Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0710587	11/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
Harrisonburg Family Practice	1831 Reservior St, Harrisonburg, 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 Harrisonburg Family Practice on 11/28/22 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: A. Based on a review of quality control (QC) records, lack of documentation, and interview, the laboratory failed to retain the "Cell Dyn 18 Plus control " manufacturer's assay information inserts documenting Complete Blood Cell (CBC) count QC acceptable ranges for nine of nine lot numbers utilized from January 1, 2021 through October 1, 2022. Findings include: 1. Review of the laboratory's end of the QC lot instrument printouts from January 1, 2021 through October 1, 2022 revealed the laboratory received and utilized nine lot numbers of the "Cell Dyn 18 Plus control ". The following QC lot numbers lacked documentation of acceptable ranges or manufacturer's package inserts: 0321, 1039, 1095, 1123, 1207, 1221, 2010, 2094 and 2178. The inspector requested to review the aforementioned package inserts. The documentation was not available for review. 2. An exit interview with the technical consultant on 11/28/22 at approximately 1600 confirmed the findings. B. Based on the review of policy and procedures (P&P), quality control (QC) records, lack of documentation, and interview with the technical consultant (TC), the laboratory failed to retain documentation of the performance of the daily Complete

	Blood Count (CBC) QC procedures for 32 of 123 days reviewed from 05/01/21 through 08/31/21 according to the P&P. Findings include: 1. Review of the P&P "Test System QC and Remedial Action Policy and Procedure" revealed the following statements, "For Hematology, run 3 levels of controls once daily. Records of all quality control activity will be maintained for two years". 2. Review of the end of the month CBC printouts for the Abbott Emerald hematology analyzer revealed lack of documentation of QC results for the following dates: May 5, 6, 10-18, 2021, June 4, 7-16, 2021 and August 5, 6, 9-24, 2021. Total of 32 of 123 days reviewed. The inspector requested to review documentation of the daily QC procedures for the above-specified dates. In an interview with the TC on 11/28/22 at approximately 1410, they stated "the daily printouts were discarded once the end of the month data was printed. I do not have that documentation. The end of the month reports should have had those dates and QC." 3. An exit interview with the TC on 11/28/22 at approximately 1600 confirmed the 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 a tour of the facility, review of policy and procedures (P&P), manufacturer's package insert, daily laboratory temperature records, lack of documentation, and interview, the laboratory failed to monitor and record the room and refrigerator temperatures, and humidity percentage (%) for 102 of 294 days reviewed from 01/01 /22 up to 10/31/22 according to the P&P for the front lab room. Findings include: 1. A tour of the laboratory on 11/28/22 at approximately 10:45 AM revealed a separate lab testing area designated as the front lab, in which the Abbott Emerald hematology analyzer was located. Patient testing for Complete Blood Count (CBC) occurred in the front lab. 2. Review of the P&P "Policy for Safety in the Laboratory Environment" revealed the following statements, "The analyzers operate at ambient temperature (18-30 C or 64-86 C) and up to 85% humidity without condensation. Quality control and calibration materials are stored in the refrigerator. Therefore, the temperature of the room and the laboratory refrigerator, along with the humidity, must be recorded daily." The review of the Cell Dyn 18 Plus Controls package insert revealed a storage requirement of 2-10 C. The established refrigerator temperature on the daily temperature logs of 2-8 C. 3. Review of the daily temperature logs for the front lab from 01/01/22 up to 10/31/22 revealed lack of documentation of room and refrigerator temperature and humidity % as follows: January - 5 days, February - 7 days, March - 5 days, April - 10 days, May - 12 days, June - 8 days, July - 13 days, August - 15 days, September- 18 days and October- 9 days. Total of 102 of 294 days. 4. An exit interview with the technical consultant on 11/28/22 at approximately 1600 confirmed the findings.
