

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D2049447	<b>(X3) Date Survey Completed</b>  06/08/2023
<b>Name of Provider or Supplier</b>  Park Nicollet Clinic - Champlin	<b>Street Address, City, State</b>  12142 Business Park Blvd N, Champlin, MN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5791</b>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(a)(c)</p> <p>(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.</p> <p>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 2022. Findings are as follows: 1. The laboratory performed Erythrocyte Sedimentation rate (ESR) testing as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory at 10:05 a.m. on 06/01/23. 2. A Vital Diagnostics Excyte M Automated ESR Analyzer was observed as present and available for use during the tour of the laboratory. 3. Monthly review of ESR quality control (QC) results was required as established in the Quality Control Plan procedure found in the Compliance360 software program. 4. Monthly ESR QC review documentation was not found during review of 2022 QA records. The laboratory was unable to provide the missing documentation upon request. 5. In an interview at 3:00 p.m., TC1 confirmed the above finding. .</p>
<b>D6063</b>	<p><b>LABORATORY TESTING PERSONNEL</b> CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p>

This CONDITION is not met as evidenced by:  
. Based on observation, review of personnel and laboratory documents, and interview and email communication with laboratory personnel, the laboratory failed to ensure staff performing moderate complexity testing meet the qualification requirements of 493.1423 to perform the functions specified in 493.1425 for the complexity of testing performed. Findings are as follows: The laboratory failed to obtain an equivalency evaluation of foreign credentials for one testing personnel performing moderate complexity testing in 2022 and 2023. See D6065. .

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:  
. Based on observation, document review, and interview and email communication with laboratory personnel, the laboratory failed to obtain a foreign credential equivalency evaluation for one of one testing personnel with foreign credentials who was performing moderate complexity testing from May 2022 through May 2023 . Findings are as follows: 1. The laboratory performed Chemistry and Hematology testing as confirmed by the Technical Consultant 1 (TC1) during a tour of the laboratory at 10:05 a.m. on 06/01/23. The following moderate complexity analyzers and test kits were observed as present and available for use during the tour: Sysmex XS-1000i hematology analyzer Vital Diagnostics Excyte M erythrocyte sedimentation rate analyzer Cardinal Health HCG Combo test kit 2. Testing Personnel 3 (TP3) was listed on the Laboratory Personnel Report (CLIA) Form CMS-209 as an employee performing moderate complexity testing. 3. TP3 completed initial training at this laboratory location on the above analyzers and test kits in May 2022 as indicated on competency assessment records provided by the laboratory. 4. Education credentials for TP3 were not found in personnel records on date of survey. The laboratory was given five days to provide the missing credentials. 5. In an email received at 10:18 a. m. on 06/06/23, TC1 provided education credentials for TP3 from West Africa. The document was generated by the West African Examination Council and entitled General Certificate of Education, dated June 1993. 6. An evaluation of foreign credentials was not provided with the General Certificate of Education. A request for this document was sent via email to TC1 at 10:23 a.m. on 06/06/23. 7. In an email received at 1:55 p.m. on 06/06/23, TC1 indicated an international education verification for TP3 had been requested. 8. In an email received at 11:56 a.m. on 06/09 /23, the Ambulatory Laboratories Manager (ALM) indicated the evaluation of foreign credentials may have been completed for TP3 but the laboratory did not have the documentation at this time. The ALM indicated the laboratory had requested the evaluation from Human Resources. .