Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0975936	01/31/2024
Name of Provider or Supplier	**Street Address, City, State**	
Orlando Health Medical Group Inc	511 Medical Plaza Dr Ste 101, Leesburg, FL	

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
D0000	Recertification survey was conducted on January 31, 2024. Orlando Health Medical Group Inc clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the Laboratory Personnel Report, Individual Quality Control Plan (IQCP) and Initial Training/Observation documentation; and interview, the laboratory failed to monitor and evaluate the overall quality of the general laboratory system and correct identified problems as evidenced by the lack of six month competency documentation for two (C, D) of four (A, B, C, D) testing personnel in 2023. (See D5209)
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 review of the Laboratory Personnel Report, Individual Quality Control Plan (IQCP) and Initial Training/Observation documentation; and interview, the laboratory failed to document the six month competency assessments on two (C,D) of four (A, B, C, D) testing personnel in 2023. This is a repeat deficiency from the recertification survey on 10/28/2021. Findings: Review of "The Laboratory Personnel Report" signed and dated by the Laboratory Director on 01/31/2024, showed there were four testing personnel. Review of the Individual Quality Control Plan (IQCP) for Activated Clotting Time (ACT) testing noted "Competency will be performed at 6 month, 1 year and annually per policy." Review of the Initial Training/Observation for Testing Personnel C listed her hire date as 03/26/2023 and her training date of 02/28/2023. Review of the Initial Training/Observation for Testing Personnel D listed her hire date as 06/12/2023 and her training date of 06/13/2023. No other competency evaluations were available for review for Testing Personnel C and D. On 01/31/2024 at 10:15 AM, Technical Consultant B stated the six month competency evaluations for Testing Personnel C and D were not completed.