Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0928015	07/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Fairway Pediatrics Llc	7020 North Highway 190 Suite C, Covington, LA	

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 was performed at Fairway Pediatrics, CLIA ID # 19D0928015 on July 12, 2023. Fairway Pediatrics was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 review of the laboratory's proficiency testing records and interview with laboratory personnel, the laboratory failed to ensure that proficiency testing attestation statements were signed by the laboratory director for four (4) of five (5) events reviewed. Findings: 1. Review of the laboratory's American Proficiency Institute (API) hematology proficiency testing records revealed the laboratory director did not sign the attestation statements for the following events: a) 2021 Hematology /Coagulation 3rd Event b) 2022 Hematology/Coagulation 2nd Event c) 2022 Hematology/Coagulation 3rd Event d) 2023 Hematology/Coagulation 1st Event 2. In interview on July 12, 2023 at 2:10 p.m., Testing Personnel 1 confirmed the laboratory director did not sign the attestation statements listed above.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure the Laboratory Director reviewed the proficiency testing performance evaluation results for five (5) of five (5) events reviewed. Findings: 1. Review of the laboratory's American Proficiency Institute (API) hematology proficiency testing records revealed the laboratory did not have documentation of the review of the performance evaluation by the laboratory director for the following events: a) 2021 Hematology /Coagulation 3rd Event b) 2022 Hematology/Coagulation 1st Event b) 2022 Hematology/Coagulation 2nd Event c) 2022 Hematology/Coagulation 3rd Event d) 2023 Hematology/Coagulation 1st Event 2. In interview on July 12, 2023 at 2:10 p.m., Testing Personnel 1 confirmed the laboratory director did not sign the proficiency test evaluation reports for the events identified above.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with laboratory personnel, the laboratory failed to maintain a complete policy for proficiency testing. Findings: 1. Review of the laboratory's policy "Proficiency Testing Procedures" revealed the laboratory did not include instructions for documentation of the following: a) Attestation to include appropriate personnel b) Performance evaluation review by the laboratory director 2. In interview on July 12, 2023 at 3:52 p.m., Testing Personnel 1 confirmed the laboratory's policy for proficiency testing did not include the information identified above.
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 laboratory's policy and procedure manual and interview with testing personnel, the laboratory failed to establish complete policies and procedures for hematology testing. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not define panic or alert values for hematology testing. 2. In interview on July 12, 2023 at 3:57 p.m., Testing Personnel 1 confirmed the laboratory policies did not include critical values for hematology testing.
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 observation and interview with laboratory personnel, the laboratory failed to ensure laboratory supplies were not used beyond their expiration date. Findings: 1. Observation by surveyors during the laboratory tour on July 12, 2023 at 1:26 p.m. revealed the following expired items: a) BD Veritor System RV Reagent D Unitized Tubes, Lot 0119836, Expiration Date: April 22, 2023, Quantity: Two (2) b) BD Veritor System RV Reagent D Unitized Tubes, Lot 0108114, Expiration Date: April 15, 2023, Quantity: One (1) c) BD microtainer K2EDTA, Lot 1337943, Expiration Date: May 31, 2023, Quantity: Fifty (50) 2. In interview on July 12, 2023 at 1:44 p. m., Testing Personnel 1 confirmed the items listed above were expired.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on observation, review of quality control records and policies, and interview with laboratory personnel, the laboratory failed to document all corrective actions taken when hematology quality control was outside the laboratory's acceptable limits for eleven (11) of sixty-six (66) days reviewed. Findings: 1. Observation by surveyors during the laboratory tour on July 12, 2023 at 1:26 p.m. revealed the laboratory utilized three levels of Horiba Minitrol quality control for hematology testing on the Horiba ABX Micros 60. 2. Review of quality control records revealed the laboratory repeated quality control that was outside the laboratory's acceptable limits but did not document corrective action steps performed on the following dates: a) May 6, 2022 - MX435_DEL High - tested two (2) times b) May 11, 2022 - MX435_DEL_Low - tested two (2) times - MX435_DEL Normal - tested two (2) times c) May 13, 2022 -

