Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1087988	10/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Fairway Medical Clinic	4910 Telephone Rd, Houston, TX	

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	The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D8100 - 42 C.F.R. 493.1771 Condition: Inspection requirements applicable to all CLIAcertified and CLIA-exempt laboratories. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
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 laboratory policies and procedures, American Board of Bioanalyts (AAB) proficiency testing records, and confirmed in interview, the individual testing the proficiency testing samples and the lab director failed to attest to the routine integration of proficiency samples into the patient workload for 2 of 3 testing events in 2019. The findings included: 1. Review of the AAB proficiency testing records from 2019 revealed no documentation of the individual testing person and lab director signing the attestation statements for the following 2 of 3 events in 2019. 2019 NonChemistry 1st, 2nd 2. An interview with the laboratory director on 10/7/19 at 1020 hours in the laboratory confirmed the above findings.
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 a review of the laboratory's American Association of Bioanalyst (AAB) proficiency testing (PT) records and staff interview, the laboratory failed to document the review of the PT results for all 2019 test events. The findings were: 1. A review of the laboratory's 2019 AAB proficiency testing records revealed that the laboratory failed to document the review of the results for all events in 2019. 2019 NonChemistry 1, 2, 3 events 2. An interview with the laboratory director on 10/7/19 at 1020 hours in the laboratory confirmed the above findings.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory records, patient test records, and confirmed in interview, the laboratory failed to establish written policies and procedures for specimen processing for CBC (complete blood count) testing on the Beckman Coulter Act diff 2 hematology analyzer. Findings were: 1. Review of the laboratory records revealed no documentation of a policy or procedure for patient preparation, collection, storage and preservation, acceptability and rejection for CBC testing on the Beckman Coulter Act diff 2 hematology analyzer. 2. An interview with the laboratory director on 10/7/19 at 1020 hours in the laboratory confirmed the above findings. He was unaware his laboratory policies were missing specimen processing.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on review of the laboratory patient test records and confirmed in interview, the laboratory failed to document the date and time it received specimens for CBC (complete blood count) testing on the Beckman Coulter Act diff2 hematology analyzer for 97 of 97 patients reviewed. Findings were: 1. Random review of the laboratory records from 2018 and 2019 revealed no documentation of the date and time for 97 of 97 patient specimens analyzed for CBC on the Beckman Coulter Act diff2 hematology analyzer. Refer to patient alias list. 2. An interview with the laboratory director on 10/7/19 at 1030 hours in the laboratory confirmed the above findings. He was unaware the laboratory was required to document the date and time it received specimens.

D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, laboratory records, and confirmed in interview, the laboratory failed to follow its policy and document the quality assessment in the preanalytical systems. Findings were: 1. Review of the laboratory policy Quality Assurance Program revealed "the QA program monitors and evaluates the quality for the service we provide. The laboratory director oversees the implementation of our plan and helps identify and correct problems as they occur. We periodically review our QA plan to minimize the possibility of recurrence of problems. When problems are identified, they are corrected and areas for improvement to this plan may be implemented where applicable." 2. Review of the laboratory records revealed the laboratory QA failed to detect and correct problems in the preanalytical systems. Refer to D5311, D5313. 3. An interview with the laboratory director on 10/7/19 at 1220 hours in the laboratory confirmed the above findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory policies, review of quality control records, review of patient final reports, and confirmed in interview, the laboratory failed to monitor and evaluate the overall quality of its analytic systems. Refer to D5403, D5421, D5469
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 records and confirmed in interview, the laboratory failed to document a step by step procedure to resolve system flags and control procedures for the CBC (complete blood count) testing on the Beckman Coulter Act Diff2 hematology analyzer. a) system flags procedure b) control procedures Findings were: a) system flags procedure 1. Review of the Beckman Coulter Act Diff 2 user manual (PN 4237495A) under parameter codes and flags revealed the following flags and corresponding suggested action for each flag. Flags 1,2,3,4, M Indication: differential parameters failed the internal regional size distributional criteria at one specific region (1,2,3,4) or multiple regions (M) Suggested action: verify results according to your laboratory's protocol * Indication: possible sample