

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0975936	(X3) Date Survey Completed 04/07/2020
Name of Provider or Supplier Orlando Health Medical Group Inc	Street Address, City, State 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 April 7, 2020. Florida Heart and Vascular Multispecialty Group PA clinical laboratory was found not in compliance with 42 CFR 493, requirements for clinical laboratories.
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain instrument printouts of the patient test results from the Avoximeter 1000E blood gases analyzer from 3/11/2020 to 4/07/2020. Findings: Review of the Avoximeter 1000E blood gases analyzer performance verification showed the instrument was validated on 3/11/2020. Review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification form (CMS-116) states the laboratory performs 500 tests annually. No instrument printouts with patient results were available for review. During an interview on 4/07/2020 at 12:48 PM, the Catheter Lab Manager stated that the nurse are throwing away the instrument printouts with the patient test results on it.</p>
D6063	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p>

This CONDITION is not met as evidenced by:
Based on record review and interview, the laboratory failed to have verification of the educational qualifications (degrees) of 2 (D, G) out of 13 Testing Personnel for the volume and complexity of tests performed (A-K). Findings: Cross Reference D6065.
Based on record review and interview, the laboratory failed to have verification of the educational qualifications (degrees) of 2 (D, G) out of 13 Testing Personnel (A-K).

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to have verification of the educational qualifications (degrees) of 2 (D, G) out of 13 (A - K) Testing Personnel. Findings: Review of the CMS 209 Laboratory Personnel Report, signed by the Laboratory Director on 4/07/2020, revealed that there are 13 employees listed as moderate complexity testing personnel. Review of personnel documentation revealed no documentation of the educational qualifications (degrees) for Testing Personnel D and G. During an interview on 4/07/2020 at 1:59 PM, the Executive Manager stated she did not have a copy of the degrees for all of the testing personnel.