

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0978828	(X3) Date Survey Completed 04/08/2022
Name of Provider or Supplier Eagan Valley Pediatrics	Street Address, City, State 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
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Laboratory Director failed to provide overall management and direction to ensure testing personnel competency was assessed annually in accordance with 493.1407 of this subpart. Findings are as follows: 1. The Laboratory Director failed to ensure 1 of 2 testing personnel in 2020 and 1 of 3 testing personnel in 2021 were evaluated annually for test procedure competency. See D6030 2. D6030 was previously cited during the 09/02/20 survey.</p>
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>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;</p>

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 2 testing personnel in 2020 and 1 of 3 testing personnel in 2021 were evaluated annually for test procedure competency. Findings are as follows: 1. The laboratory was cited for non-performance of annual competency evaluations during the two previous surveys conducted on 04/19/18 and 09/02/20. 2. Annual competency evaluations were not found on date of current survey, 04/08/22, for 1 of 2 testing personnel in 2020 records and 1 of 3 testing personnel in 2021 records. See D6054. 3. In an interview at 2:15 p.m. on 04/08/22, Testing Personnel 1 confirmed the above finding. *This is a repeat citation. This deficiency was previously cited during the 09/02/20 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 2 testing personnel in 2020 and 1 of 3 testing personnel in 2021. 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 1:05 p.m. on 04/08/22. 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 2020 Hematology annual competency assessment for TP2 was not found during review of the laboratory's records. The laboratory was unable to provide the document upon request. 4. 2021 Hematology and Microbiology annual competency assessments for TP2 were not found during review of the laboratory's records. The laboratory was unable to provide the documents upon request. 5. In an interview at 2:15 p.m. on 04/08/22, TP1 confirmed the above finding. *This is a repeat citation. This deficiency was previously cited during the 04/19/18 and 09/02/20 surveys.*