

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0948889	(X3) Date Survey Completed 11/07/2018
Name of Provider or Supplier Mayer J Saad Md Pc	Street Address, City, State 2950 Hempstead Turnpike, Levittown, 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
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: Based on review of the laboratory records and interview with the laboratory director, the laboratory failed to verify the accuracy of the interpretation of UroVysion fluorescence in situ hybridization(FISH) images from urine specimen testing at least twice per year, in calendar year 2017. FINDINGS: The laboratory director confirmed, on November 7, 2018 at approximately 2:30 PM, the surveyor's review of laboratory records finding that the laboratory had failed to document the twice yearly verification for the FISH analysis in calendar year 2017. Approximately 50 patients' samples were tested and reported for FISH analysis in 2017.</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</p>

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 the pathology laboratory's procedure manual and interview with the laboratory director/technical supervisor, the laboratory failed to establish written procedures for: 1. Transportation of biopsy and urine specimens from three other locations in Howard Beach, Levittown and Forest Hills to the Westbury office to be forwarded to the technical component laboratory; 2. A criteria of what to include in the body of the pathology report; 3. A procedure describing laboratory's turnaround time for the histopathology, urine cytology and FISH from sample collection to processing and to when final diagnosis is determined by the pathologist and entered into the lab computer system; 4. Retention of FISH images. 5. Policy for significant and unexpected findings.

D5633

CYTOLOGY

CFR(s): 493.1274(d)(1)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening.

This STANDARD is not met as evidenced by:

Based on surveyor's review of the pathology laboratory procedure manual, lack of laboratory documents, interview and confirmation with the current laboratory director /pathologist, the laboratory failed to follow laboratory's written procedures to ensure that the technical supervisor established workload limits for the pathologist when performing primary screening of the non-gynecologic specimens from January 21, 2017 through July 17, 2017. Approximately 50 non-gynecologic cytology slides were reviewed and reported during this time frame.