| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 14D0944992 | 11/14/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Arlington Pediatrics Ltd | 3325 N Arlington Hts Rd Ste 100-A, Arlington Heights, IL | |

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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| **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 record review, lack of documentation, and an interview with the laboratory director (LD); the laboratory failed to retain the patient test records for the Strep A testing performed for at least 2 years for 14 out of 14 patients. Findings include: 1. The laboratory's procedures manual, patients' test logs, electronic medical records (EMR) were reviewed. 2. The Illumigen test procedures revealed the following: *The kits were used to test for Strep Group A. *Upon completion of the test, a printout is generated with the patient's test result. 3. The patients' test log and EMR revealed the following: *Fourteen (14) patients were selected from the test logs who were tested using the Illumigen. *The result printouts of 14 out 14 patients were not provided. *All 14 patients had Strep A test results in their respective EMR records. 4. The laboratory failed to retain the patients' test printouts for 14 out of 14 patients. 5. The LD confirmed on 11/14/2019 at 2:35 PM, that the laboratory did not keep the patients' test printouts from the Illumigen test. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. |

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| | This STANDARD is not met as evidenced by:<br>Based on record review and an interview with the laboratory director (LD); the laboratory failed to follow written quality control procedures for the Bacteriology tests performed. Findings include: 1. The laboratory's individual quality control plan (IQCP) and the Illumigen quality control (QC) logs from December of 2017 through October of 2019 were reviewed. 2. The IQCP quality control (QC) plan revealed the following: *The laboratory has to perform external control testing with a positive and negative control sample every month and with each new kit lot or shipment. 3. The Illumigen-QC logs revealed the following: *The laboratory failed to perform external controls in the months of April of 2018 and March of 2019. *The laboratory failed to perform external controls on 2 out of 12 new tests kits received, prior to testing patients. 4. On a Recertification survey conducted on 11/14/2019 at 2:30 PM, the LD confirmed the above findings. |
| **D5801** | TEST REPORT<br>CFR(s): 493.1291(a)<br><br>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.<br><br>This STANDARD is not met as evidenced by:<br>REPEAT DEFICIENCY Based on record review and an interview with the laboratory director (LD); the laboratory failed to accurately and reliably enter test results into the patient's electronic medical records (EMR), for 9 out of 9 patients. Findings include: 1. The Illumigen Strep Group A manufacturer's package insert, the patients' electronic records, and patients' test logs were reviewed. 2. The laboratory was using the Illumigen Step Group A test kit. 3. The Illumigen package insert required the statement "Presumptive negative" to be used when reporting negative test results, to indicate further testing is required to confirm. 4. The patients' test log and EMR reports revealed that 9 out of 9 negative patients' test results were entered in the patients' EMRs as "Negative". 5. The laboratory failed to accurately enter into the EMR the statement "Presumptive Negative" for 9 out of 9 patients. 6. The LD confirmed on 11/14/2019 at 2:35 PM the above findings. |
| **D6054** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, the Laboratory Personnel Report (CMS 209), and an |

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| | interview with the laboratory director (LD); the technical consultant (TC) failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually, after the first year, affecting 6 out of 10 testing personnel (TP). Findings: 1. The CMS 209, the personnel files for the years of 2017 through 2019, and the procedures' manual were reviewed. 2. The CMS 209 and TP files revealed the following: *The LD is designated the TC of the laboratory. *Ten (10) TP were listed as authorized to test patients using the Strep A Illumigen test kits. *In the year of 2018, the TC failed to evaluate the competencies of 6 out of 10 TP. *In the year of 2017, the TC failed to evaluate the competencies of 5 out of 7 TP. *Documentation showed that competencies performed in 2019 were conducted 2 and 3 weeks before the date of the recertification survey. 3. The TC failed to follow the laboratory's competency policy to assess TP competency, at least annually. 3. On a Recertification survey conducted on 11/14/2019 at 2:35 PM, the LD confirmed the above findings. |
| **D6063** | LABORATORY TESTING PERSONNEL<br>CFR(s): 493.1421<br><br>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on record review and an interview with the laboratory director (LD); the laboratory failed to ensure individuals meet the qualification requirements of 493. 1423, to perform the functions specified in 493.1425 for the complexity of tests performed in the specialty of Microbiology for 2 out of 11 testing personnel (TP). Findings: 1. The laboratory failed to ensure that laboratory personnel meet the education requirement for moderately complex testing, prior to testing patients. See D6065. |
| **D6064** | TESTING PERSONNEL QUALIFICATIONS<br>CFR(s): 493.1423(a)<br><br>Each individual performing moderte complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, lack of documentation, the Laboratory Personnel Report (CMS-209) and an interview with the laboratory director (LD); the laboratory failed to ensure laboratory employees meet the education qualification requirements for performing moderately complex testing in the specialty of Microbiology for 2 out of 11 testing personnel (TP). Findings: 1. The employee files and CMS-209 were reviewed. 2. The CMS 209 lists 11 TP (TP9 and TP12) performing Wet mounts and Microscopic Urinalysis testing in the laboratory. 3. The employee files of TP9 and TP12 revealed the following: *TP1 and TP2 were authorized to perform patient testing; *TP1 and TP2 had no education credentials in their files. *The laboratory failed to ensure TP1 and TP2 met the education requirement for performing moderately complex testing, prior to testing patients. 4. On a recertification survey conducted 11/14/2019 at 2:35 PM, the LD confirmed the above findings. |