Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0919336	06/20/2025
Name of Provider or Supplier	**Street Address, City, State**	
Family Health Clinic, Inc	600 Randolph Street, Radford, 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 Family Health Clinic, INC on June 18, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The recertification inspection also included an off-site interview with the laboratory director on 6/20/25. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows and include three Conditions under 42 CFR part 493 CLIA Regulation: D2000 - 42 CFR. 493.801 Condition: Enrollment and Testing of Samples, D5400 - 42 CFR. 493.1250 Condition: Analytic Systems, D6000 - 42 CFR. 493.1403 Condition: Laboratories performing moderate complexity testing- Laboratory Director.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services CASPER 0096D CLIA Application and Survey Summary Report (CMS CASPER 0096D), CMS CLIA Laboratory Application for Certification form (CMS 116), proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to enroll in a hematology PT program for Complete Blood Count (CBC) for sixteen (16) of twenty-six (26) months reviewed (survey timeframe: 4/13/23 - 6/18/25, timeframe of non enrollment: 1/1/25-4/9/25). Findings include: 1. Review of the CASPER

	0096D report during pre-survey preparation revealed a lack of hematology PT scores for the following speciality and analytes in calendar year 2024 and year to date 2025: 0760 HEMATOLOGY 0765 Cell Identification 0775 Red Blood Cell Count, RBC 0785 Hematocrit, HCT 0795 Hemoglobin, HGB 0805 While Blood Cell Count, WBC 0815 Platelets, PLT 2. Review of the CMS 116 form revealed that the laboratory director confirmed patient CBC testing in the speciality of hematology during the 26 month review timeframe of 4/13/23 to 6/18/25. 3. Review of the laboratory's available American Proficiency Institute (API) PT records for the review timeframe outlined above (2023 Events 2-3, Remedial Event #83R), a total of three events, revealed no PT records for calendar year 2024 and year to date 2025. The inspector inquired regarding the lack of PT documentation for 2024 Events 1-3 and the expected 2025 Event 1. The office manager stated on 6/18/25 at 1 PM, "I noticed that we did not have any 2024 records. Our previous McKesson sales rep was relied upon to enroll us in proficiency testing. When I recently discovered that the 2024 and 2025 enrollment deadlines were missed, we contacted API and placed a late order. Both years' enrollment deadlines were missed." 4. The inspector requested to review the laboratory's late enrollment for 2025 hematology PT modules. The provided API PT order (dated 4/9/25) revealed that the hematology module ordered would include partial annual shipment to include Event 2 and 3 (shipping dates in July and October 2025). 5. Interviews with the lead testing personnel and office manager on 6/18/25 at 2:00 PM, and lab director on 6/20/25 at 10 AM 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 a review of available laboratory policies/procedures, Centers for Medicare and Medicaid Services Laboratory Personnel Report form, tour, manufacturer's package insert instructions, hematology quality control (QC) records, patient test logs, QC protocols, manufacturer user guide, lack of documentation, and interviews, the laboratory failed to: 1. document the new director's approval (signature and date) of the laboratory's policies/procedures for twenty-five (25) of 25 months -May 2023 to 6 /18/25 (Refer to D5407); 2. ensure that three (3) of 3 Sysmex XN-L Check hematology QC vials in use, stored in the laboratory were within the manufacturer's expiration dates as observed 6/18/25 (Refer to D5417); 3. perform daily hematology QC procedures per their protocol on four of one hundred nineteen days from 1/2/25 to 6/18/25 while reporting seventy-one patient Complete Blood Count results (Refer to D5447); and 4. follow protocol to perform/review statistical analysis to identify shifts and/or trends for the XN Check Tri Level control materials utilized to evaluate accuracy of the Sysmex Hematology analyzer for twenty-six (26) of 26 months reviewed - timeframe of April 13, 2023 to June 18, 2025 (Refer to D5469).
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d)

