user manual for Medonic M Series analyzer the laboratory had to perform daily, weekly, monthly and semiannual maintenance actions. Review of the Maintenance log for 2019 (August to December), 2020 and 2021 (January to April) revealed that the laboratory failed to document the monthly maintenance in September 2019; April, May, June and December 2020. During an interview on 05/06/2021 at 10:00 am, the TP A confirmed that there was no documentation of all required maintenance for the period of reference.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control

	materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and interview with testing person (TP) A, the laboratory failed to perform calibration verification procedures of the Medonic M Series Analyzer at least every 6 months from 12/30/2019 to 10/23/2020. Findings include: - Review of the Medonic M Series Analyzer calibration records revealed that the laboratory performed calibrations on 12/30/2019 and 10/23/20. During an interview on 05/06/2021 at 10:00 a.m., TP A confirmed that the laboratory failed to perform instrument calibration every 6 months in the period of 12/30/2019 to 10/23/2020.