Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 24D0398909	**(X3) Date Survey Completed** 06/28/2023
Name of Provider or Supplier Pediatric And Young Adult Medicine	**Street Address, City, State** 1804 7th Street W Suite 200, Saint Paul, 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**
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to establish a written competency assessment procedure to follow when assessing all testing personnel performing all non-waived tests. Findings are as follows: 1. The laboratory performed non-waived testing under the subspecialty of Bacteriology and Hematology as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 9:10 a.m. on June 28, 2023. 2. A competency assessment procedure was not found during review of laboratory policies and procedures. The laboratory was unable to provide a competency assessment procedure upon request the day of survey June 28, 2023. 3. In an interview at 11:59 a.m. on June 28, 2023, TP1 confirmed the laboratory did not have an established competency assessment policy. .
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If

	the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Laboratory Director failed to delegate the responsibilities of the Technical Consultant to a qualified individual. The laboratory performs testing on approximately 2,592 patient specimens annually. Findings are as follows: 1. The Technical Consultant role was not established on the Form CMS-209 Laboratory Personnel Report (CLIA) on date of survey, June 28, 2023. 2. In an interview on June 28, 2023 at 9:30 a.m., Testing Personnel 1 (TP1) stated the Laboratory Director would be the one to perform the TC role and marked the CMS-209 to reflect this. 3. Record review of competency assessments performed on 7 of 8 testing personnel found that TP1 was performing the review/observation rather than the TC or someone meeting the qualification requirements of the TC. 4. Review of TP1 qualification documents confirmed TP1 did not meet the minimum qualification requirements to be a TC. A High School and Medical Assistant Diploma were provided. 5. In an interview at 09:46 a.m. on June 28, 2023, TP1 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 observation, document review, and interview with laboratory personnel, the Technical Consultant failed to assess competency at least semi-annually during the first year of patient specimen testing for one of four testing personnel (TP) hired between June 2021 and June 2023. Findings are as follows: 1. The laboratory performed non-waived testing under the subspecialty of Bacteriology and Hematology as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory at 9:10 a.m. on June 28, 2023. 2. The Sysmex XP 300 hematology analyzer and the Selective Strep Agar media and incubator to perform throat cultures was observed as present and available for use during the tour. 3. Semi-annual competency assessments were not found for TP5 for throat cultures and the hematology testing performed on the Sysmex XP 300. TP5 hired in February 2022. Initial training as well an annual competency performed in January 2023 were found. 4. The laboratory was unable to provide the missing documents upon request. 5. In an interview at 9:50 a.m. on June 28, 2023, TP1 confirmed the above finding. .