

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2120160	(X3) Date Survey Completed 10/29/2018
Name of Provider or Supplier Universtity Of Miami Hospital And Clinics- Lennar	Street Address, City, State 5555 Ponce De Leon Blvd, Coral Gables, 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
D2098	<p>ENDOCRINOLOGY CFR(s): 493.843(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on College of American Pathologist (CAP) proficiency testing (PT) record review and Technical Supervisor (TS) interview, the facility failed to obtain an 80 % proficiency test score for the 3rd event of 2017 for the specialty of Endocrinology. Findings include: Record review of CAP Endocrinology proficiency test results revealed that the laboratory received a score of 60 % for the test for serum detection of human chorionic gonadotropin (hCG) and Endocrinology for 2017 3rd event CAP PT. During an interview on 10/29/2018 at 11:30 AM, the TS confirmed that the laboratory failed the Endocrinology event of reference.</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: Based on record review and interview with the Histopathology Technical Supervisor</p>

(HTP), the laboratory failed to document the histopathology room humidity during 2016, 2017 and 2018. Findings include: Review of the cryostat manual Leica CM1950 indicated a requirement for room humidity not above 60 %. Quality control records of histopathology room revealed that no documentation of humidity done during 2016, 2017 and 2018. During an interview on 10/29/18 at 3:00 p.m., the HTP confirmed that there was no record of room humidity for the period of reference.