Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 10D0671907	**(X3) Date Survey Completed** 10/23/2019
Name of Provider or Supplier University Of Miami Diabetes Research	**Street Address, City, State** 1450 Nw 10th Ave Room 3033, Miami, 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 conducted on 10/23/2019 found that the University of Miami Diabetes Research clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) 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. This STANDARD is not met as evidenced by: Based on record review of College of American Pathologists (CAP) proficiency testing records and interview with General Supervisor (GS), the laboratory failed to score at least 80 % on Potassium (K) and Sodium (Na) for 1 (2nd event of 2019) out of 6 (2017 3rd ; 2018 1, 2 and 3rd; 2019 1st and 2nd) events for Routine Chemistry reviewed. Findings include: Review of CAP proficiency records revealed a score of 60 % for K and 0 % for Na in the 2nd event of 2019. During an interview on 10/23 /2019 at 11:30 AM, the GS confirmed the failed proficiency testing score.
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 perform annual competency assessment for 1 out of 2 testing personnel (TP) for 2 out of 2 years

	reviewed and failed to perform initial and semiannual competency assessment for 1 TP that started in 2019. Findings include: 1)Review of CMS 209 Laboratory Personnel Report form, dated and signed by the Laboratory Director on 10/17/2019 revealed that: -The Laboratory Director, Clinical Consultant and Technical Supervisor was the same person. -General Supervisor was also Testing personnel (TP) # A. -TP# B started in the laboratory in February 2019. 2) Review of personnel files revealed that there was no documentation of the annual competency assessment for TP # A for 2018 and 2019 3) TP # B started on 2/2019 in that position. There was no initial and 6 months competency assessment documented for TP # B. During an interview on 10/23 /2019 at 11:00 AM, with GS, she confirmed that there was no documentation of the competency assessments listed above for the period of reference.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on review of the analyzer manual and staff interview, the laboratory failed to document room humidity and temperature requirement to ensure optimal operation for the Cobas 6000 Analyzer for 2 out of 2 years reviewed. The findings include: A review of Cobas 6000 Analyzer manual revealed a requirement for optimal operation, of a range of room temperature of 18 to 32 degrees C., and humidity between 30 to 85 %. A review of temperature logs for 2018 and 2019, revealed no documentation of room humidity and temperature. During an interview on 10/23/19 at 9:30am, the General Supervisor (GS) confirmed that there was no documentation of the room temperature and humidity for the period of reference.