| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 33D2113712 | 08/01/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| A&I Medical Pc | 1773 East 19th Street, Suite 1, Brooklyn, 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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| **D3027** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(1)<br><br>Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor's review of pathology & cytology test reports and an interview with the pathologist/laboratory director, the laboratory failed to retain test requisitions /courier logs for patients' pathology & urine cytology specimens, sent to the technical component laboratory with each set of samples. FINDINGS: 1. This Physician Office Laboratory (POL) is using a technical component/professional component (TC/PC) split for histopathology and cytology specimens. 2. The laboratory director /pathologist on August 1, 2018 at approximately 1:30 PM confirmed the surveyor's findings that the laboratory failed to retain test requisitions/courier logs for patients' pathology & urine cytology specimens, sent to the technical component laboratory with each set of samples from March 1, 2017 through October 20, 2017. |
| **D3029** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(2)<br><br>Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance.<br><br>This STANDARD is not met as evidenced by:<br>Based on a lack of the histology and cytology procedure manuals and an interview with the current laboratory director/pathologist, the laboratory failed to retain the |

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| | histology and cytology procedure manuals from the previous pathologist /laboratory director implemented in June 2015 through October 17, 2017. |
| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of Quality Control (QC) records for stain quality and reactivity for the histology & cytology slides & FISH images, and an interview with the current laboratory director/pathologist, the laboratory failed to retain copies of the previous pathologist QC records for stains used for both histology & cytology and FISH images from March 1, 2017 through October 17, 2017. FINDINGS: The laboratory director/pathologist, confirmed on August 1, 2018 at approximately 1:45 PM, that the laboratory failed to retain copies of the previous pathologist QC records for stains used for both histology & cytology slides and FISH images from March 1, 2017 through October 17, 2017. |
| **D3039** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(5)<br><br>Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on a lack of the histology and cytology Quality Assessment (QA)/Quality Improvement Plan (QIP) records and an interview with the current laboratory director /pathologist, the laboratory failed to retain the QA/QIP records for the calendar year 2017. FINDINGS: The laboratory director/pathologist confirmed on August 1, 2018 at approximately 1:00 PM, the surveyor's findings that the laboratory failed to retain the QA/QIP records to include a review of the following records and documentation: twice yearly verification for the histology, cytology and FISH images; quality control documentation for the stains; workload work sheets; workload assessment records; maintenance records for the microscope; and annual statistical evaluation documentation for cytology cases that were examined and reported during the calendar year 2017. |
| **D5311** | SPECIMEN SUBMISSION, HANDLING, AND REFERRAL<br>CFR(s): 493.1242(a)<br><br>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. |

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| | This STANDARD is not met as evidenced by:<br>Based on surveyor's review of the histology/cytology procedure manual, lack of EastGene Laboratories service/reference manual and confirmed in an interview with the current laboratory director/pathologist, the laboratory failed to establish written procedures for specimen collection for urine cytology, specimen transportation and specimen referral. FINDINGS: The current laboratory director/pathologist confirmed on August 1, 2018 at approximately 2:00 PM, the surveyor's findings that the laboratory failed to establish written procedures for specimen collection for urine cytology, specimen transportation and specimen referral. The laboratory failed to: a. retain a service/reference manual for East Gene Laboratories to ensure that the histology and urine cytology specimens are collected according to the reference laboratory requirements for preparation of the slides and FISH images. b. establish a log sheet for both offices to ensure that the specimens are transported in a timely manner to the reference laboratory. c. establish a method for tracking the specimens sent from both office locations to the reference laboratory. |
| **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 surveyor's review of the cytology procedure manual and interview with the pathologist/laboratory director, the laboratory failed to establish written 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. FINDINGS: The pathologist/laboratory director confirmed on August 1, 2018 at approximately 1:30 PM, that the laboratory failed to establish written policies and procedures for a program designed to detect errors in the performance of cytological examinations and the reporting of results annually. |
| **D5631** | CYTOLOGY<br>CFR(s): 493.1274(c)(6)<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)(6) An evaluation of the case reviews of each individual examining slides against the laboratory's overall statistical values, documentation of any discrepancies, including reasons for the deviation, and, if appropriate, corrective actions taken. |

