

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0992370	(X3) Date Survey Completed 07/18/2019
Name of Provider or Supplier Sharon A Stokes Md Pa	Street Address, City, State 3276 Greenwald Way N, Kissimmee, 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 was conducted on July 10, 2019. Sharon A Stokes MD PA was found not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory procedure manual did not include step by step instructions for the performance of KOH and Wet Mount Preparations. Findings: Review of the procedure manual for the laboratory showed that there was no procedure that listed the step by step performance of KOH and Wet Mount Preparations. During an interview on 7/18/19 at 11:20 AM, the General

Supervisor stated they were unable to locate a procedure with step by step instructions on the performance of KOH and Wet Mount Preparations.