Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1064681	10/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Orlando Health Medical Group, Inc	1560 Santa Barbara Blvd, The Villages, 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 26, 2021 to 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 E performed PT for the 2020 2nd event. Review of the API PT showed Testing Personnel A and Testing Personnel E, each performed a portion of the PT for the 2020 3rd event and 2021 1st, 2nd, and 3rd events. Review of the Laboratory Personnel Report, signed and dated by the Laboratory Director on 10/26 /2021, listed six Testing Personnel. Review of a copy of the Laboratory Personnel Report with the 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 10/26/2021 at 11:13 AM, Testing Personnel A and Testing Personnel E stated they were the only ones who performed the PT.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)

	The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director failed to sign the attestation form for Proficiency Testing (PT) for one (2020 3rd) of five events (2020 2nd, 3rd, 2021 1st, 2nd) for the specialty of hematology for blood gas hemoglobin. Findings: Review of the American Proficiency Institute (API) PT Attestation Statement noted "Signatures Required - Testing personnel and Laboratory Director must physically sign an attestation statement for PT results, and retain the signed statement (or a copy) for a minimum of 2 years." Review of the API PT attestation statement for the 3rd event in 2020 showed the signature of the Laboratory Director was missing . On 10/26/2021 at 11:53 AM, Testing Personnel A stated the signatures were missing.
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 record review and staff interview, the laboratory failed to monitor and evaluate the overall quality of the general laboratory system and correct identified problems. Findings: Cross Reference D5209: 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. This is a repeat deficiency from the survey on 12/12/19 to 12/13/19.
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. This is a repeat deficiency from the survey on 12/12/19 to 12/13 /19. Findings: Review of "The Laboratory Personnel Report" signed and dated by the Laboratory Director on 10/26/2021 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 reevaluation of competency will be performed and documented every year thereafter." Review of a copy of the Laboratory Personnel Report with the 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. 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 10/26/19 at 12:03 PM, Testing Personnel E stated competencies in 2020 were not done. On 10/28/21 at 1:05 PM, Testing Personnel A stated there were missing competencies.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document review and evaluation of proficiency testing (PT) for five of five (2020 2nd, 3rd, 2021 1st, 2nd) event performance evaluations for the specialty of hematology for blood gas hemoglobin. Findings: Review of the American Proficiency Institute (API) PT showed the Laboratory Director failed to sign "Proficiency Testing Performance Evaluation" forms for the 2020 2nd and 3rd events, and the 2021 1st and 2nd events. The Laboratory Personnel Report, signed and dated by the Laboratory Director on 10 /26/2021, showed the Laboratory Director was the only Clinical Consultant and Technical Consultant. The Laboratory Director was the only person qualified to sign the PT performance evaluation for this laboratory. On 10/26/2021 at 10:39 AM, Testing Personnel E stated the Laboratory Director had not signed the performance reviews.
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 the effective date of 05/01/2016, showed no critical values were listed for blood gas tests, total hemoglobin, oxyhemaglobin, and calculated oxygen saturation, and hematology test activated clotting time. On 10/28/2021 at 1:15 PM, Testing Personnel A stated the critical values were not listed
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 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 postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory's quality assessment program failed to correct identified problems in the postanalytic system. Findings: Cross Reference D5805: 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. This is a repeat deficiency form the survey on 12/12/19 to 12/13/19.
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. This is a repeat deficiency form the survey on 12/12/19 to 12/13/19. 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 10/26/2021 at 12:58 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 and address of the laboratory and the normal ranges were not on the printout. 2. Review of the assessment sheet showed the name and address of the laboratory, and the normal ranges were not on the assessment sheet. On 10/26/2021 at 1:00 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.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review and staff interview, the Laboratory Director failed to provide overall management and direction of the laboratory. Cross Reference D6007: Based on record review and staff interview, the Laboratory Director failed to ensure that testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance, including the postanalytic phases of testing. Cross Reference D6030: Based on record review and staff interview, the Laboratory Director failed to ensure testing personnel were competent and their competencies were documented.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director failed to ensure testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance, including postanalytic phases of testing. Findings: The Laboratory Director failed to ensure the reports given to patients with laboratory

	results listed 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. This is a repeat deficiency from the survey on 12/12/19 to 12/13/19. (See D5805)
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director failed to ensure testing personnel were competent and their competencies were documented. Findings. The Laboratory Director failed to ensure all testing personnel's training and competency evaluations were fully documented in 2020 and 2021 for six of six testing personnel. This is a repeat deficiency from the survey on 12/12/19 to 12/13/19. (See D5209)