Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0928015	05/29/2019
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, LLC-CLIA ID # 19D092815 on May 29, 2019. Fairway Pediatrics was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director 42 CFR 493.1421 CONDITION: Laboratories performing moderate complexity testing; Testing Personnel
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to retain instrument printouts that included flags for Complete Blood Count (CBC) testing. Findings: 1. Review of the laboratory's "Complete Blood Count Flag Policy" revealed "Any flagged CBC's that contain an $! or * will be held for a total of 15 minutes & again repeated; If a specimen results in another flag, a fresh specimen will be collected and processed. All platelet flags should be re-run after 15 minutes or redrawn then sent to a reference lab to verify a manual count." 2. In interview on May 29, 2019 at 11:50 am, Personnel 3 stated for CBC results with flags the laboratory waits fifteen (15) minutes then retests the sample. Personnel 3 stated often times the flags go away after the sample is retested. Personnel 3 stated the laboratory does not keep the initial flagged instrument printout. Personnel 3 stated she was unable to determine flagged samples that had been repeated.
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: I. Based on record review and interview with personnel, the laboratory failed to ensure written policies and procedures to assess competency for one (1) of two (2) Technical Consultants were complete. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the Laboratory Director and Personnel 2 were listed as Technical Consultants. 2. Review of the laboratory's policies and procedures revealed the laboratory did not have a policy for competency assessment of Technical Consultant including frequency of performance. 3. Review of personnel records for Personnel 2 revealed a competency assessment for duties as Technical Consultant was not performed. 4. In interview on May 29, 2019 at 9:30 am, Personnel 2 stated he was added as a Technical Consultant. Personnel 2 confirmed he did not have a competency assessment performed for Technical Consultant duties. Personnel 2 further stated he was unaware it was required since he is a physician. II. Based on record review and interview with personnel, the laboratory failed to establish written policies and procedures to assess competency for testing personnel. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. In interview on May 29, 2019 at 10:30 am, Personnel 3 stated the laboratory did not have a personnel competency policy.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to perform an assessment for Hematology proficiency test (PT) results that scored less than one hundred (100) percent. Findings: 1. Review of the laboratory's 2017 and 2018 American Proficiency Institute (API) PT results revealed the laboratory received the following "unacceptable" results: 2017 3rd Event: Sample HEM-15 for Red Cell Count, API grade: "unacceptable"-80% 2018 3rd Event: Sample HEM-14 for Granulocytes, API grade: "unacceptable"- 80% 2018 3rd Event: Sample HEM-12 for Monocytes, API grade: "unacceptable"-80% 2. Review of the laboratory's PT records revealed the laboratory did not perform assessments for the "unacceptable" by API PT results. 3. In interview on May 29, 2019, Personnel 3 stated for the identified PT

	results she thought nothing further needed to be done since the scores were 80%. Personnel 4 further stated she was unaware any score below 100 % needed to be investigated.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish complete policies and procedures. Findings: 1. Review of the laboratory's documents and records revealed the laboratory did not have written polices and procedures that included: a) Complete Blood Counts (CBC) flagging issues that may occur on the Horiba ABX, to include what alternate methods/actions are required b) Record Retention requirements c) Performance specification: detailed procedures for performing accuracy and precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference range studies, acceptability criteria for studies, and actions to take when data from the studies fail to meet acceptability criteria 2. In interview on March 9, 2017 at 11:22 am, Personnel 2 stated the laboratory did not have a policy and procedure manual. Personnel 2 stated the laboratory follows the user's guide provided to them when instrument was installed.
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 personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manual revealed the following written procedures were not included: a)

