| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 10D1064681 | 12/13/2019 |
| **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 |
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| **D0000** | AMENDED 1/22/2020 A recertification survey was conducted on 12/12/19 - 12/13 /19. Florida Heart and Vascular Multispecialty Group PA clinical laboratory was found not in compliance with 42 CFR 493, requirements for clinical laboratories. Based on the survey findings an Immediate Jeopardy situation was identified and the laboratory was notified of the Immediate Jeopardy at 2:30 PM on 12/13/19. The laboratory failed to perform three levels of liquid quality control for the Oxicom 2100 pO2 (partial pressure of oxygen) analyzer weekly. The laboratory failed to perform two levels of liquid quality control for the Hemochron Jr Signature Plus ACT (activated clotting time) analyzer when a new shipment was received and once per 30 calendar days. The laboratory failed to perform calibrations on the Oxicom 2100 pO2 analyzer since its initial calibration. (D5400) The following Conditions were not met: D2000 - 493.801 Enrollment and Testing of Samples D5200 - 493.1230 General Laboratory Systems D5400 - 493.1250 Analytic Systems D6000 - 493.1403 Moderate Complexity Laboratory Director |
| **D2000** | ENROLLMENT AND TESTING OF SAMPLES<br>CFR(s): 493.801<br><br>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.<br><br>This CONDITION is not met as evidenced by:<br>Based on record review and interview, the laboratory failed to enroll in proficiency testing with an approved proficiency testing (PT) program from the time patient |

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| | testing started in July 2018 to December 12, 2019 in the specialty of Routine Chemistry. Findings: Review of PT records from the American Proficiency Institute (API) showed that there was no proficiency testing performed on the analyte pO2 (partial pressure of oxygen) from when patient testing started in July 2018 to December 12, 2019. During an interview on 12/12/19 at 9:46 AM, the Laboratory Consultant stated that the laboratory was not enrolled in PT for pO2. |
| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the laboratory failed to maintain the documentation showing they ran internal controls on the Oxicom 2100 pO2 (partial pressure of oxygen) analyzer and the Hemochron Jr Signature Plus ACT (activated clotting time) analyzer from when patient testing started in July 2018 to December 31, 2018. Findings: 1. Review of the "Hemochron Q/C Log Sheet" showed that records for the internal controls were not available for review from when patient testing started in July 2018 to December 31, 2018. . During an interview on 12/12/19 at 11:00 AM, the Laboratory Consultant stated that the laboratory did not save the 2018 records. 2. Review of the "Oxicom 2100 Daily Check Log" showed that records for the internal controls were not available for review from when patient testing started in July 2018 to December 31, 2018. During an interview on 12/12/19 at 11:00 AM, the Laboratory Consultant stated that the laboratory did not save the 2018 records. |
| **D5200** | GENERAL LABORATORY SYSTEMS<br>CFR(s): 493.1230<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on record review and interview, the laboratory's quality assessment program 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 competency assessments on testing personnel in 2018 and 2019. Cross Reference D5291 Based on record review and interview, the laboratory failed to follow their procedures for monitoring, assessing and correcting problems. The laboratory failed to perform any quality assurance reviews. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235 |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the laboratory failed to fully document competency assessments on testing personnel in 2018 and 2019. Findings: Review of "The Laboratory Personnel Report" signed and dated by the Laboratory Director on 12 /12/19 showed that there were 8 testing personnel (A, B, C, D, E, F, G, H). The laboratory had competency evaluation forms for ACT (Activated Clotting Time) competency and pO2 (partial pressure of oxygen) competency. The laboratory policy titled "Personnel Training and Competency" read, "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." 1. Review of the competency records showed that there was no ACT or pO2 competency on testing personnel A, B, C, and F for 2018. During an interview on 12 /12/19 at 11:10 AM, the Cath Lab Manager stated that testing personnel A, B, C, D, E, and F started working in 2018 in the lab. During an interview on 12/12/19 at 11:12 AM, the Cath Lab Manager acknowledged that competency assessments were not completed on all the testing personnel. 2. Review of the competency assessment performed in 2018 showed that the competency assessment forms were not signed by the Laboratory Director. During an interview on 12/12/19 at 9:28 AM, the Laboratory Consultant confirmed that the competency assessment performed in 2018 were not signed by the Laboratory Director. 3. Review of the competency records showed that there was no ACT or pO2 competency on testing personnel A, B, C, D, E, F, and G in 2019. During an interview on 12/12/19 at 11:10 AM, the Cath Lab Manager stated that testing personnel G started 9 months ago and testing personnel H started two weeks ago. During an interview on 12/12/19 at 11:12 AM, the Cath Lab Manager acknowledged that competency assessment had not been performed in 2019 for all testing personnel except for Testing Personnel H who was still in training. |
| **D5291** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(a)<br><br>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the laboratory failed to follow their procedures for monitoring, assessing and correcting identified problems. Findings: Review of the laboratory's procedure titled "Quality Assurance Plan" showed the laboratory had 3 Quality Assurance (QA) forms, "Director's Review of Monthly Clinical Pathology Quality Assessment," "Monthly Quality Assurance Report" and "Monthly QA Report Checklist." There were no QA forms available for review from when patient testing started in July 2018 to December 12, 2019. During an interview on 12/12/19 at 11:30 AM, the Laboratory Consultant stated that the laboratory had not done any QA reviews. |
| **D5400** | ANALYTIC SYSTEMS |

