Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0975936	10/28/2021
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	A recertification survey was conducted on October 28, 2021. Florida Heart and Vascular Multispecialty Group PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have all testing personnel rotate through performance of proficiency testing (PT) samples for five of five events (2020 2nd, 3rd, 2021 1st, 2nd) for the specialty of hematology. Findings: Review of the American Proficiency Institute (API) PT for the blood gas hemoglobin showed Testing Personnel A and Testing Personnel E, each performed a portion of the PT for the 2020 2nd and 3rd event, and 2021 1st, 2nd, and 3rd events. Review of the Laboratory Personnel Report, signed and dated by the Laboratory Director on 10/27 /2021, listed six Testing Personnel. Review of a copy of the Laboratory Personnel Report from their other laboratory with the same testing personnel with hire dates added showed Testing Personnel A was hired 11/2018, Testing Personnel B was hired 03/08/2021, Testing Personnel C was hired 04/2020, Testing Personnel D was hired 04 /2021, Testing Personnel E was hired 03/2020, and Testing Personnel F was hired 01 /27/2020. On 10/28/2021 at 10:20 AM, Testing Personnel A stated they were the only ones who performed PT.
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 documenting the Avoximeter 1000E blood gas instrument for four (March - June) of 10 months (March - December) the instrument was used in 2020. Findings: Review of the laboratory's QC records showed the log titled, "Avoximeter 1000E Daily QC Log" for recording the liquid controls was not available for review from March through June of 2020. Review of the laboratory's QC records titled, "Avoximeter 1000E Maintenance Log" showed maintenance was performed on the instrument from March through December 2020. On 10/28/2021 at 11:35 AM, Testing Personnel A stated she did not know were the logs were located.
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 record review and staff interview, the laboratory failed to fully document training and competency assessments on six of six (A, B, C, D, E, F) testing personnel in 2020 and 2021. Findings: Review of "The Laboratory Personnel Report" signed and dated by the Laboratory Director on 10/27/2021 showed there were six testing personnel. The laboratory's policy titled "Personnel Training and Competency" noted, "Training and Competency documentation will be done after the 90 day orientation period, at 6 months and a reevaluation of competency will be performed and documented every year thereafter." Review of a copy of the Laboratory Personnel Report including hire dates showed Testing Personnel A was hired 11/2018, Testing Personnel B was hired 03/08/2021, Testing Personnel C was hired 04/2020, Testing Personnel D was hired 04/2021, Testing Personnel E was hired 03/2020, and Testing Personnel F was hired 01/27/2020. Review of the competency evaluation documentation for Testing Personnel A showed there was no annual competency performed in 2020. Review of the competency evaluation documentation for Testing Personnel B showed there was no documentation of training and competency after the 90 days orientation period in 2021. Review of the competency evaluation documentation for Testing Personnel C showed there was no documentation of training and competency after the 90 days orientation period or at six months in 2020. Review of the competency evaluation documentation for Testing Personnel D showed there was no documentation of training and competency after the 90 days orientation period in 2021. Review of the competency evaluation documentation for Testing Personnel E showed there was no documentation of training and competency after the 90 days orientation period or at six months in 2020.. Review of the competency evaluation documentation for Testing Personnel F showed there was no documentation of competency at six months in 2020. On 10/28/21 at 1:05 PM, Testing Personnel A stated there were missing competencies.
D5403	PROCEDURE MANUAL

	CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory's procedure manual failed to include a list of the alert (critical) values in their procedure manual from 05/01 /2016 to 10/28/2021. Findings: Review of the laboratory's procedure titled "Critical Results Reporting" with effective date of 05/01/2016, showed no critical values were listed for blood gas tests, total hemoglobin, oxyhemaglobin, calculated oxygen saturation, and the hematology test activated clotting time. On 10/28/2021 at 1:15 PM, Testing Personnel A stated the critical values were not listed
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and staff interview, the reports given to patients with laboratory results failed to list the correct name and address of the laboratory where testing was performed and reference intervals (normal values) for three of three patients test reports reviewed. Findings: 1. Review of the Avoximeter 1000E blood gas instrument printouts showed the name, address of the laboratory, and the normal ranges were not on the printout. On 10/28/2021 at 12:30 PM, Testing Personnel A stated she gave patients who requested a copy of their laboratory results a copy of the instrument printout but the name, address of the laboratory, and the normal ranges were not on the printout. 2. Review of the assessment sheet showed the name, address

	of the laboratory, and the normal ranges were not on the assessment sheet. On 10/28 /2021 at 12:55 PM, Testing Personnel A stated she had given the assessment sheet with the laboratory results to patients, but the name, address of the laboratory, and the normal ranges were not included on the assessment sheet.