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 a tour of the front lab testing area and interviews with the technical consultant (TC), the laboratory failed to label the two vials of 10 % potassium hydroxide (KOH) with an open date, revised expiration date or reference lot number at the date of survey on 11/28/22. Findings include: 1. A tour of the front lab testing area on 11/28/22 at approximately 1545 revealed a microscope and two amber vials in the cabinet above the microscope. The two amber vials were labeled as 10% KOH. The vials lacked an open date, revised expiration date or reference lot number. In an interview with the TC on 11/28/22 at approximately 1550, the TC stated, "the solution is poured from a larger bottle into the vials." In addition, the inspector noted that both amber vials contained visible particulates. The inspector requested to review the original bottle of the 10% KOH solution or the manufacturer's instructions for use. The TC could not locate either of the requested items at the date of the survey. 2. An exit interview with the technical consultant on 11/28/22 at approximately 1600 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 policy and procedures (P&P), tour of the laboratory, quality control (QC) records, temperature and humidity records, lack of documentation and interview, the current quality assessment (QA) plan failed to identify and address analytic issues in the subspecialty of the hematology and mycology from 01/01/21 up to the date of survey on 11/28/22. Findings include: 1. Review of Abbott Emerald QC records, tour of the front lab testing area on 11/28/22 at approximately 1545, and the front lab temperature and humidity records revealed the following: - Lack of documentation of the Cell Dyn 18 Plus control package inserts (Refer to D3031 part A), - Lack of documentation of daily QC procedures for 32 of 123 days from 05/01/21 through 08/31/21 (Refer to D3031 part B), - Lack of documentation of the front lab room and refrigerator temperatures and humidity percentage (%) for 102 of 294 days reviewed from 01/01/22 up to 10/31/22 (Refer to D5413), and - Lack of documentation of an open date, revised expiration date or reference lot number on the two vials of 10 % potassium hydroxide (KOH) (Refer to D5415). 2. Review of the P&P "Quality Assurance Program" revealed instructions for performing QA assessments each month to include but not limited to the review of monthly QC printouts, proficiency testing, patient test management, specimen collection and laboratory errors. The laboratory documents the QA reviews on a monthly check list. The current QA plan did not provide instructions for reviewing and providing

	corrective actions for room or refrigerator temperature or humidity percentages and monitoring the KOH solutions in the front lab, or ensuring manufacturer package inserts were maintained. 3. Review of the QA monthly check lists from 01/01/21 up to the date of survey on 11/28/22 revealed lack of documentation of the identification and corrective actions the above-specified analytic issues. 4. An exit interview with the technical consultant on 11/28/22 at approximately 1600 confirmed the findings.
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 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 laboratory director failed to ensure that three of three new TP had documentation of initial training and assessment prior to performing Complete Blood Count (CBC) patient testing in 2021 and up to the date of survey on 11/28/22 according to the P&P. Findings include: 1. Review of the CLIA CMS-209 Form revealed three new TP from 01/01/21 up to the date of survey on 11/28/22 (TP A-C). See attached TP code sheet. 2. Review of the P&P "Policy for Personnel Assessment" (signed and reviewed by the lab director on 01/24/14) revealed the following statements, "Orientation and training is begun immediately upon hiring. After review of all policy and procedures, the new employee is observed in his/her performance of those duties included in the job description. All of this documented on the Personnel Competence Record. Patient testing may not be performed by the employee until completion of orientation and training and the completion of the appropriate training forms kept in the personnel file." 3. Review of TP A-C records revealed lack of documentation of the orientation and training for the CBC testing performed with the Abbott Emerald hematology analyzer. The inspector requested to review the documents. No documents were available for review. During an interview with technical consultant on 11/28/22 at 11:45 AM, they stated, "TP A was hired in 2020 but didn't start patient testing until 2021. The nurse manager does the training of the CBC testing because the instrument is in the front lab." 4. An exit interview with the technical consultant on 11/28/22 at approximately 1600 confirmed the findings.