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| | CFR(s): 493.1250<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>AMENDED 1/22/2020 Based on record review and interview, the laboratory's quality assessment program failed to monitor and evaluate the overall quality of the analytic system and correct identified problems. Findings: Cross Reference D5413. Based on record review and interview, the laboratory failed to record the temperature and humidity of the room where testing was performed from when patient testing started in July 2018 to December 12, 2019. Cross Reference D5429. Based on record review and interview, the laboratory failed to document the maintenance performed on the Oxicom 2100 pO2 (partial pressure of oxygen) analyzer and the Hemochron Jr Signature Plus ACT (Activated Clotting Time) analyzer from when patient testing started in July 2018 to December 12, 2019. Cross Reference D5447. Based on record review and interview, the laboratory failed to perform quality controls at least once a day that patient specimens were tested on the Oxicom 2100 pO2 (partial pressure of oxygen) analyzer and the Hemochron Jr Signature Plus ACT (activated clotting time) analyzer from when patient testing started in July 2018 to December 12, 2019. Cross Reference D5535. Based on record review and interview, the laboratory failed to perform calibrations on the Oxicom 2100 pO2 (partial pressure of oxygen) analyzer according to manufacturer's specifications from when patient testing started in July 2018 to December 12, 2019. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the laboratory failed to record the temperature and humidity of the room where testing was performed from when patient testing started in July 2018 to December 12, 2019. Findings: Review of the instruction manual for the Oxicom 2100 showed that the operating environment temperature should be between 65-85 degrees Fahrenheit (18.3-29.4 degrees Celsius). No room temperature or humidity logs were available for review. During an interview on 12/12 /19 at 4:05 PM, the Laboratory Consultant acknowledge that the laboratory was not recording the temperature or humidity of the room where the testing was performed. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS |

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| | CFR(s): 493.1254(a)(1)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the laboratory failed to document the maintenance performed on the Oxicom 2100 pO2 (partial pressure of oxygen) analyzer and the Hemochron Jr Signature Plus ACT (Activated Clotting Time) analyzer from when patient testing started in July 2018 to December 12, 2019. Findings: 1. Review of the instruction manual for the Oxicom 2100 showed that section 5 of the manual on maintenance and section 5.1 titled "Maintenance Schedules" noted daily, weekly, quarterly and semiannually maintenance to be performed. There were no records of maintenance performed available for review. During an interview on 12/12/19 at 2:29 PM, the Laboratory Consultant acknowledged the lab had not recorded the maintenance for the Oxicom 2100 analyzer. 2. Review of the instruction manual for the Hemochron Jr Signature Plus showed the routine maintenance to be performed on the analyzer. There were no records of maintenance available for review. During an interview on 12/12/19 at 2:49 PM, the Laboratory Consultant acknowledged the lab had not recorded the maintenance for the Hemochron analyzer. |
| **D5447** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(i)(g)<br><br>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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the laboratory failed to perform quality controls at least once a day that patient specimens were tested on the Oxicom 2100 pO2 (partial pressure of oxygen) analyzer and the Hemochron Jr Signature Plus ACT (activated clotting time) analyzer from when patient testing started in July 2018 to December 12, 2019. Findings: 1. Review of the laboratory's quality control records for the Oxicom 2100 pO2 analyzer showed that no records of external liquid controls were available for review from when patient testing started in July 2018 to December 12, 2019. During an interview on 12/12/19 at 11:30 AM, the Laboratory Consultant stated that the laboratory was not running liquid controls for pO2. 2. Review of the laboratory's quality control records for the Hemochron Jr Signature Plus ACT analyzer showed that no records of external liquid controls were available for review from when patient testing started in July 2018 to December 12, 2019. During an interview on 12/12/19 at 11:30 AM, the Laboratory Consultant stated that the laboratory was not running liquid controls for ACT. |
| **D5535** | ROUTINE CHEMISTRY<br>CFR(s): 493.1267(a)(d) |

