Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0978828	02/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Eagan Valley Pediatrics	14135 Cedar Ave, Apple Valley, MN	

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 Eagan Valley Pediatrics laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on February 9, 2024. The following standard-level deficiencies were cited: 493.801 Testing of proficiency samples 493.1254 Maintenance and function checks 493.1289 Analytic Systems Quality Assessment .
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 document review and interview with laboratory personnel, the Laboratory Director (LD) failed to attest to the integration of proficiency testing samples into the routine patient workload on one of five occasions in 2022 and 2023. In addition, Testing Personnel (TP) failed to do the same on two of five occasions in the same time period. Findings are as follows: 1. The laboratory performed moderate complexity Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:00 a.m. on 02/09/24. 2. The Laboratory performed proficiency testing using the American Proficiency Institute (API) in 2022 and 2023. 3. The LD's signature and the TP's signature were required on the attestation statements for all PT events as indicated in the Proficiency Test Policy and Procedure found in the Policies and Procedures manual. 4. The Laboratory Director failed to sign the attestation statement for one of five PT events reviewed from 2022 and 2023. See below. APT event 2023 Hematology -3 5. The TP failed to sign the attestation

	statement for two of five PT events reviewed from 2022 and 2023. See below. API event 2022 Hematology -3 2023 Hematology -3 5. In an interview at 11:00 a.m. on 02 /09/24, TP1 confirmed the above finding. .
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 observation, document review, and interview with laboratory personnel, the laboratory failed to perform and document manufacturer required maintenance for the single Hematology analyzer in use in 2022 and 2023. Findings are as follows: 1. The laboratory performed moderate complexity Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:00 a.m. on 02/09/24. 2. A Sysmex KN-21N hematology analyzer was observed as present and available for use during the tour of the laboratory. 3. Manufacturer maintenance requirements for the Sysmex KN-21N analyzer were established in the manufacturer's KN-21N Operator's Manual. See below. Maintenance schedule Frequency Action Daily Shut down Weekly Clean sampling valve tray Monthly Clean waste chamber Clean transducer Quarterly Clean sample rotor valve 4. Documentation of the above required maintenance was not found for the time period reviewed, April 2022 - January 2024. The laboratory was unable to provide the missing documentation upon request. 5. The laboratory performed approximately 625 hematology tests annually as indicated on documentation provided by the laboratory on date of survey. 6. In an interview at 12:55 p.m. on 02/09/24, TP1 confirmed the above findings. TP1 indicated all maintenance activities, with the exception of the weekly maintenance, were tracked and prompted by the analyzer software. TP1 indicated maintenance was performed when prompted by the analyzer software but was not documented. .
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to establish a thermometer maintenance protocol and perform and document thermometer function check activities for one of one thermometers in 2023. Findings are as follows: 1. The laboratory performed moderate complexity Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:00 a.m. on 02/09/24. 2. The following thermometer was observed in the laboratory as present and in use during the tour: Type - Control Solutions VFC

	400 Vaccine Temperature Data Logger Location - Refrigerator Serial number - 7862975685 Calibration expiration - 11/08/23 The refrigerator held Hematology testing supplies and patient specimens. 3. A thermometer function check protocol was not found during review the laboratory's Policies and Procedures manual. 4. Thermometer function check documentation was not found during review of laboratory records. 5. The laboratory was unable to provide a thermometer maintenance protocol or documentation of thermometer function checks for the above equipment upon request. 6. The laboratory performed approximately 625 hematology tests annually as indicated on documentation provided by the laboratory on date of survey. 7. In an interview at 12:20 p.m. on 02/09/24, TP1 confirmed the above 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 observation, document review, and interview with laboratory personnel, the laboratory failed to follow an established quality assurance procedure in seven of twenty two months reviewed from April 2022 through January 2024. Findings are as follows: 1. The laboratory performed moderate complexity Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:00 a.m. on 02/09/24. 2. A Sysmex KN-21N hematology analyzer was observed as present and available for use during the tour of the laboratory. 3. Ten chart audits were required monthly as established in the Policy and Procedure Monthly Clerical Error Chart Audit procedure found in the Monthly Clerical Error Chart Audit manual. 4. Chart audit documentation from July 2023 through January 2024 was either incomplete or not found during review of laboratory records. See below. 2023 Month Charts audited July 3 August 0 September 5 October 0 November 0 December 0 2024 Month Charts audited January 0 The laboratory was unable to provide the missing documentation upon request. 5. The laboratory performed approximately 625 hematology tests on patient specimens annually as indicated on documentation provided by the laboratory on date of survey. 6. In an interview at 12:25 p.m. on 02/09/24, TP1 confirmed the above finding. .