Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0671907	08/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
University Of Miami Diabetes Research	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	An announced CLIA recertification survey was conducted at UNIVERSITY OF MIAMI DIABETES RESEARCH from 08/13/2025 to 08/14/2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiency:
D3007	FACILITIES CFR(s): 493.1101(b) (b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs. This STANDARD is not met as evidenced by: Based on observation, record review and Laboratory Director (LD) interview the laboratory was running patient samples and research samples in the same analyzer and with the same supplies from 10/04/2025 to 07/14/2025. Findings included: 1-During the tour of the laboratory on 08/13/2025 at 10:00 AM, the surveyor observed the following analyzers: one Roche Cobas C501 and one Roche Cobas E601. 2-Review of Patient #1 results revealed that the laboratory tested on 10/04/2025 at 4:44 PM for C-Peptide, Insulin and Hemoglobin A1C and tested P#2 on 07/14/2025 at 10:18 AM. 3-Review of instrument print outs for Research samples from the same analyzers revealed that the laboratory tested 3 research samples (R#1, R#2 and R#3) for C-peptide and Insulin on 10/04/2025 at11:41 AM and the laboratory tested on 07/15 /2025 at 10:51 AM nine research samples (R#1, R#2, R#3, R#5, R#6, R#7, R#8 and R#9) for A1-C. 3- The laboratory had no documentation of using separate reagents and separate times for the Clinical and Research operation. During an interview on 08 /13/2025 at 3:30 PM, the LD confirmed that laboratory failed to have separate reagents and time for Clinical and Research operation.