Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0977441	06/24/2020
Name of Provider or Supplier	**Street Address, City, State**	
Orlando Health Medical Group Inc	4106 W Lake Mary Blvd Ste 215, Lake Mary, 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	A recertification survey was conducted on June 24, 2020. Central Florida Urology Associates clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain quality control (QC) records for the NanoEnTek Frend instrument for approximately 500 patients per year. Findings: Review of the laboratory's records showed that the NanoEnTek Frend instrument verification for PSA (prostate specific antigen) was performed on 9/12/18. Review of the laboratory's records showed the laboratory failed to retain the package insert for Cliniqa Liquid QC Immunoassay Controls and the Frend PSA test cartridges. The laboratory was only able to provide the package inserts for the controls currently in use. During an interview on 6/24/20 at 3:38 PM, Testing Personnel A stated she did not know they needed to keep the package inserts.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to label the PSA (prostate specific antigen) quality control vials currently in use with the open date and expiration date. Findings: Examination of the Cliniqa Liquid QC Immunoassay Controls on 6/24/20 at 4:08 PM, showed the PSA quality control vials for level 1 and level 2 did not have the open date and the new expiration date after the vials were opened. Review of the package insert for the controls noted "Once opened, vials of controls are stable for 30 days when stored tightly capped at 2 - 8 degrees C." During an interview on 6/24/20 at 4:10 PM, Testing Personnel A stated she did not write the open or the new expiration date on the control vials.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform quality control lot to lot comparisons from 9/12/18 to 6/24/20 for PSA (prostate specific antigen) controls. Findings: Review of the quality control logs showed that there were no lot to lot comparisons of the PSA controls for the NanoEnTek Frend instrument. Review of the "Quality Control (QC) Procedure" noted that "If laboratories rely on commercial companies to establish statistical limits for controls, the laboratory must have documentation to verify that its control results correlate with the established limits." Review of the "External QC New Lot Number Verification" worksheet noted that "Before putting new lot of control materials into use, verify the new control performs as expected by parallel testing with the current lot number." The worksheet also noted that the comparison of the new lot number to current lot number of controls should be run "5 times for CLIA" (Clinical Laboratory Improvement Amendments). During an interview on 6/24/20 at 3:39 PM, Testing Personnel A stated she did not perform lot to lot comparison on the control.