Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1093008	09/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
Aguilar Pediatrics	6830 Hospital Drive Ste 206, Rosedale, MD	

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
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 review of the proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory failed to ensure that the PT samples were routinely performed by the testing personnel (TP) who performed hematology testing. Findings: 1. The "Laboratory Personnel Report (CLIA)" (CMS-209 form) listed five TP. Five of the five TP listed were performing moderate complexity hematology testing. 2. The hematology PT records from 2022 and 2023 included five events which were reviewed. One of the five TP listed on the CMS-209 performed the PT testing for three of the five events and another TP performed the testing for two of the five events. During the survey the TC confirmed that the other three TP had been trained and were performing hematology testing in the lab for at least three to six months. 3. During the survey on 09/18/2023 at 12:15 PM, the TC confirmed that the PT testing system failed to include rotation of the PT specimens among the five TP listed on the CMS-209.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step

	performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the policy and procedure manual and interview with the technical consultant (TC), the laboratory's policy and procedure manual failed to provide normal values for ages 1-2 and 3-4 years old and identify each of the components of the complete blood count (CBC) normal values in the procedure manual. Findings: 1. The "Normal Values of Complete Blood Count" procedure listed three different normal patient values depending on the age of the patient. Normal values were listed for patients age 0-1 years, 2-3 years, and 4-18 years. The procedure did not include normal patient ranges for 1-2 years and 3-4 years. 2. The procedure listed reference ranges for each of the three different normal patient values but failed to include the identification of each of the components of the CBC, e.g. white blood count (WBC), and red blood count (RBC) etc... 3. During the survey on 09/18/2023 at 12:15 PM, the TC confirmed that the procedure manual failed to include normal patient ranges for 1-2 years and 3-4 years.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of final reports and interview with the technical consultant (TC), the laboratory failed to ensure that the final test report included the normal values for the interpretation of the patient test results that were listed in the "Normal Values of Complete Blood Count" procedure. Findings: 1. The "Normal Values of Complete Blood Count" procedure listed three different normal patient values depending on the age of the patient. Normal values were listed for patients aged 0-1 years, 2-3 years, and 4-18 years. The TC stated that the normal patient values are programmed into the hematology analyzer and will print the appropriate values based on the date of birth (DOB) entered prior to testing the specimen. 2. The final report for Sample number 01302023 was tested on 06/30/2023. The patient's DOB was 01/30/2023 which would

	make the patient approximately 5 months old at the time of testing. The normal values that were listed for the patients' test results were for a patient that was 2-3 years old. 3. The final report for Sample number 04062022 was tested on 06/26/2023. The patient's DOB was 04/06/2022 which would make the patient approximately 15 months old. The normal values that were listed for the patients test results were for a patient that was 2-3 years old. The procedure manual failed to include normal values for patients' 1-2 years old. 4. During the survey on 09/18/2023 at 12:15 PM, the TC confirmed that the hematology analyzer failed to provide an accurate normal value as defined in the "Normal Values of Complete Blood Count" procedure manual.