

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0160314	(X3) Date Survey Completed 02/26/2020
Name of Provider or Supplier Jeffrey T Layne Md	Street Address, City, State 1181 Old Country Road, Suite 8, Plainview, 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 Quality Control (QC) records and interview with the the laboratory supervisor/testing person, the laboratory failed to follow the manufacturer's instructions for performing external positive and negative controls for the Siemens Multistix Urine testing from calendar year 2018 through the survey date. FINDINGS: 1. The packet insert for the Siemens Multistix 10 SG requires that external positive and negative controls be performed with each new Vial of Multistix 10 SG reagent Strip opened. 2. The laboratory supervisor/testing person confirmed on February 26, 2020 at approximately 1:00 PM that the laboratory only tested positive QC and failed to test negative QC with each vial of Multistix opened from calendar year 2018 through the survey date. 3. Approximately 4,000 patient specimens were tested and reported for urinalysis during this time frame.</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</p>

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 surveyor review of laboratory's records and interview with the laboratory supervisor/testing person, the laboratory failed to establish a written policy/procedures for the preventive maintenance of the laboratory's microscope.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
Based on a surveyor's review of the laboratory's procedure manual and an interview and confirmed with the laboratory supervisor/testing person, the laboratory failed to have a procedure manual that is up-to-date and accurate and the laboratory director failed to approve (sign and date) the laboratory procedure manual. FINDINGS: 1. The procedure manual was not approved, signed and dated; 2. The current procedure manual still lists the previous procedures that the laboratory no longer performs.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

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 the surveyors review of the laboratory's procedure manual and an interview with the laboratory supervisor, the laboratory failed to follow their established Quality Assurance (QA) procedure which requires a monthly QA review. Findings Include: On February 26, 2020 at approximately 1:00 PM, it was confirmed by the laboratory supervisor that the laboratory has not performed their monthly QA review as per their policy since calendar year 2017.