	MX435_DEL High - tested two (2) times d) May 16, 2022 - MX435_DEL High - tested two (2) times e) December 6, 2022 - MX438X High - tested two (2) times f) December 10, 2022 - MX438X Normal - tested two (2) times g) December 15, 2022 - MX438X Low - tested four (4) times h) December 27, 2022 - MX438X Normal - tested three (3) times i) May 10, 2023 - MX441 Low - tested two (2) times j) May 20, 2023 - MX441 Low - tested two (2) times - MX441 High - tested two (2) times k) May 22, 2023 - MX441 Normal - tested two (2) times 3. Review of the laboratory's "Quality Control Flowsheet" revealed the laboratory had instructions for corrective action when quality control was outside the laboratory's acceptable limits but did not include instructions for corrective action documentation. 4. In interview on July 12, 2023 at 3:16 p.m., Testing Personnel 1 confirmed corrective action was not documented for quality control outside the laboratory's acceptable limits on the dates identified above.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policy and procedure manual, laboratory documents, and temperature logs as well as interview with laboratory personnel, the laboratory failed to perform corrective actions when the room temperature was not maintained within acceptable limits for two (2) of six hundred thirty-eight (638) days reviewed. Findings: 1. Review of the laboratory's policy and procedure manual revealed a policy for performing corrective actions when the temperature is not maintained within acceptable limits. 2. Review of the laboratory document titled "Inservice Laboratory In Reference To Temperature Logs" revealed instructions for performing and documenting corrective actions when temperatures exceed acceptable limits. 3. Review of the laboratory's temperature logs revealed the laboratory's acceptable room temperature range was 18-32 degrees Celsius/65-90 degrees Fahrenheit. 4. Further review of the laboratory's temperature logs revealed the room temperature was outside of the acceptable range on the following days without corrective action: December 11, 2021: Room temperature documented as 2 degrees Celsius March 20, 2023: Room temperature documented as 16 degrees Celsius 5. In interview on July 12, 2023 at 3:30 p.m., Testing Personnel 1 confirmed corrective actions were not performed on the days identified above. II. Based on review of the laboratory's policy and procedure manual and temperature logs as well as interview with laboratory personnel, the laboratory failed to perform corrective actions when refrigerator temperatures were not maintained within acceptable limits for one (1) of six hundred thirty-eight (638) days reviewed. Findings: 1. Review of the laboratory's policy and procedure manual revealed a policy for performing corrective actions when temperatures are not maintained within acceptable limits. 2. Review of the laboratory document titled "Inservice Laboratory In Reference To Temperature Logs" revealed instructions for performing and documenting corrective actions when temperatures exceed acceptable limits. 3. Review of the laboratory's temperature logs revealed the laboratory's acceptable temperature range for the refrigerator was 2-8 degrees Celsius. 4. Further review of the laboratory's temperature logs revealed the laboratory's refrigerator temperature was outside of the acceptable range on October 22, 2022 (documented as 1 degrees Celsius) and corrective action was not performed. 5. In

	interview on July 12, 2023 at 3:30 p.m., Testing Personnel 1 confirmed corrective actions were not performed on the date identified above.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory's Quality Assurance monitors failed to identify and correct quality issues in Analytic Systems. Findings: 1. The laboratory failed to establish complete policies and procedures for hematology testing. Refer to D5403. 2. The laboratory failed to ensure laboratory supplies were not used beyond their expiration date. Refer to D5417. 3. The laboratory failed to document all corrective actions taken when hematology quality control was outside of acceptable limits for eleven (11) of sixty-six (66) days reviewed. Refer to D5783. 4. The laboratory failed to perform corrective actions when room temperature was not maintained within acceptable limits for two (2) of six hundred thirty-eight (638) days reviewed. Refer to D5785 I. 5. The laboratory failed to perform corrective actions when refrigerator temperatures were not maintained within acceptable limits for one (1) of six hundred thirty-eight (638) days reviewed. Refer to D5785 II.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to provide overall management and direction to the laboratory. Findings: 1. The laboratory failed to ensure laboratory supplies were not used beyond their expiration date. Refer to D5417. 2. The laboratory failed to perform corrective actions when room temperature was not maintained within acceptable limits for two (2) of six hundred thirty-eight (638) days reviewed. Refer to D5785 I. 3. The laboratory failed to perform corrective actions when refrigerator temperatures were not maintained within acceptable limits for one (1) of six hundred thirty-eight (638) days reviewed. Refer to D5785 II.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of

	the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested as required. Refer to D2009.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the proficiency testing evaluations were reviewed. Refer to D5211.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established and maintained to assure quality laboratory services were provided. Refer to D5783.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Findings: 1. The laboratory failed to maintain a complete policy for proficiency testing. Refer to D5291. 2. The laboratory's Quality Assurance monitors failed to identify and correct quality issues in Analytic Systems. Refer to D5791.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5403.