Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1093008	10/28/2021
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and interview with the technical consultant at 2:00 pm on the day of survey, the laboratory did not have the attestation statement for the 2020 MLE event 3 proficiency testing challenge. Findings: 1. The laboratory performs proficiency testing for hematology 3 times a year and with each event, sent to the laboratory) the proficiency test provider includes a written statement that the director and testing staff sign stating testing be performed in the same manner as patient testing; 2. Review of proficiency test records for MLE 3 in 2020 shows that the attestation statement was not included in the laboratory records; and 3. This was confirmed during interview with the technical consultant during the survey.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview with the technical consultant at 2:00 pm on the day of survey, the laboratory director did not ensure that the competency of the technical consultant was assessed annually. Findings: 1. The laboratory director

	reviewed a quiz that that the technical consultant took to assess knowledge; 2. The laboratory director signed two competency check quizzes for the technical consultant for 2021, but did not sign one for 2020, as the competency review is to be performed annually; and 3. This was confirmed during interview with the technical consultant during the survey.
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 record review and interview with the technical consultant at 2:00 pm on the day of survey, the laboratory did not ensure the normal patient reference ranges as stated from the hematology written procedure agreed with the final report and the normal hematology reference ranges reported for the patient. Findings: 1. The laboratory written procedure stated that the normal reference range for a patient white blood cell count was 5.9 - 17.5 K/mcl, but one of one patient report reviewed had a range of 5.4 - 16 K/mcl; 2. The laboratory written procedure stated that the normal reference range for a patient red blood cell count was 3.5 - 5.5 million/mm3, but patient report had a range of 3.5 - 5 million/mm3; and 3. This was confirmed during interview with the technical consultant during the survey.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on record review and interview with the technical consultant at 2:00 pm on the day of survey, the laboratory did not ensure that hematology controls were not used past expiration. Findings: 1. The laboratory record documenting the receipt of quality control reagents and the date they were placed in use did not include control reagents

	that were not expired between the dates of March 8 and March 19 of 2021; 2. Control lot MX427 was documented as expired March 5, 2021, there was no other control documented for use with an expiration date that was not expired between March 8 and March 19 of 2021; and 3. This was confirmed during interview with the technical consultant during the survey.
D6119	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(6) The technical supervisor is responsible for ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly. This STANDARD is not met as evidenced by: Based on record review and interview with the technical consultant at 2:00 pm on the day of survey, the laboratory did not ensure that the laboratory took corrective actions prior to reporting patient results when hematology quality control failures occurred and did not notify the technical consultant and testing staff did not write up the corrective action as stated in the written procedures (instead the technical consultant wrote the initial corrective action reports). Findings: 1. The laboratory written procedure for accepting quality control results to assure accurate patient testing states that all three levels of controls (high, mid and low levels of control) must fall within acceptable ranges before patient testing can begin; 2. The corrective action report completed by the technical consultant on March 26, 2021 for quality control failures occurring on March 19, 17 and 11, 2021 stated that the steps taken to solve this problem was that two of the 3 quality control results were within range and that testing could be performed; 3. The March 26, 2021 corrective action report was written days after the quality control failures occurred and these failures were not reported to the director and resolved on the day they occurred; 4. On March 8, 2021, the result for the high level of platelet control was 593/mcl (acceptable range is 498 to 588/mcl) and nine patients were tested on that day. The laboratory did not complete a corrective action form, the technical consultant was not notified, corrective action procedures were not followed, staff accepted the failed high level quality control test result and performed patient testing, even though only two of the three quality control results were acceptable; 5. On August 3.2021 the result of the high quality control level for platelet count did not meet the laboratorys criteria for acceptability and was 581 mcl (acceptable range 435 to 565 mcl) patient testing was performed and corrective action was not taken; 6. On July 28, 2021 the result of the high quality control level for platelet count was 572 mcl (acceptable range 435 to 565 mcl) patient testing was performed and corrective action was not taken; and 7. This was confirmed during interview with the technical consultant during the survey.