

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2178763	<b>(X3) Date Survey Completed</b>  05/03/2022
<b>Name of Provider or Supplier</b>  University Of Miami Hospital And Clinics	<b>Street Address, City, State</b>  2801 Ne 213 Street, Aventura, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey conducted on 05/03/2022 found the clinical laboratory UNIVERSITY OF MIAMI HOSPITAL AND CLINICS not in compliance with 42 CFR Part 493, Requirements for Laboratories.
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on observation, procedure manual review and interview, the laboratory failed to update the policy for Peripheral Blood Manual Differential Stain. Findings include: - During the laboratory tour on 05/03/2022 at 10:00 AM the surveyor found that the stain used for the Peripheral Blood Manual Differential Stain was the HEMA-QUIK</p>

of Fisher Scientific. -Review of the procedure manual signed by the laboratory director (LD) on 05/01/2022, revealed that the policy HEM-04 Manual Wright Stain described the procedure for the stain of the Peripheral Blood Smear and listed the reagents used: Methanol for Wright Stain, Wright Stain and Wright Stain/Buffer Mixture. The Manual Wright Stain policy was not updated to the reagent currently in use, the HEMA-QUIK and failed to include the step by step of the HEMA-QUIK stain procedure. During an interview on 05/03/2022 at 11:00 AM, the General Supervisor confirmed that the laboratory failed to update the policy for the Manual Blood Smears Stain with the current stain in use.