	Quality control to include: how to perform verification of new lot of control material, corrective action procedures for unacceptable results to include contacting service and patient assessments. 2. In interview on May 29, 2019, Personnel 3 confirmed the identified procedures were not include in the laboratory's policy and procedure manual.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to address White Blood Cell flags appearing on Complete Blood Counts (CBC) per manufacturer requirements. Findings: 1. Observation by surveyor during laboratory tour on May 29, 2019 revealed the laboratory utilizes the Horriba ABX Micros 60 analyzer for Complete Blood Count (CBC) testing. 2. Review of the ABX Micros 60 User's manual revealed the following flag information: "The ABX Micros 60 has a system of WBC Differential flags alerting the operator to the possible presence of pathological cells, abnormal volume distribution histograms, or abnormal elevated populations such as the excessive presence of Eosinophils and Basophils. a) L1-indicates an abnormal number of cells in comparison with the Lymphocytes in the 30 fl to 60 fl zone. The pathological elements which may be found in this area include: platelet aggregates and nucleated red blood cells b) M2-flag indicates an excessive number of cells in the 130 fl to 160 fl zone. The pathological elements which may be found in this area will include: lymphoblasts, myelocytes, atypical lymphocytes, and basophilia c) G1-flag indicates an excessive number of cells in the 160 fl to 220 fl zone. The pathological elements which may be found in this area will include: eosinophilia, myelocytes, neutrohpil polynucleose d) G2-flag indicates an excessive number of cells in the 220 fl to 250 fl zone. This flag makes it possible to follow an abnormal Granulocyte peak displacement. Some of the cell variances will include anomalies in the cell membrane of the granulocytes, possible lyse flow error, fluidic errors, old blood (after 6 to 8 hours) unrefrigerated, and granulocyte cell size less than 250 fl. e) G3-flag indicates an excessive number of cells larger than 400 fl. The pathological elements which may be found in this area will include: metamyelocytes and many types of immature cells." "All abnormal distribution flagged samples should be reviewed following your laboratory's review criteria or review a stained smear to confirm the differential results. Redraw and retest the blood sample as required." 3. Review of the laboratory's "Complete Blood Count Flag Policy" revealed the policy did not include white blood cell flags. 4. Review of random selection of patient reports revealed the following two (2) of (5) patients were reported without flags addressed per manufacturer requirements: December 15, 2018: Patient PT00011262-1: "Flags: WBC Flags: G1" May 1, 2019: Patient PT00011640-1: "Flags: WBC M2G1G2" 5. In interview on May 29, 2019 at 1:01 pm, the Laboratory Director stated the laboratory does not have a policy that addresses the identified flags. Personnel 2 and 3 stated for the identified flags any further action is left up to the discretion of the physician.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to label opened Hematology controls with an expiration date. Findings: 1. Observation by surveyor during the laboratory tour on May 29, 2019 revealed the laboratory utilizes the Horiba ABX Micros 60 analyzer with Minitrol 16 Tri Level Controls for Complete Blood Count (CBC) testing. 2. Review of the Minitrol 16 Tri-Level Control package insert revealed "Opened tubes are stable for 16 days provided they are handled properly, and provided the in section 'Instructions for use' are followed." 3. Further observation by surveyor during the laboratory tour on May 29, 2019 revealed the following opened controls in the laboratory's refrigerator without expiration date labeling : Minitrol Lot # MX417N, open date written on tube "5/20 /19" Minitrol Lot # MX417L, open date written on tube "5/20/19" Minitrol Lot # MX417H, open date written on tube "5/20/19" 4. In interview on May 29, 2019, Personnel 3 confirmed the laboratory the identified open controls were not labeled with an expiration date.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to document corrective actions performed when the refrigerator temperature was not maintained between 2 degrees to 8 degrees Celsius. Findings: 1. Review of the laboratory's "Temperature Log" revealed "Refrigerator needs to be +35F - 46F (2-8 C). If temperatures fall outside of desired ranges, contact VFC immediately." 2. Further review of the laboratory's "Temperature Logs" for January 2018 through May 2019 revealed the refrigerator temperature was documented outside of the acceptable limits without documented corrective action for the following thirteen (13) days: July 2, 2018: morning recorded temperature 1 degree Celsius July 3, 2018: morning recorded temperature 1 degree Celsius, afternoon recorded temperature 1 degree Celsius August 16, 2018: morning recorded temperature 1 degree Celsius, afternoon recorded temperature 1 degrees Celsius August 28, 2018: afternoon recorded temperature 1 degree Celsius October 5, 2018: morning recorded temperature 1

