

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1089781	(X3) Date Survey Completed 09/19/2022
Name of Provider or Supplier University Of Miami Hospital And Clinics	Street Address, City, State 8932 Sw 97th Ave, 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 09/19/2022 found the UNIVERSITY OF MIAMI HOSPITAL AND CLINICS clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to follow the procedure manual last approved on 06/2021, for the policy STA-Neoplastine CI Plus Assay Stago Prothrombin time (PT) and PTT assay Satellite Activated Partial Thromboplastin Time (aPTT) at least since 11/17/2020. Findings include: -During the laboratory tour on 09/19/2022 at 9:45 AM, the surveyor found that the centrifuge for the processing of the samples for the PT and aPTT test was the LabCorp 642 E. - Review of the policy for PT and aPTT test revealed that in the Specimen Collection and Handling section, it explained that: "Centrifuge all capped specimens at 5000 rpm's for 2 minutes in the centrifuge (Statspin Express 3)". -Review of the preset speed for the Labcorp centrifuge revealed that the centrifuge was set up for 3300 rpm for 10 minutes. During an interview on 09/19/2022 at 11:00 AM, the Technical Supervisor confirmed that the laboratory failed to update the policy for PT and aPTT tests with the centrifuge currently in use.</p>