Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2036991	12/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
University Of Miami Hospital And Clinics -	8100 Sw 10th Street Crossroad Business Park Big 3, Plantation, 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 12/28/2021 found the UNIVERSITY OF MIAMI HOSPITAL AND CLINICS PLANTATION clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and staff interview, the Laboratory Director (LD) or a designee failed to sign PT attestation statements for 3 out of 6 (2020-2021) testing events reviewed for the specialties of Chemistry and Hematology. Findings include: Review of College of American Pathologists (CAP) PT records showed the LD or designee failed to sign CAP attestation statements attesting to the routine integration of the PT samples into the patient workload using the laboratory's routine methods for the following testing events in 2021: -Chemistry: Event A, Event B and Event C. -Clinical Microscopy: Event A and Event B. -Coagulation: Event A, Event B, Event C. -Hematology: Event A, Event B, Event C. -Peripheral Blood Smears: Event A and Event B. During an interview on 12/28/2021 at 12:30 PM, the laboratory manager confirmed that the laboratory failed to have the LD or designee to sign attestation for the events of reference.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other

	supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, record review and staff interview, the laboratory failed to label controls and calibrator currently in use with the open date and new expiration date. Findings include: - During laboratory tour on 12/28/2021 at 9:30 AM the surveyor observed the following: a) Examination of XN-CHECK hematology controls for the Sysmex XN-100 analyzer level 1, 2 and 3 showed that did not have the new expiration date for the vials currently in use. Review of the package insert for the controls noted " Open vials and vials which have been sampled by cap piercing will retain stability for 7 days if stored at 2-8 degrees Celsius after being re-capped. b) Examination of 2 calibrator vials (A and B) for automated systems (c.f.a.s.) for the Roche Cobas Integra analyzer, stored at -20 degrees Celsius revealed that vial A, had opening date but no new expiration date and vial B had no open and new expiration date. Review of package insert for the calibrator noted " Stability of the components in the reconstitute calibrator at -15 to -25 C 4 weeks (when frozen once)" During an interview on 12/28 /2021 at 12:30 PM, the Testing Personnel A, confirmed that controls in use were missing the label information described above.