	(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), policies, lack of documentation, and interviews, the laboratory failed to document an approval/review of policies and procedures after a change in director for twenty-five (25) of 25 months (May 2023 to the date of the survey, on June 18, 2025). Findings include: 1. An interview and review of the CMS 209 personnel form with the office manager on 6/18/25 at 11:30 AM, revealed that a Laboratory Director (LD) change occurred during the recertification survey timeframe of 4/13/23-6/18/25. The new LD (LD A) took the position on 5/13/23. *See Personnel Code Sheet. 2. Review of the available policies/procedures revealed that LD A failed to document a review/approval after taking over the directorship of the laboratory services in May 2023. The inspector inquired regarding a record of the current LD's approval of the laboratory procedures. Documentation was not available for review. 3. Interviews with the lead testing personnel and office manager on 6/18/25 at 2:00 PM, and LD A on 6/20/25 at 10 AM confirmed the above findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 a tour, review of manufacturer's package insert instructions, and interviews, the laboratory failed to ensure that three (3) of 3 Sysmex XN-L Check hematology quality control (QC) vials in use and stored in the laboratory were within the manufacturer's expiration dates as observed on June 18, 2025. Findings include: 1. During a laboratory tour on 6/18/25 at 10:30 AM, the inspector noted the following 3 hematology QC vials stored in the laboratory refrigerator opened for use: Level 1 (Lot Number 50671401) expiration date of 6/17/2025; Level 2 (Lot Number 50671402) expiration date of 6/17/2025; Level 3 (Lot Number 50671403) expiration date of 6/17 /2025; 3 of 3 were QC vials were expired while in use. The inspector inquired of the open date for the vials outlined above. No open date was able to be confirmed. The inspector noted no new lot numbered (in date) QC stored in the laboratory refrigerator. 2. A review of the manufacturer's hematology QC package insert revealed the open vial stability to be fourteen days and instructions to "not use beyond expiration date, discard once outdated". 3. The laboratory inspector inquired if the observed, expired QC vials were in use for monitoring the Sysmex hematology instrument quality functions. The primary testing personnel confirmed the expired QC vials were in use. The office manager stated on 6/18/25 at 10:45 AM, "We realized that we were out of in date QC and ordered a new lot. We are waiting for it to be shipped to us." 4. Interviews with the lead testing personnel and office manager on 6 /18/25 at 2:00 PM, and lab director on 6/20/25 at 10 AM confirmed the above findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)

	(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on a review of daily hematology quality control (QC) records, patient test logs, lack of documentation, policies, manufacturer's user guide, and interviews, the laboratory failed to perform daily hematology QC procedures per their protocol on four (4) of one hundred nineteen (119) days from 1/2/25 to 6/18/25 while reporting seventy-one (71) patient Complete Blood Count (CBC) panel results. Findings include: 1. Review of the daily Sysmex XN 430 hematology QC records and patient CBC test logs from 1/2/25 to the date of the inspection, 6/18/25, revealed the following 4 dates lacked documentation of QC procedures: 3/26/25 - 20 patients reported; 3/27/25 - 12 patients reported; 3/28/25 - 15 patients reported; 3/31/25 - 24 patients reported; A total of 71 patient CBC results were reported without QC verification. The inspector requested to review QC for the dates outlined above. No records were available for review. 2. Review of the laboratory's policies revealed a "Quality Assessment" protocol that outlined (under heading Analytic), "QC is completed, analyzed, and accepted each day of testing". 3. Review of online Sysmex XN 430 User Guide revealed instructions in Section 2, "Quality control is performed in order to monitor an instrument's performance over time. XN-L Check tri level is the quality control material used to monitor the performance of the XN analyzer each day of operation. Quality control should be run according to licensing agency regulations." 4. Interviews with the lead testing personnel and office manager on 6/18/25 at 2:00 PM, and lab director on 6/20/25 at 10 AM confirmed the above findings.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(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. (d)(10)(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. (d)(10)(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. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) protocols, hematology QC records, manufacturer guide, lack of documentation, and interviews, the laboratory failed to follow their protocol to perform/review statistical analysis to identify shifts and/or trends for the XN Check Tri Level control materials utilized to evaluate accuracy of the Sysmex analyzer for twenty-six (26) of 26 months reviewed (timeframe of April 13, 2023 to June 18, 2025). Findings include: 1. Review of the laboratory's policies revealed a "Hematology Calibration and Quality Control QA Tracking" protocol that outlined that quantitative QC results are to be graphed, reviewed for shifts/trends, corrective action taken, and lab director to review all QC results monthly. 2. Review of the hematology QC records for the Sysmex XN analyzer from 4/13/23 to 6/18/25 revealed no documentation of the QC levey jennings (LJ) graphs per the protocol