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| | For blood gas analyses, the laboratory must perform the following: (a) Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer. (d) Document all control procedures performed, as specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the laboratory failed to perform calibrations on the Oxicom 2100 pO2 (partial pressure of oxygen) analyzer according to manufacturer's specifications from when patient testing started in July 2018 to December 12, 2019. Findings: Review of the instruction manual for the Oxicom 2100 showed that section 4 provided instructions on performing calibrations on the the analyzer. Section 5 of the manual read, "The calibration should be confirmed twice a year." Review of the laboratory's records showed that the analyzer was calibrated on 4 /16/18. There were no other calibration records available for review. During an interview on 12/12/19 at 9:32 AM, the Laboratory Consultant acknowledged that the laboratory had not performed any other calibrations on the Oxicom 2100 analyzer after 4/16/18. |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>AMENDED 1/22/2020 Based on record review and interview, the Laboratory Director failed to provide overall management and direction in the laboratory. Cross Reference D6007 Based on record review and 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 analytic phases of testing. Cross Reference D6015 Based on record review and interview, the Laboratory Director failed to ensure that the laboratory was enrolled in an approved proficiency testing (PT) program for all analytes tested in the laboratory. Cross Reference D6021 Based on record review and interview, the Laboratory Directory failed to ensure the quality assessment programs were maintained to assure quality of laboratory services provided from when patient testing started in July 2018 to December 12, 2019. Cross Reference D6030 Based on record review and staff interview, the Laboratory Director failed to ensure that testing personnel were competent and that their competency was maintained. |
| **D6007** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(1)<br><br>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 |

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| | testing;<br><br>This STANDARD is not met as evidenced by:<br>AMENDED 1/22/2020 Based on record review and 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 analytic phases of testing. Findings: The Laboratory Director failed to ensure the temperature and humidity of the room where testing was performed was recorded from when patient testing first started in July 2018 to December 12, 2019. (See D5413) The Laboratory Director failed to ensure the maintenance performed on the Oxicom 2100 pO2 (partial pressure of oxygen) analyzer and the Hemochron Jr Signature Plus ACT (Activated Clotting Time) analyzer was documented from when patient testing started in July 2018 to December 12, 2019. (See D5429) The Laboratory Director failed to ensure that the laboratory perform quality controls at least once a day that patient specimens were tested on the Oxicom 2100 pO2 (partial pressure of oxygen) analyzer and the Hemochron Jr Signature Plus ACT (activated clotting time) analyzer from when patient testing started in July 2018 to December 12, 2019. (See D5447) The Laboratory Director failed to ensure that the laboratory performed calibrations on the Oxicom 2100 pO2 analyzer according to manufacturer's specifications from when patient testing started in July 2018 to December 12, 2019. (See D5535) |
| **D6015** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)<br><br>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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the Laboratory Director failed to ensure that the laboratory was enrolled in an approved proficiency testing (PT) program for all analytes tested in the laboratory. Findings: The Laboratory Director failed to ensure that the laboratory was enrolled in proficiency testing with an approved PT program in the specialty of Routine Chemistry for the analyte pO2 (partial pressure of oxygen) from when patient testing started in July 2018 to December 12, 2019. (See D2000) |
| **D6021** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by: |

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| | Based on record review and interview, the Laboratory Directory failed to ensure the quality assessment programs were maintained to assure quality of laboratory services provided from when patient testing started in July 2018 to December 12, 2019. Findings: The Laboratory Director failed to ensure procedures were followed for monitoring, assessing and correcting problems. The Laboratory Director failed to ensure the laboratory performed quality assurance reviews. (See D5291) |
| **D6030** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(12)<br><br>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;<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the Laboratory Director failed to ensure testing personnel were competent and that their competency was maintained. Findings. The Laboratory Director failed to ensure all testing personnel had competency evaluations in 2018 and 2019, and failed to sign the competency evaluations in 2018. (See D5209) |