

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2042476	(X3) Date Survey Completed 03/10/2020
Name of Provider or Supplier Scott Berman, Md Pc	Street Address, City, State 2500 Route 347, Building 12, Stony Brook, NY	
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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of the Siemens Multistix 10SG vial and Henry Schein urine hCG kit package inserts, lack of laboratory quality control (QC) records and an interview with the office manager, the laboratory failed to test QC material for the Siemens 10 SG Multistix and failed to document the lot number and the expiration date of each vial of Multistix and each kit of Henry Schein urine hCG opened. FINDINGS: 1. The office manager confirmed on March 10, 2020 at approximately 10:30 AM, that the laboratory failed to follow the manufacturer's instruction for Siemens 10 SG Multistix which requires positive and negative external controls to be performed when a new vial of test strips is opened. 2. The laboratory failed to document the lot number and the expiration date of each vial of Multistix and each kit of urine pregnancy opened.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by:</p>

	<p>Based on the lack of twice yearly verification and confirmed at survey with the office manager, the laboratory failed to verify the accuracy for KOH and Wet Mount tests at least twice per year.</p>
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 lack of written standard operating procedures (SOP) and confirmed at survey with the office manager, the laboratory failed to establish written policies /procedures for the KOH and wet mount tests.</p>
D5403	<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 surveyor review of laboratory's records and interview with the office manager, the laboratory failed to establish a written policy/procedures for: 1. Requirements for patient preparation; specimen collection, labeling, processing; 2. Corrective action for inadequate slides; 3. Step-by-step procedure for microscopic examination of KOH and wet mount and interpretation of results; 4. Twice per year verification and remediation of any discrepant results found during the twice yearly verification of KOH and wet mount test; 5. Preventive maintenance of the microscope.</p>
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p>

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on a lack of Quality Assessment (QA) records and confirmed at survey with the office manager, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the general laboratory systems.