handling problem; possible dual RBC population; possible interference with WBC count; vote out of fitted curve, sweepflow error; possible sample interference or instrument problem. Suggested action: follow your laboratory's protocol; thoroughly mix and rerun the sample. if flag does not repeat, report result; if flag repeats, clean the aperture as instructed in zapping the aperture; if after cleaning, problem persists, contact your Beckman coulter representative. X Indication: review results. X flag indicates that one of more of multiple aperture alert criteria was not met. Suggested action: thoroughly mix and rerun the sample. if flag does not repeat, report result; if flag repeats, lean the aperture as instructed in zapping the aperture; if after cleaning, problem persists, contact your Beckman coulter representative. 2. Review of the laboratory procedures revealed no documentation of a policy or procedure to resolve system flags for the CBC results from the Beckman Coulter Act Diff2 hematology analyzer. b) control procedures 3. Review of the IQAP (Interlaboratory Quality Assurance Program) notes from 01/2019 to 04/2019 (report ID 463281) revealed "most parameters are flagged when the CVI is greater than 2.0 or the SDI is less than -2.0 or greater than 2.0 The RDW and WBC differential parameters are flagged when the CVI is greater than 3.0 or the SDI is less than -3.0 or greater than 3.0... Please review your CVI for the following parameter(s). Refer to your IQAP manual for troubleshooting suggestions. 069100 WBC/Leuk." 4. Review of the IQAP notes from 04/2019 to 05/2019 (report ID 4658706) revealed "most parameters are flagged when the CVI is greater than 2.0 or the SDI is less than -2.0 or greater than 2.0 The RDW and WBC differential parameters are flagged when the CVI is greater than 3.0 or the SDI is less than -3.0 or greater than 3.0... Please review your CVI for the following parameter(s). Refer to your IQAP manual for troubleshooting suggestions. 089700 WBC/Leuk. Please review your CVI for the following parameter(s). Refer to your IQAP manual for troubleshooting suggestions. 089700 MPV Please review your CVI for the following parameter(s). Refer to your IQAP manual for troubleshooting suggestions. 079700 Plt/Thromb. Please review your CVI for the following parameter (s). Refer to your IQAP manual for troubleshooting suggestions. 079700 MPV Please review your CVI for the following parameter(s). Refer to your IQAP manual for troubleshooting suggestions. 069700 WBC/Leuk." Please review your CVI for the following parameter(s). Refer to your IQAP manual for troubleshooting suggestions. 069700 Hgb Please review your CVI for the following parameter(s). Refer to your IQAP manual for troubleshooting suggestions. 069700 MCV." 5. Review of the laboratory procedures revealed no documentation of a policy or procedure to

	troubleshoot the above quality control parameters per the manufacturer's instructions. 6. An interview with the laboratory director on 10/7/19 at 1220 hours in the laboratory confirmed the above findings. He acknowledged that he should add that to the policy.
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 review of the manufacturer's instructions, laboratory patient records, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions to ensure system flags were verified prior to reporting patient results for 15 of 25 CBC (complete blood count) testing on the Beckman Coulter Act diff 2 hematology analyzer in 2018 to 2019. Findings were: 1. Review of the Beckman Coulter Act Diff 2 user manual (PN 4237495A) under parameter codes and flags revealed the following flags and corresponding suggested action for each flag. Flags 1,2,3,4, M Indication: differential parameters failed the internal regional size distributional criteria at one specific region (1,2,3,4) or multple regions (M) Suggested action: verify results according to your laboratory's protocl * Indication: possible sample handling proble; possible dual RBC population; possible interference with WBC count; voteout of fitted curve, sweepflow error; possible sample interference or instrument problem. Suggested action: follow your laboratory's protocol; thoroughly miix and rerun the sample. if flag does not repeat, report result; if flag repeats, clean the aperture as instructed in zapping the aperture; if after cleaning, problem persists, conntact uour beckman coulter representative. X Indication: review results. X flag indicates that one of more of multiple aperture alert criteria was not met. Suggested action: thoroughly miix and rerun the sample. if flag does not repeat, report result; if flag repeats, lean the aperture as instructed in zapping the aperture; if after cleaning, problem persists, conntact your beckman coulter representative. 2. Random review of the laboratory patient test records from 12/2018 to 09/2019 revealed the laboratory reported 15 of 25 CBC results with no documentation of the corrective action to resolve the system flags. Date patient ID flags 12/05/18 002152008 *, X 12/05/18 117291981 *, X 12/05/18 012042005 * 12/19/18 012282014 M 12/19/18 009042013 3 12/20/18 005021987 * 12/21/18 010202011 M 01/02/19 012301956 3 01/02/19 010062006 X 01/02/19 005211938 3 01/02/19 003192017 2 01/04/19 012282014 2, M 01/14/19 007311988 * 09/04/19 001021935 3 08/20/19 006131976 M, * 3. An interview with the laboratory director on 10/7/19 at 1010 hours in the laboratory confirmed the above findings.