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| | This STANDARD is not met as evidenced by:<br>Based on surveyor's review of cytology procedures, laboratory records and an interview with the pathologist/laboratory director, the laboratory failed to establish and follow a procedure to include an evaluation of the case reviews against the laboratory's overall statistical values, document any discrepancies, including reasons for the deviation, and, if appropriate, the corrective actions taken. FINDINGS: The pathologist/laboratory director, confirmed on August 1, 2018 at approximately 2:00 PM , that the laboratory failed to establish and follow a procedure to include an evaluation of the case reviews against the laboratory's overall statistical values, document any discrepancies, including reasons for the deviation, and, if appropriate, the corrective actions taken |
| **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:<br>Based on surveyor's review of the laboratory's cytology procedure manual, laboratory records and confirmed in an interview with the pathologist/laboratory director, the laboratory failed to follow their established policies and procedures to ensure that workload limits would be reassessed at least every 6 months and adjusted when necessary for the pathologist who performs the primary screening of non-gynecologic cytology slides. FINDINGS: The pathologist/laboratory director, confirmed on August 1, 2018 at approximately 1:30 PM, that the laboratory failed to follow their established policies and procedures to ensure that workload limits would be reassessed at least every 6 months and adjusted when necessary for the pathologist who performs the primary screening of non-gynecologic cytology slides. |
| **D5645** | CYTOLOGY<br>CFR(s): 493.1274(d)(3)<br><br>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor's review of the laboratory's cytology procedure manual, cytology records, current workload form in use and confirmed in an interview with the laboratory director/pathologist, the laboratory director acting as the technical supervisor failed to follow written policies and procedures for the workload limits. FINDINGS: The laboratory failed to maintain the workload records for the previous pathologist/technical supervisor who performed primary screening from October 17, 2017 through June 22, 2018. |
| **D5655** | CYTOLOGY |

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| | CFR(s): 493.1274(e)(4)<br><br>(e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor's review of urine cytology procedures and confirmed in an interview with the pathologist/laboratory director, the laboratory failed to establish and follow written policies and procedures to ensure that unsatisfactory slides are identified and reported as unsatisfactory. |
| **D5659** | CYTOLOGY<br>CFR(s): 493.1274(e)(6)<br><br>(e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(6) Corrected reports issued by the laboratory indicate the basis for correction.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor's review of the cytology procedure manual and an interview with the pathologist/laboratory director, the laboratory failed to establish and follow a procedure for a corrected report for histopathology, urine cytology, and FISH diagnosis on the patient's final report. FINDINGS: The pathologist/laboratory director confirmed on August 1, 2018 at approximately 1:15 PM, that the laboratory failed to establish a written procedure to specify the laboratory's requirements for a corrected report to include who would be responsible for the correction, how the report would be corrected and how the cause or reason for the correction would be included in the corrected or amended report. |
| **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 surveyor's review of laboratory records and findings and an interview with the pathologist/laboratory director, the laboratory director failed to fulfill his responsibilities and provide overall management of the laboratory. Refer to D6082 and D6094. |
| **D6082** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(1)<br><br>The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. |

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| | This STANDARD is not met as evidenced by:<br>Based on surveyor's review of laboratory records and an interview with the pathologist /laboratory director, the laboratory director failed to ensure that the laboratory provides quality services for all aspects of test performance, which includes the preanalytic phases of testing. Refer to D5311. |
| **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 identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor's review of laboratory records, histology & cytology QA policies /procedures and an interview with the pathologist/laboratory director, the laboratory failed to follow the established QA policies to identify failures in quality laboratory services. FINDINGS: The laboratory director failed to identify failures as follows: a. record retention D3027, D3029, D3031 and D3039 b. establish written procedures D5629 and D5631 c. maintain workload records D5637 d. corrected reports D5655 and D5659 |