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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 33D1039708 | (X3) Date Survey Completed 12/07/2023 |
| Name of Provider or Supplier Farshad Shafizadeh Md Pc | Street Address, City, State 461 Park Avenue South, 5th Floor, Rm 503, New York, 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 |
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| 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 review of the laboratory's cytology manual and interview with the pathologist/technical supervisor (TS), the laboratory failed to draft, approve, and maintain standard operating procedures including instructions for inadequate slide detection, performance of subsequent corrective action, as well as establishment of pathologist specimen screening workload limits. FINDINGS: 1. The laboratory's current, approved standard operating procedure manual did not include instructions for inadequate slide detection criteria, performance of subsequent corrective action, as</p> |

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| | <p>well as establishment of pathologist cytology specimen screening workload limits. 2. The pathologist/TS confirmed the findings on December 7, 2023, at 2:15 P.M.</p> |
| <p>D5633</p> | <p>CYTOLOGY CFR(s): 493.1274(d)(1)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's cytology manual, lack of documentation, and interview with the pathologist/TS, the laboratory failed to establish and maintain written instructions for pathologist specimen screening limits. FINDINGS: 1. The laboratory's current, approved standard operating procedure manual did not include instructions for pathologist non-gynecologic specimen screening workload limits. 2. Approximately three hundred non-gynecologic cytology slides were screened, reviewed and results reported from January 1, 2023, to December 7, 2023. 3. The pathologist/TS confirmed the findings on December 7, 2023, at 2:15 P.M. Refer to D6106.</p> |
| <p>D5637</p> | <p>CYTOLOGY CFR(s): 493.1274(d)(1)(ii)</p> <p>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's cytology manual, lack of cytology workload records, and interview with the pathologist/TS, the laboratory failed to draft, approve, and maintain standard operating procedures including instructions ensuring that pathologist specimen screening workload limits would be reassessed at least every six months and adjusted when necessary. FINDINGS: 1. The laboratory's current, approved standard operating procedure manual did not include instructions for pathologist non-gynecologic cytology specimen screening workload limits to be reassessed at least every six months and adjusted when necessary. 2. The pathologist /TS confirmed the findings on December 7, 2023, at 2:00 P.M. Refer to D6106.</p> |
| <p>D5639</p> | <p>CYTOLOGY CFR(s): 493.1274(d)(2)(i)</p> <p>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the Following: (d)(2) The maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides (one patient specimen per slide; gynecologic, nongynecologic, or both) irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and must not be employed as an individual's performance target. In addition-- (d)(2)(i) The maximum number of 100 slides is examined in no less than an 8-hour workday;</p> |

This STANDARD is not met as evidenced by:
Based on review of the laboratory's cytology manual and interview with the pathologist/TS, the laboratory failed to draft, approve, and maintain standard operating procedures including instructions for ensuring that maximum number of slides examined in a twenty-four hour period did not exceed one hundred slides, regardless of the site or location. FINDINGS: 1. The laboratory's current, approved standard operating procedure manual did not include instructions ensuring that maximum number of slides examined by the pathologist in a twenty-four hour period did not exceed one hundred, regardless of site or location. 2. The pathologist/TS confirmed the findings on December 7, 2023, at 2:05 P.M. Refer to D6106.

D5641

CYTOLOGY
CFR(s): 493.1274(d)(2)(ii)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined;

This STANDARD is not met as evidenced by:
Based on review of the laboratory's cytology manual and interview with the pathologist/TS, the laboratory failed to draft, approve, and maintain standard operating procedures including instructions establishing pathologist slide specimen review limits for an eight hour workday. FINDINGS: 1. The laboratory's current, approved standard operating procedure manual did not include instructions ensuring that the workload limit for the pathologist, when examining slides in less than an eight hour workday, would be prorated using a period of eight hours to determine the number of slides that may be examined. a. The formula utilized to establish the workload limits was as follows: Number of hours examining slides X 100 / 8 to determine maximum slide volume to be examined. 2. The pathologist/TS confirmed the findings on December 7, 2023, at 2:05 P.M. Refer to D6106.

D5643

CYTOLOGY
CFR(s): 493.1274(d)(2)(iii)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(iii) Nongynecologic slide preparations made using liquid-based slide preparatory techniques that result in cell dispersion over one-half or less of the total available slide may be counted as one-half slide; and (d)(2)(iv) Technical supervisors who perform primary screening are not required to include tissue pathology slides and previously examined cytology slides (gynecologic and nongynecologic) in the 100 slide workload limit.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's pathology manual, lack of pathologist workload records documentation, and interview the pathologist/TS, the pathologist failed to document the number of hours spent examining cytology slides from January 1, 2023, to December 7, 2023. FINDINGS: 1. The pathologist, as the primary reader(s), failed

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| | <p>to document, maintain records of the total number of slides examined in a twenty-four hour period as well as document the number of hours spent examining slides from January 1, 2023, to December 7, 2023. 2. The pathologist stated, "that the number of slides screened, and the hours screened, were not documented for this location." 3. The pathologist/TS confirmed the findings on December 7, 2023, at 2:30 P.M. Refer to D6106.</p> |
| <p>D5647</p> | <p>CYTOLOGY CFR(s): 493.1274(d)(4)</p> <p>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(4) Records are available to document the workload limit for each individual.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's cytology manual, lack of workload limit records, and confirmed by interview with the pathologist/laboratory director (LD)/TS, the laboratory failed to draft, approve, and maintain standard operating procedures including instructions ensuring that workload records for the individual performing primary screening of non-gynecologic cytology slides were maintained. FINDINGS: 1. The laboratory's current, approved standard operating procedure manual did not include instructions ensuring that the non-gynecologic cytology slide workload records were documented, maintained, and available for review. 2. The pathologist/LD /TS confirmed the findings on December 7, 2023, at 2:30 P.M. Refer to D6106.</p> |
| <p>D6076</p> | <p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory's standard operating procedures and interview with the pathologist/TS, the LD failed to ensure overall management of the laboratory as well as maintain current, approved, and complete instructions for performing laboratory's cytology procedures. Refer to D6106.</p> |
| <p>D6106</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's cytology manual and an interview with the pathologist/TS, the LD failed to maintain current, approved, and complete instructions for performing the laboratory's cytology procedures. Refer to D5403, D5633, D5637, D5639, D5641, D5645, and D5647.</p> |