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 review of the manufacturer's instructions, laboratory records, and confirmed in interview, the laboratory failed to ensure humidity criteria was consistent with the manufacturers instructions for CBC (complete blood count) analysis on the Beckman Coulter Act Diff2 hematology analyzer for 10 of 25 days reviewed from 01/2019 to 09 /2019. Findings were: 1. Review of the Beckman Coulter Act Diff 2 user manual (PN 4237495A) under ambient temperature and humidity revealed "keep room temperature between 61-95 F and humidity at 20-85% without condensation." 2. Review of the laboratory temperature records from 01/2019 to 09/2019 revealed documentation had an acceptable humidity of "up to 85%." 3. Random review of the temperature records from 01/2019 to 09/2019 revealed 10 of 25 days with the humidity outside of the acceptable range of 20-85%. date humidity 1/18/19 16 2/08/19 16 2/18/19 16 2/25/19 16 3/05/19 16 3/20/19 16 4/01/19 16 4/12/19 16 5/29/19 16 4. Review of the above dates revealed the laboratory performed CBC testing. A random sampling of the testing included the following: 1/18/19 02081960; 04191951; 01061999 2/08/19 012171987; 010272001; 08102010 2/18/19 012132001; 010232006; 2/25/19 03122013; 07181969 3/05/19 04052006; 02112012 3/20/19 004142011; 05171950 4/01/19 02131985; 0111242009 4/12/19 02121988; 010202009 5/29/19 012041970; 011211991 5. An interview with testing person #1 on 10/7/19 at 1000 hours in the laboratory confirmed the above findings. She was unaware there was a lower limit for humidity.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory records, patient test records, and confirmed in interview, the laboratory failed to document the verification studies for the Beckman Coulter Act Diff 2 hematology analyzer. Findings were: 1. Review of the laboratory records revealed no documentation of the accuracy, precision, reportable range, or normal reference study for the Beckman Coulter Act Diff 2 hematology analyzer (system ID 990744). 2. Random review of the laboratory patient test records from 2018 - 2019 revealed the laboratory performed CBC (complete blood count) since 2018. Refer to patient alias list. 3. An interview with testing person #1 on 10/7/19 at 0940 hours in the laboratory confirmed the above findings. She was unaware the laboratory was required to perform studies prior to testing.
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 review of the manufacturer's instructions, laboratory records, and confirmed in interview, the laboratory failed to document maintenance required per the manufacturer's instructions for CBC (complete blood count) testing on the Beckman Coulter Act Diff 2 hematology analyzer. Findings were: 1. Review of the Beckman Coulter Act Diff 2 user manual (PN 4237495A) under general maintenance revealed a daily startup and shutdown maintenance. 2. Review of the laboratory records from 2018 and 2019 revealed no documentation of the above maintenance. 3. Review of the CMS116 revealed the laboratory performed 3000 CBC tests annually. 4. An interview with the testing person #1 on 10/7/19 1025 hours in the laboratory confirmed the above findings.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control records and confirmed in interview, the laboratory failed to verify the quality control established ranges for the Coulter 4C-ES Cell Control for CBC (complete blood count) testing on the Beckman Coulter Act Diff 2 hematology analyzer. Findings were: 1. Review of the instructions for use for the Coulter 4C-ES Cell Control (7504598-EA) revealed "before your current cell control lot(s) expire, perform the following on your new lot(s): Confirm that recovered values are within the TABLE OF EXPECTED RESULTS OR Establish your own laboratory mean" 2. Random review of the quality control data from 08/2019 and 09/2019 revealed no documentation of the verification of the expected ranges for the following lot numbers of the Coulter 4C-ES Cell control (06800, 07800, 08800, exp 11/4/19). 3. Review of the CMS116 revealed the laboratory performed 3000 CBC tests annually. 4. An interview with the testing person #1 on 10/7/19 at 1020 hours in the laboratory confirmed the above findings. She was unaware she needed to verify the ranges. She stated she was only trained to input the ranges and begin testing.
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 review of the laboratory policy, laboratory records, and confirmed in interview, the laboratory failed to follow its policy and document the quality assurance in the analytical systems. Findings were: 1. Review of the laboratory policy Quality Assurance Program revealed "the QA program monitors and evaluates the quality for the service we provide. The laboratory director oversees the implementation of our plan and helps identify and correct problems as they occur. We periodically review our QA plan to minimize the possibility of recurrence of problems. When problems are identified, they are corrected and areas for improvement to this plan may be implemented where applicable." 2. Review of the laboratory records revealed the laboratory QA failed to detect and correct problems in the analytical systems. Refer to D5411, D5413, D5421, D5429, D5469 3. An interview with the laboratory director on 10/7/19 at 1220 hours in the laboratory confirmed the above findings.