	degree Celsius October 24, 2018: afternoon recorded temperature 1 degree Celsius October 26, 2018: afternoon recorded temperature 1 degree Celsius October 31, 2018: morning recorded temperature 1 degree Celsius November 1, 2018: afternoon recorded temperature 1 degree Celsius November 5, 2018: morning recorded temperature 1 degree Celsius, afternoon recorded temperature 1 degree Celsius November 6, 2018: afternoon recorded temperature 1 degree Celsius November 12, 2018: afternoon recorded temperature 1 degree Celsius March 1, 2019: afternoon recorded temperature 0 degree Celsius 3. In interview on May 29, 2019, Personnel 3 confirmed the laboratory did not have documentation that corrective actions were performed for the identified dates.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure the laboratory personnel were performing test methods as required for accurate and reliable results. Refer to D6014. 2. The Laboratory Director failed to ensure the laboratory followed the corrective action plan for unacceptable proficiency testing results. Refer to D6019. 3. The Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D6024. 4. The Laboratory Director failed to ensure laboratory personnel performing moderate complexity testing met state of Louisiana licensure requirements. Refer to D6029. 5. The Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency. Refer to D6030. 6. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6031. 7. The Laboratory Director failed to provide written job descriptions for all Laboratory Personnel. Refer to D6032.
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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel were performing test methods as required for accurate and reliable results. Findings: 1. The laboratory failed to address

	White Blood Cell flags appearing on Complete Blood Counts (CBC) per manufacturer requirements. Refer to D5411. 2. The laboratory failed to label opened Hematology controls with an expiration date. Refer to D5415.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory followed the corrective action plan for unacceptable proficiency testing results. Refer to D5221.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5781.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by:

	Based on record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performing moderate complexity testing met state of Louisiana licensure requirements. Refer to D6064.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency. Refer to D5209 I and D5209 II.
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 observation, record review, and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to establish complete policies and procedures. Refer to D5401. 2. The laboratory failed to have a complete policy and procedure manual. Refer to D5403.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen

	processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to provide written job descriptions for all Laboratory Personnel. Findings: 1. Review of the laboratory's policy and procedure manual and personnel records revealed the laboratory did not have a written job description for the Laboratory Director and Technical Consultant. 2. In interview on May 29, 2019 Personnel 3 confirmed the laboratory did not have a written job descriptions for the identified personnel.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to establish complete policies and procedures. Refer to D5401. 2. the laboratory failed to have a complete policy and procedure manual. Refer to D5403. 1. The laboratory failed to address White Blood Cell flags appearing on Complete Blood Counts (CBC) per manufacturer requirements. Refer to D5411. 2. The laboratory failed to label opened Hematology controls with an expiration date. Refer to D5415.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on record review, and interview with personnel, the Technical Consultants failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D5781.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultants failed to perform a competency assessment at least semi-annually during the first year

	for one (1) of four (4) testing personnel reviewed. Findings: 1. In interview on May 29, 2019, Personnel 3 stated Personnel 5 was hired since the laboratory's previous recertification survey. 2. In further interview, the Office Manager stated Personnel 5 was hired as a part-time employee on April 3, 2017 then moved to full-time on October 16, 2017. 3. Review of personnel records for Personnel 5 revealed the laboratory did not have documentation of a semi-annual competency assessment during the first year of employment. 4. In interview on May 29, 2019 at 10:13 am, Personnel 3 stated she did not see a semi-annual competency assessment for Personnel 5.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on record review, the laboratory failed to provide documentation of individuals who meet the state of Louisiana licensure requirements to perform moderate complexity testing. Refer to D6064.
D6064	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a) Each individual performing moderte complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure one (1) of four (4) testing personnel met the state of Louisiana licensure requirement. Findings: 1. Review of personnel records revealed the following personnel did not meet the State of Louisiana (R. S. 37:131 - 1329 "Louisiana Clinical Laboratory Personnel Law" requirement: Personnel 6: no documentation of issued license 2. In interview on May 29, 2019, Personnel 3 confirmed Personnel 6 did not have a state of Louisiana license for laboratory testing.