Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2011410	10/24/2023
Name of Provider or Supplier	**Street Address, City, State**	
Fairlawn Surgery Center, Llc	2030 Stephenson Avenue, Roanoke, VA	

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	An announced CLIA Validation survey was conducted at the Fairlawn Surgery Center on 10/24/23 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
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 the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), proficiency testing (PT) records, and interviews, the lab failed to rotate the chemistry and hematology (coagulation) PT among all three testing personnel (TP) for three of three events in 2022 and for the first two event in 2023. Findings include: 1. Review of the CMS-209 personnel form revealed four TP performing chemistry and hematology using the i-STAT hand-held analyzer and Chem 8+ and prothrombin time /Internal Normalized Ratio (PT/INR) cartridges in the calendar year 2022 and up to date of survey on 10/24/23. 2. Review of the Wisconsin State Laboratory of Hygiene (WSLH) PT records revealed that the same TP personnel (TP-A) performed all three of the chemistry and hematology events in 2022 and the first two chemistry and hematology events in 2023. 3. An exit interview with the clinical director on 10/24/23 at approximately 12:30 confirmed the findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of policy and procedure (P&P), external quality control (QC) records, lack of documentation, Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), and interview, the lab failed to follow the established P&P of performing at least two levels of external QC materials on weekly basis for the non-waived Abbott i-STAT Chem 8+ cartridge and prothrombin time/Internal Normalized Ratio (PT/INR) cartridge analytes from 01/01 /22 up to the date of survey on 10/24/23. Findings include: 1. Review of the P&P's for the Individualized Quality Control Program (IQCP) for the non-waived Abbott i-STAT Chem 8+ cartridge and PT/INR cartridge revealed the following statements: "Action Plan (signed by the lab director on 04/23/20)." "Based on the QA measures, which addresses all risks identified via the Risk Assessment, in addition to QA measures that address all tests, it is our policy that the performance of external controls will be conducted on a weekly bases and/or with each new lot number or shipment of test devices. The laboratory director will continue to monitor these controls on a monthly bases." "Quality Control Requirements (signed by the lab director on 04/27/21)" "The following are the external QC requirements for each individual test performed by Fairlawn Surgery Center- i-STAT- two levels of controls weekly or with new shipment or lot number." 2. Review of the QC test logs for the non-waived Abbott i-STAT Chem 8+ cartridge analytes sodium, potassium, chloride, carbon dioxide, urea nitrogen, creatinine, glucose, ionized calcium, hematocrit and PT /INR revealed a lack of documentation of the lab performing external QC procedures on a weekly basis. The review revealed the lab performed QC procedures each month and with each new lot number of cartridges received from 01/01/22 up to the date of survey on 10/24/23. 3. Review of the CMS 116 application revealed total annual testing volume of 175 tests in the subspecialty of chemistry and 25 tests in the subspecialty of hematology. 4. An exit interview with the clinical director on 10/24/23 at approximately 12:30 confirmed the findings.
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 the review of policy and procedures (P&P), lack of documentation, and interview, the lab director (LD) failed to follow the established P&P's for performing and documenting the quality assurance (QA) reviews for 22 of 22 months reviewed.

	Dates of review include 01/22/22 up to the date of survey on 10/24/23. Findings include: 1. Review of P&P revealed the following statements: "Quality Assurance Review with Staff" (signed by the LD on 04/27/21), "the laboratory director will discuss with the staff on at least a monthly basis the results of the quality assurance and ways the laboratory can improve the quality of its work." "Quality Control Assessment" (signed by the LD on 04/27/21), "the laboratory director will review all quality control charts and logs on at least a monthly basis. QC should be evaluated for trends and shift occurring with control values. The QC should be signed off monthly by the laboratory director." 2. Review of the monthly QC records from 01/01/22 up to the date of survey on 10/24/23 revealed a lack of documentation of review by the LD. The inspector requested to review documentation of QA reviews or staff meeting minutes as described by the P&P's. The documentation was not available for review. 3. An exit interview with the clinical director on 10/24/23 at approximately 12:30 confirmed the findings.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), policy and procedures (P&P), testing personnel (TP) records, lack of documentation, and interview, the technical consultant (TC) failed to performed and sign the annual competency assessments for three of three TP in 2022. Dates of record review include 01/01/22 up to the date of survey on 10/24/23. Findings include: 1. Review of the CLIA CMS-209 form and an interview with the clinical director on 10 /24/23 at 10:20 AM revealed three TP performed patient testing in calendar year 2022 and one TC. 2. Review of the 2022 annual competency assessments records for the three TP revealed a lack of documentation of performance and approval by the designated TC. 3. An exit interview with the clinical director on 10/24/23 at approximately 12:30 confirmed the findings.
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 the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, and interview, the technical consultant (TC) failed to perform a semi-annual competency assessment for one of one new TP in 2022. Dates of record review include 01/01/22 up to the date of survey on 10/24/23. Findings include: 1. Review of the CLIA CMS-209 form revealed one TC and one new TP (TP #1) in 2022. 2. Review of TP #1 competency records revealed an initial competency assessment performed on 05/23/22 and an annual competency assessment on 07/24/23. The records lacked documentation of a semi-

	annual competency assessment. The inspector requested to review a semi-annual competency assessment for TP #1. The documentation was not available for review. 3. An exit interview with the clinical director on 10/24/23 at approximately 12:30 confirmed the findings.