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 patient results and confirmed in interview, the laboratory failed to have the units and reference range on each CBC (complete blood count) patient report for 97 of 97 patients reviewed from 01/2019 to 09/2019. The findings were: 1. Random review of patient charts from 01/2019 to 09/2019 patient results revealed all 97 test results did not contain the units nor the reference range. Refer to patient alias list. 2. An interview with the testing person #1 on 10/7/19 at 0945 hours in the laboratory confirmed the above findings.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, laboratory records, and confirmed in

	interview, the laboratory failed to follow its policy and document the quality assessment in the post analytical systems. Findings were: 1. Review of the laboratory policy Quality Assurance Program revealed "the QA program monitors and evaluates the quality for the service we provide. The laboratory director oversees the implementation of our plan and helps identify and correct problems as they occur. We periodically review our QA plan to minimize the possibility of recurrence of problems. When problems are identified, they are corrected and areas for improvement to this plan may be implemented where applicable." 2. Review of the laboratory records revealed the laboratory QA failed to detect and correct problems in the post analytical systems. Refer to D5805. 3. An interview with the laboratory director on 10/7/19 at 1220 hours in the laboratory confirmed the above findings.
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 review of instrument verification records, review of patient final reports, and confirmed in interview, the laboratory director failed to provide overall management and direction of the laboratory. (refer to D6007, D6013, and D6020)
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on a review of laboratory analytic systems it was revealed that the laboratory director failed to ensure that testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance in Hematology. Refer to D5403
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance

	characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the laboratory verification records and confirmed in interview, the laboratory director failed to ensure the laboratory documented complete verification studies for the Beckman Coulter Act Diff 2 hematology analyzer prior to start of patient testing. Refer to D5421
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 review of the laboratory quality control (QC) records and confirmed in interview, the laboratory director failed to ensure the laboratory established and maintained a quality control program. Refer to D5469
D8100	INSPECTION REQUIREMENTS CFR(s): 493.1771 Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable. This CONDITION is not met as evidenced by: Based on review of the laboratory's CLIA certificate, patient test records and staff interview, the laboratory failed to obtain a CLIA certificate prior to performing patient testing. The laboratory started waived testing on 04/06/16 and non-waived testing on 05/09/18. (refer to D8105).
D8105	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(e)(f)(g) (e) Reinspection. CMS or a CMS agent may reinspect a laboratory at any time to evaluate the ability of the laboratory to provide accurate and reliable test results. (f) Complaint inspection. CMS or a CMS agent may conduct an inspection when there are complaints alleging noncompliance with any of the requirements of this part. (g) Failure to permit CMS or a CMS agent to conduct an inspection or reinspection results in the suspension or cancellation of the laboratory's participation in Medicare and Medicaid for payment, and suspension or limitation of, or action to revoke the laboratory's CLIA certificate, in accordance with subpart R of this part.

	This STANDARD is not met as evidenced by: A. Based on review of the laboratory's Certificate of Registration, review of the 2016-2019 patient test records, and confirmed in interview, the laboratory failed to obtain a CLIA certificate prior to performing 10 patient samples for waived and non-waived testing. The findings were: 1. A review of the laboratory's Certificate of Registration revealed the laboratory's certificate was issued by CMS on 01/15/19. 2. Random review of the laboratory records from 2016 to 2019 revealed the laboratory performed 2 non-waived CBC testing on 05/09/18 prior to the laboratory receiving their certificate of registration on 01/15/19. Refer to patient alias list. 3. Random review of the laboratory records from 2016 to 2019 revealed the laboratory performed 8 waived Glucose and urinalysis testing prior to the laboratory receiving their certificate of registration on 01/15/19. Refer to patient alias list. 4. An interview with the laboratory director on 10/7/19 at 1210 hours in the laboratory confirmed the above findings. B. Based on review of the CMS 116 records, random reivew of 8 laboratory records from 2016-2018, and confirmed in interview, the laboratory failed to cease patient testing during its revocation period of March 15, 2016 to March 14, 2018. Findings were: 1. Review of the CMS notice letter of revocation dated 4/5/16 revealed "Based on information in the CLIA data base, you are currently listed as the laboratory director for Fairway Medical Clinic. Please note that sections 42 U.S.C. 263a(i)(3) and 42 C.F. R. 493.1840(a)(8) prohibit the owner(s) or operator(s) (including director - see 42 C.F. R. 493.2) of laboratories that have had their certificates revoked from owning or operating (or directing) a laboratory for at least two years from the date of the revocation. This prohibition applies to the owner(s) as well as the director at the time that the deficiencies were found which led to the revocation action. The two year period is in effect from March 15, 2016 to March 14, 2018...Your laboratory is required to cease all operations (to include waived tests, Provider Performed Microscopy Procedures, and moderate and high complexity tests)." 2. Random review of the laboratory records from 2016 to 2018 revealed the laboratory performed 8 waived Glucose and urinalysis testing beginning 04/06/16. Refer to patient alias list. 3. An interview with the laboratory director on 10/7/19 at 1210 hours in the laboratory confirmed the above findings.