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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>33D0984877   | <b>(X3) Date Survey Completed</b><br><br>08/07/2019 |
| <b>Name of Provider or Supplier</b><br><br>Allied Pediatrics & Family Medicine   | <b>Street Address, City, State</b><br><br>2154 New Bridge Road, Bellmore, NY |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
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| <b>D1001</b>              | <p><b>CERTIFICATE OF WAIVER TESTS</b><br/>CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on surveyor's review of the manufacturer's package inserts for the UriSpec Plus analyzer, UriSpec Multistix and interview with the practice manager and the testing personnel, the laboratory failed to follow the manufacturer's requirements for performing external positive and negative controls with each new vial opened for the UriSpec Plus Multistix from January 2018 to survey date. <b>FINDINGS:</b> 1. On August 7, 2019 at approximately 3:00 PM, the practice manager and the testing personnel confirmed that the required external positive and negative quality controls were not performed for urine Dip Sticks from January 2018 through the survey date. 2. Approximately 500 patients specimens were tested and reported for urinalysis from January 2018 through the survey date.</p> |
| <b>D2010</b>              | <p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b><br/>CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on a surveyor's review of proficiency testing records and an interview and confirmed with the practice manager and the testing personnel, the laboratory routinely tests patient Hematology samples once, but tested proficiency testing</p>  |

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|                     | <p>samples in triplicates for all three events in 2018 and the first and second events in 2019.</p>  |
| <p><b>D5221</b></p> | <p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b><br/>CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on a surveyor's review of American Academy of Family Physicians (AAFP) Proficiency Testing (PT) reports and interview with the practice manager and the testing personnel, the laboratory failed to evaluate, perform and document remedial action for the PT scores less than 100%. Findings: 2018 third event: Red Blood Cells (RBC) = 80% 2019 first event Platelets = 60%</p>   |
| <p><b>D5471</b></p> | <p><b>CONTROL PROCEDURES</b><br/>CFR(s): 493.1256(e)(1)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on the surveyor's review of laboratory's Quality Control (QC) records and an interview with the practice manager and the testing personnel, the laboratory failed to check each new batch, lot number and/or shipment of 0.04 bacitracin disk for positive and negative reactivity from January 2018 through the survey date. FINDINGS: 1. The practice manager and the testing personnel confirmed on August 7, 2019 at approximately 3:00 PM, that the laboratory failed to check each new batch, lot number and/or shipment of 0.04 bacitracin disks for positive and negative reactivity from January 2018 through the survey date. 2. The laboratory failed to document the lot number and the expiration dates of the bacitacin disks used from January 2018 through the survey date. 3. Approximately 1500 patient specimens were tested and reported for throat culture during the above time period.</p> |
| <p><b>D5477</b></p> | <p><b>CONTROL PROCEDURES</b><br/>CFR(s): 493.1256(e)(4)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.</p>  |

This STANDARD is not met as evidenced by:

Based on a surveyor's review of bacteriology Quality Control (QC) documentation and an interview with the practice manager and the testing personnel, the laboratory failed to perform QC as required from January 2018 through survey date. The laboratory failed to: 1. Perform and document the sterility for the SSA Media lot; 2. Document the physical characteristics of the SSA Media for any deterioration; 3. Approximately 1500 specimens were tested and reported for throat culture during the above time period.