

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1095458	(X3) Date Survey Completed 10/24/2018
Name of Provider or Supplier Ocala Health Primary Care Llc	Street Address, City, State 4850 Se 110th St, Belleview, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with Technical Consultant #B the laboratory failed to perform competency evaluation on the Clinical Consultant #B for 2 out of 2 years (2017-2018) reviewed. Findings Included: Review of the CMS 209 revealed 2 Clinical Consultants (#A-which is the Laboratory Director and #B). Review of competency evaluations revealed no competency evaluations performed on Clinical Consultant #B in 2017 and 2018. During an interview on 10/24/18 at 11:00 AM Technical Consultant #B confirmed that no competency evaluations were performed on Clinical Consultant #B.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review and interview with Technical Consultant #B the laboratory failed to record room temperature in the laboratory for 2 out of 2 years (2017-2018) reviewed. Findings Included: Review of reagents used for testing revealed that they should be stored 2-35 degrees Celsius. Review of temperature charts revealed no room temperatures recorded. During an interview on 10/24/18 at 11:51 AM the Technical Consultant #B confirmed that the room temperature was not being recorded.