Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0978828	04/19/2018
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
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) 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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to establish a function check procedure and maintain function check records for all laboratory equipment. Findings are as follows: The laboratory performed Chemistry, Hematology, and Microbiology testing as confirmed by Testing Personnel 1 (TP-1) during a tour of the laboratory on 04/19/18 at 9:05 a.m. A. Refrigerators 1. Two Danby single-door refrigerators were observed as present and available for use during a tour of the laboratory. 2. A Fisher Scientific digital electronic temperature monitor was observed as attached to each of the refrigerators to display internal temperatures. Monitor Unit Manufacturer Calibration Serial Number Expiration Date 3154 3 / 2018 3155 3 / 2018 3. The laboratory was unable to provide a function check procedure or calibration records for the above equipment upon request. 4. In an interview on 04/19/18, at 11:30 a.m., TP-1 confirmed that the thermometer units were outside of the manufacturer calibration period, and that a function check procedure for the above equipment had not been established, and function check records for the thermometers were not available. B. Incubator 1. A Boekol Inc. Incubator was observed as present and available for use during a tour of the laboratory. 2. The incubator was equipped with an internal digital temperature

	display, but no other temperature monitoring device. 3. The laboratory was unable to provide a function check procedure or calibration records for the above equipment upon request. 4. In an interview on 04/19/18, at 11:30 a.m., TP-1 confirmed that a function check procedure for the above equipment had not been established, and function check records for the thermometers were not available. .
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 document review and interview with laboratory personnel, the laboratory failed to perform calibration verification on a hematology analyzer at least once every 6 months. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Testing Personnel 1 (TP-1) during a tour of the laboratory on 04/19/18 at 9:05 a.m. 2. A Sysmex KN-21 hematology analyzer was observed as present and available for use during a tour of the laboratory. 3. The laboratory exceeded the 6 month calibration verification interval for the Sysmex KN-21 hematology analyzer on one occasion in the time period reviewed; March 2016 through date of survey. See below: Previous cal. Subsequent cal. Time elapsed 01/27/17 10/25/17 9 months 4. The laboratory was unable to provide additional calibration verification records between 01 /27/17 and 10/25/17. 5. In an interview on 04/19/18 at 2:45 p.m., the TP-1 confirmed the above findings. .
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 (TC) failed to assess the competency of 2 of 4 new Testing Personnel at least twice annually during the first year of testing. Findings are as follows: 1. The laboratory performed Chemistry, Hematology, and Microbiology testing as confirmed by Testing Personnel 1 (TP-1) during a tour of the laboratory on 04/19/18 at 9:05 a.m. 2. Semi-annual competency assessments for 2 of 4 Testing Personnel (TP) were not found during review of laboratory records as follows: Testing Personnel Testing Area TP-4 Throat Culture Hematology TP-5 Throat Culture Hematology 3. The laboratory was unable to provide the required documentation upon request. 4. In an interview on 04/19/18 at 10:30 a.m., the TP-1 confirmed the above findings. .
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 observation, document review and interview with laboratory personnel, the Technical Consultant failed to ensure comprehensive competency assessments for 3 of 4 Testing Personnel were performed annually. Findings are as follows: 1. The laboratory performed Chemistry, Hematology, and Microbiology testing as confirmed by Testing Personnel 1 (TP-1) during a tour of the laboratory on 04/19/18 at 9:05 a.m. 2. Annual competency assessments for 3 of 4 Testing Personnel (TP) were not found during review of laboratory records as follows: Testing Personnel Testing Area Year TP-2 Throat Culture 2017 Hematology 2017 TP-3 Throat Culture 2016 Throat Culture 2017 Hematology 2017 TP-4 Throat Culture 2017 Hematology 2017 3. The laboratory was unable to provide the missing competency assessments upon request. 4. In an interview on 04/19/18 at 10:30 a.m., the TP-1 confirmed the above findings. .