

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D1033968	(X3) Date Survey Completed 03/18/2025
Name of Provider or Supplier Stark Family Health Center Inc	Street Address, City, State 4465 Fulton Drive Nw #100, Canton, OH	
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
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review and an interview with the Laboratory Director (LD), the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems with the moderately complex testing procedures in the subspecialties of Routine Chemistry, Toxicology and Endocrinology. This deficient practice had the potential to affect all patient testing procedures performed in this laboratory between 03/14/2025 through 03/18/2025. Findings Include: 1. The laboratory failed to ensure that the laboratory's reagents were not used when they had exceeded their expiration dates. (Refer to D5417) 2. The laboratory failed to perform and document maintenance protocol which was necessary for accurate and reliable test results and test result reporting in the subspecialties of Routine Chemistry, Endocrinology and Toxicology (Refer to D5429)</p>