Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0232087	10/26/2022
Name of Provider or Supplier	**Street Address, City, State**	
Carilion Family Medicine Parkway	415 South Pollard Street, Vinton, 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 Recertification survey was conducted at the Carilion Family Medicine Parkway on 10/26/22 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: The laboratory is performing COVID-19 testing and is in compliance with the applicable COVID-19 reporting requirements.
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 the review of policy and procedures (P&P), quality control (QC) records, lack of documentation, and interviews, the lab failed to retain documentation of the performance of the daily QC procedures for the 20 analytes assayed on the Beckman Coulter DxC 700 chemistry analyzer from 01/11/21 up to 08/27/21. Findings include: 1. Review of the P&P revealed a general procedure to perform and review chemistry QC materials each day of patient testing for the following analytes: alanine aminotransferase (ALT), albumin, alkaline phosphatase (ALP), asparate aminotransferase (AST), direct bilirubin, total bilirubin, BUN (Urea), total calcium, carbon dioxide (CO2), cholesterol, chloride, creatinine, glucose, HDL cholesterol, LDLD, potassium, total protein, sodium, triglyceride and total hemoglobin A1C. 2. Review of available printed daily QC documents from the Beckman Coulter DxC 700 chemistry analyzer located in a cardboard box revealed a date of 09/24/21. The inspector requested to review documentation prior to 09/24/21. In an interview with the testing personnel on 10/26/22 at approximately 11:15 AM, they stated, "I'm not sure where those records would be, the other testing personnel was in charge of that."

	In an additional interview with the technical consultant on 10/26/22 at approximately 11:30 AM, they stated that the instrument should be able to retrieve the records from the hard drive. The inspector and the testing personnel attempted to retrieve the requested data from the chemistry analyzer. The last date available for review via the chemistry analyzer hard drive was 08/30/21. The instrument was unable to retrieve the requested data from 01/11/21 up to 08/27/21. The technical consultant and the inspector searched the room in which previous chemistry QC records were stored, to include calendar year 2019 and 2020. The requested records from 01/01/21 up to 08/27 /21 were not available for review. 3. An exit interview with the technical consultant on 10/26/22 at approximately 1500 confirmed the findings.
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 the review of policy and procedures (P&P), lack of documentation and interview, the lab failed to have an established policy for the retention of daily quality control (QC) procedures performed in the subspecialty of chemistry at the date of survey on 10/26/22. Findings include: 1. Review of the P&P revealed lack of documentation of record retention policy for the daily QC procedures performed in the subspecialty of chemistry. Cross Reference D3031. 2. An exit interview with the technical consultant on 10/26/22 at approximately 1500 confirmed the findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test

	system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), review of policy and procedures (P&P), calibration verification and linearity records, lack of documentation, and interviews, the lab failed to follow the established P&P of performing calibration verification procedures for the 14 of 20 chemistry analytes every six months from 12 /17/21 up to the date of survey on 10/26/22. Findings include: 1. Review of the CMS 116 application revealed the lab performs the following analytes on the Beckman Coulter DxC 700 chemistry analyzer: alanine aminotransferase (ALT), albumin, alkaline phosphatase (ALP), asparate aminotransferase (AST), direct bilirubin, total bilirubin, BUN (Urea), total calcium, carbon dioxide (CO2), cholesterol, chloride, creatinine, glucose, HDL cholesterol, LDLD, potassium, total protein, sodium, triglyceride and total hemoglobin A1C. 2. Review of the P&P revealed a calibration verification policy that stated the procedure to be completed every six month. 3. Review of available calibration verification records revealed the lab utilizes the Audit MicroControl Linearity materials to perform the verifications and linearity procedures. The following analytes were assayed and reviewed on 06/24/22: total hemoglobin A1C, CO2, total bilirubin, direct bilirubin, HDL cholesterol, and LDLD (total of six). In addition, the review revealed lack of documentation of the performance and review of the aforementioned procedures every six months at the date of survey on 10/26/22 for the following analytes: alanine aminotransferase (ALT), albumin, alkaline phosphatase (ALP), asparate aminotransferase (AST), BUN (Urea), total calcium, cholesterol, chloride, creatinine, glucose, potassium, total protein, sodium, and triglycerides (last performed on 12/17/21). The inspector requested to review additional verification and linearity procedures. The documentation was not available for review at the date of survey on 10/26/22. 4. An exit interview with the technical consultant on 10/26/22 at approximately 1500 confirmed the findings.
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 the review of the Centers for Medicare and Medicaid Services CLIA

	Laboratory Application for Certification form (CMS 116), policy and procedures (P&P), available chemistry quality control (QC) records, lack of documentation, and interviews, the current quality assurance plan failed to include a written policy that defined a mechanism to identify and address shifts and trends with the BioRad Assayed mulitqual chemistry QC materials at the date of survey on 10/26/22. Findings include: 1. Review of the CMS 116 application revealed the lab performs the following analytes on the Beckman Coulter DxC 700 chemistry analyzer: alanine aminotransferase (ALT), albumin, alkaline phosphatase (ALP), asparate aminotransferase (AST), direct bilirubin, total bilirubin, BUN (Urea), total calcium, carbon dioxide (CO2), cholesterol, chloride, creatinine, glucose, HDL cholesterol, LDLD, potassium, total protein, sodium, triglyceride and total hemoglobin A1C. 2. Review of the P&P revealed a QA plan containing the following statements, "2. Quality Control and Instrumentation- performed monthly with the following focus: a) are calibration and controls run as required by written policy? b) has appropriate corrective action been taken and documented for out of range controls and calibrations? c) if out of range controls or calibrations are found have patient reports been evaluated for the date range involved?" The P&P lacked documentation of written steps and instructions for a defined mechanism that would identify and address shifts and trends with the BioRad Assayed multiqual QC materials used to assay the aforementioned analytes. 3. The inspector requested to review documentation of a mechanism that would identify shifts and trends with the aforementioned QC materials. In an interview with the testing personnel on 10/26/22 at approximately 1300, they stated that prior to the departure of the previous testing personnel in September 2021, the Levey-Jennings statistical charts were reviewed within the Beckman Coulter DxC 700 chemistry analyzer (Cross Reference D3031). They stated that as of June 2022, they were now printing the Levey-Jennings statistical charts for review. 4. An exit interview with the technical consultant on 10/26/22 at approximately 1500 confirmed the findings.
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), policy and procedures (P&P), available chemistry quality control (QC) records, lack of documentation, and interviews, the laboratory director failed to 1) ensure chemistry QC records were retained for review (Refer to D3031); 2) ensure an established policy for the retention of daily quality control (QC) procedures performed in the subspecialty of chemistry (Refer to D5403); 3) ensure calibration verification procedures were performed in accordance to written P&P (Refer to D5439); and 4) the current quality assurance plan included a written policy that defined a mechanism to identify and address shifts and trends with the BioRad Assayed mulitqual chemistry QC materials (Refer to D5791).