| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 33D1039708 | 02/08/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Farshad Shafizadeh Md Pc | 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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| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the proficiency test verification records and an interview with the laboratory director on the day of the survey, the laboratory failed to verify the accuracy of the interpretation of FISH testing. Findings Include: On February 8, 2018, at approximately 1:30 PM the laboratory director confirmed in a telephone interview, that the laboratory failed to perform twice annual verification for FISH testing from April 2017 through the date of this survey. Approximately 80 patient specimens were tested and reported for FISH testing during this time. |
| **D5475** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(3)(g)<br><br>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of quality control (QC) stain records for histopathology, and an interview with the laboratory director during a telephone interview, the laboratory failed to document the QC test results for the FISH images. Findings Include: The laboratory director confirmed via a telephone interview at approximately 1:30 PM that |

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| | the laboratory failed to perform and document the quality of the FISH images read from April 2017 through the date of this survey. Approximately 80 patient specimens were tested and reported for FISH testing during that time. |
| **D5629** | CYTOLOGY<br>CFR(s): 493.1274(c)(5)<br><br>(c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms.<br><br>This STANDARD is not met as evidenced by:<br>Based on a lack of cytology procedures and confirmed by the laboratory director in a telephone interview at approximately 1:30 PM, the laboratory failed to established policies and procedures for a program to evaluate and compare the laboratory statistics annually to detect errors in the performance of cytological examinations and reporting results. The procedure must include: 1. Cytology cases examined; 2. Specimens processed by specimen type; 3. Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation). |
| **D5633** | CYTOLOGY<br>CFR(s): 493.1274(d)(1)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a lack of urine cytology procedurs and confirmed by the laboratory director in a telephone interview at approximately 1:30 PM, the laboratory failed to establish written policies and procedures to ensure that a maximum workload limit was set for the person who performed primary screening for non-gynecologic specimens. |
| **D5637** | CYTOLOGY<br>CFR(s): 493.1274(d)(1)(ii)<br><br>(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.<br><br>This STANDARD is not met as evidenced by: |

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| | Based on a lack of urine cytology procedures and confirmed by the laboratory director in a telephone interview at approximately 1:30 PM, the laboratory failed to establish and follow written policies and procedures to ensure that the workload limit for the individual who performs primary screening is reassessed at least every six months and adjusted when necessary. |
| **D5639** | CYTOLOGY<br>CFR(s): 493.1274(d)(2)(i)<br><br>(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;<br><br>This STANDARD is not met as evidenced by:<br>Based on a lack of urine cytology procedures and confirmed by the laboratory director in a telephone interview at approximately 1:30 PM, the laboratory failed to have written policies and procedures to ensure that the maximum number of slides examined by an individual in 24-hours does not exceed 100 slides. |
| **D5641** | CYTOLOGY<br>CFR(s): 493.1274(d)(2)(ii)<br><br>(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;<br><br>This STANDARD is not met as evidenced by:<br>Based on a lack of urine cytology procedures and confirmed by the laboratory director in a telephone interview at approximately 1:30 PM, the laboratory failed to establish written policies and procedures for workload limits for the individual examining slides in less than an 8-hour workday. |
| **D5647** | CYTOLOGY<br>CFR(s): 493.1274(d)(4)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a lack of urine cytology procedures and confirmed by the laboratory director in a telephone interview at approximately 1:30 PM, the laboratory failed to establish |

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| | written policies and procedures to ensure that records are maintained and available to document the workload for the individual who performs primary screening of non-gynecologic cytology slides. |
| **D5891** | POSTANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1299(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on the surveyors review of the laboratory's procedure manual and a telephone interview with the laboratory director, the laboratory failed to follow their established Quality Assurance (QA) procedure which requires a monthly QA review. Findings Include: At approximately 1:30 PM, it was confirmed by the laboratory director that the laboratory has not performed their monthly QA review as per their procedure since they started testing in April 2017. |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on a laboratory records, procedures and confirmed by the laboratory director in a telephone interview at approximately 1:30 PM, the laboratory director failed to fulfill his responsibilities and provide overall management of the laboratory and ensure compliance with all CLIA regulations and standards. Refer to D6093, D6094 |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of QC records and confirmed by the laboratory director in a telephone interview at approximately 1:30 PM, the director failed to ensure that the QC program for histopathology was followed to assure the quality of laboratory services. Refer to D5475 |
| **D6094** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to |

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| | identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory's records and confirmed by the laboratory director in a telephone interview at approximately 1:30 PM, the laboratory director failed to ensure that the laboratory's quality assessment (QA) program was followed and perform their QA reviews. Refer to D5217 and D5891 |
| **D6130** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(c)(2)(3)<br><br>(c) In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary.<br><br>This STANDARD is not met as evidenced by:<br>Based on a lack of workload limit records and by the laboratory director in a telephone interview at approximately 1:30 PM, the laboratory director failed to establish the workload limit for the individual who examines slides and reassess the workload at least every six months. Refer to: D5633, D5637, D5639, D5641 and D5647 |