Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0978828	09/02/2020
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
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 observation, document review, and interview with laboratory personnel, the laboratory failed to include accurate reference intervals (normal values) for one Hematology analyte in the procedure manual. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:10 a.m. on 09/02/20. 2. A Sysmex KN-21 hematology analyzer was observed as present and available for use during the tour of the laboratory. 3. The White Blood Cell (WBC) reference intervals found in the normal values chart provided by the laboratory was discrepant with that indicated on

	the 55 month old patient test report reviewed on date of survey. See below. Analyte Chart Patient Report WBC 5.5 - 15.5 4.5 - 15.5 4. In an interview at 12:00 p.m. on 09 /02/20, TP1 confirmed the above finding. .
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Laboratory Director failed to ensure 1 of 1 new testing personnel in 2018 was evaluated semi-annually for test procedure competency and 1 of 1 testing personnel in 2018 and 3 of 3 testing personnel in 2019 were evaluated annually for test procedure competency. Findings are as follows: 1. The laboratory was cited for non-performance of semi-annual and annual competency evaluations during the previous survey conducted on 04/19/18. 2. A semi-annual competency assessment was not found on date of survey for 1 of 1 testing personnel hired in 2018. See D6053 3. Annual competency evaluations were not found on date of current survey for 1 of 3 testing personnel in 2018 records and 3 of 3 testing personnel in 2019 records. See D6054. 4. In an interview at 10:45 a.m. on 01/03/20, Testing Personnel 1 confirmed the above finding. .
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 document review and interview with laboratory personnel, the technical consultant failed to ensure competency was assessed at least semiannually during the first year of patient specimen testing for 1 of 1 new testing personnel hired in 2018. Findings are as follows: 1. The laboratory performed Microbiology and Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10:10 a.m. on 09/02/20. 2. The Quality Assurance procedure located in the Policies and Procedures manual indicated personnel were evaluated semi-annually during the first year of employment and annually thereafter. 3. Laboratory records indicated Testing Personnel 3 (TP3) was trained and initially assessed for testing competency on 04/05/18. A semiannual competency assessment for TP3 was not found in laboratory records. 4. The laboratory was unable to provide the missing semi-annual

	competency documents upon request. 5. In an interview at 10:45 a.m. on 09/02/20, TP1 confirmed the above findings. *This is a repeat citation. The deficiency was previously cited during the 04/19/18 survey.* .
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the technical consultant failed to evaluate the competency of 1 of 3 testing personnel in 2018 and 3 of 3 testing personnel in 2019. Findings are as follows: 1. The laboratory performed Microbiology and Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 10.10 a.m. on 09/02/20. 2. The Quality Assurance procedure located in the Policies and Procedures manual indicated personnel were evaluated semi-annually during the first year of employment and annually thereafter. 3. A 2018 competency assessment for TP1 was not found during review of the laboratory's records. The laboratory was unable to provide the document upon request. 4. A 2019 competency assessment for TP1, TP2, and TP3 was not found during review of the laboratory's records. The laboratory was unable to provide the documents upon request. 5. In an interview at 10:45 a.m. on 09/02/20, TP1 confirmed the above finding. *This is a repeat citation. The deficiency was previously cited during the 04/19/18 survey.*