	outlined above. The inspector requested to review the lab director reviewed QC graphs for each of the XN Check Tri Levels for each of the 26 months of review. No documentation was available. 3. During an interview with the primary testing personnel on 6/18/25 at 11 AM, the inspector inquired how the laboratory checks or prints the Sysmex LJ QC charts. The primary testing personnel stated, "I print the three QC results each day that I run but I was never shown how to pull up the QC charts on the instrument. I do not check the QC charts." 4. Review of the Sysmex analyzer guide revealed a training checklist that included the heading "Quality Control" which outlined the following training competency requirements for operators: Processing QC, Checking QC Charts, and X-BarM Program. 5. Interviews with the lead testing personnel and office manager on 6/18/25 at 2:00 PM, and lab director on 6/20/25 at 10 AM confirmed the above findings.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, hematology quality control (QC), policies, patient test logs, manufacturer's user guide, monthly quality assessment (QA) forms, lack of documentation, and interviews, the laboratory's current QA policy failed to identify and address analytic concerns in the speciality of hematology for twenty six (26) of 26 months reviewed (timeframe of survey 4/13/23 - 6/18/25). Findings include: 1. Review of PT records, daily hematology quality control (QC) records, patient test logs, policies, and manufacturer's user guide and a lack of documentation revealed the following analytic concerns in the speciality of hematology: - failure to enroll/perform proficiency testing on regulated hematology analytes in calendar year 2024. Refer to D2000. - failure to perform statistical analysis to identify shifts/trends for Sysmex XN Check Tri Level QC for twenty six (26) of 26 months reviewed. Refer to D5469. 2. Review of the monthly QA forms revealed a protocol for the laboratory director to review, document problem areas detected, and provide corrective action plan when failures were identified on the QA Tracker log sheets. The inspector noted that for each of the 26 months reviewed the forms failed to document corrective action for the above noted analytic concerns. The inspector noted that the forms had been marked "yes" to indicate that the PT and QC tasks were completed while record review revealed that the tasks had not been completed. 3. Interviews with the lead testing personnel and office manager on 6/18/25 at 2:00 PM, and lab director on 6/20/25 at 10 AM 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 a review of the Centers for Medicare and Medicaid Services CASPER 0096D CLIA Application and Survey Summary Report, CMS CLIA Laboratory Application for Certification form, CMS Laboratory Personnel Report form, proficiency testing records, quality control (QC) protocols, hematology QC records, manufacturer guide, patient test logs, monthly quality assessment (QA) forms, lack of documentation, and interviews, the laboratory director (LD) failed: 1. to ensure the overall quality of services provided by failing to ensure timely enrollment in the laboratory PT program for six of six regulated hematology analytes for two (2) of 2 calendar years as observed on the date of the inspection, June 18, 2025. Refer to D6015; and 2. to identify quality assessment failures as they occurred for twenty six (26) of 26 months reviewed (timeframe of survey 4/13/23 - 6/18/25). Refer to D6020.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services CASPER 0096D CLIA Application and Survey Summary Report (CMS CASPER 0096D), CMS CLIA Laboratory Application for Certification form (CMS 116), proficiency testing (PT) records, lack of documentation, and interviews, the laboratory director (LD) failed to ensure that the laboratory timely enrolled in a PT program for six of six hematology analytes White Blood Cell Count (WBC), Red Blood Cell Count (RBC), Hemoglobin (HGB), Hematocrit (HCT), Platelet Count (PLT), and Cell Identification (Cell ID) for two (2) of 2 calendar years as observed on the date of the inspection, June 18, 2025. Refer to D2000. Findings include: 1. Review of the CMS CASPER 0096D report revealed a lack of PT scores for six of six hematology analytes: WBC, RBC, HGB, HCT, PLT, and Cell ID during calendar year 2024 for Events 1, 2, 3 and 2025 Event 1. 2. Review of the CMS 116 form revealed that the LD confirmed testing in the specialty of hematology: WBC, RBC, HGB, HCT, PLT, and Cell ID within the Complete Blood Count panel reported on the Sysmex hematology analyzer during the review timeframe of 4/13/23 to 6/18/25. 3. Review of laboratory's American Proficiency Institute (API) hematology PT records, a total of three events (2023 Events 2-3, Remedial Event #83R), revealed no records for 2024 Events 1-3 nor expected 2025 Event 1 for the hematology speciality analytes outlined above. 4. The inspector requested to review the PT records for 2024 Events 1-3 and 2025 Event 1. The office manager stated on 6/18/25 at 1 PM, "Both years' enrollment deadlines were missed." 5. Interviews with the lead testing personnel and office manager on 6/18/25 at 2:00 PM, and lab director on 6/20/25 at 10 AM confirmed the above findings.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by:

	Based on review of proficiency testing records, the Centers for Medicare and Medicaid Services Laboratory Personnel Report form, policies, quality control (QC) protocols, hematology QC records, manufacturer guide, patient test logs, monthly quality assessment (QA) forms, lack of documentation, and interviews, the laboratory director failed to identify Hematology QA failures as they occurred for twenty six (26) of 26 months reviewed (timeframe of survey 4/13/23 - 6/18/25). *Refer to D5793.