

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0110124	<b>(X3) Date Survey Completed</b>  01/24/2019
<b>Name of Provider or Supplier</b>  Valley Pediatric Associates	<b>Street Address, City, State</b>  470 N Franklin Turnpike, Ramsey, NJ	
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>
<b>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to ensure that all Testing Personnel (TP) who perform Bacteriology Tests participated in the College of American Pathologist (CAP) PT events in the calendar years 2017 and 2018. The finding includes: 1. A review of the PT attestation forms revealed 2017 PT was performed by a TP no longer employed there and 2018 PT was performed by TP #3 listed on the CMS form 209. 2. The TP #1 listed on CMS 209 confirmed on 1/24/19 at 10:30 am that PT events were not rotated amongst TP.</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to perform CA correctly on five of five TP from 12/3/17 to the date of survey. The finding includes: 1. A review of CA revealed all CA procedures were used to assess each task listed on the CA. a.</p>

	<p>Example: Assessment of test performance (PT/Blind samples) and Direct Observation of Instrument Maintenance were used to assess: i. Swabbing and plating of patients throat culture ii. Perform and repeat of rapid strep iii. Patient instruction on obtaining midstream iv. Performance of routine urine culture and reporting results v. Performance of routine throat culture and reporting results vi. Proper instruction in blood collection and testing procedure to perform hemoglobin and lead level vii. Performance and documentation of taxo disc testing 2. The TP #1 listed on CMS 209 confirmed on 1/24/19 at 10:25 am that CA was not done correctly.</p>
<p><b>D5411</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Manufacturer's Package Insert (MPI), Test Reports (TR), and interview with the Testing Personnel(TP), the laboratory failed to follow the Uricult manufacturer's instruction for reading Urine Cultures from 2/3/17 to the date of survey. The finding includes: 1. The laboratory reported the results as Positive and Negative but the MPI interpretation was: a. Normal - Less than 10,000 CFU/ml urine. b. Doubtful - 10,000 - 100,000 CFU/ml urine. c. Positive - Greater than 100,000 CFU /ml urine. 2. The TP #1 listed on CMS 209 confirmed on 1/24/19 at 1:00 pm that the laboratory did not follow the MPI.</p>
<p><b>D5807</b></p>	<p><b>TEST REPORT</b> CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor review of the Final Reports (FR) and interview with the Testing Personnel (TP), the laboratory failed to have a Reference Range (RR) for Throat Culture tests and Urine Colony counts on the FR from 2/3/17 to the date of the survey. The TP #1 listed on CMS 209 confirmed on 1/24/19 at 12:20 pm that the above tests did not have a RR on the FR.</p>
<p><b>D5891</b></p>	<p><b>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1299(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Testing</p>

Personnel (TP), the laboratory failed to have a procedure to verify manually entered Throat Culture and Urine Colony Count (UCC) results entered into the Patient's Medical Record for accuracy from 2/3/17 to the date of the survey. The TP #1 listed on CMS 209 confirmed on 1/24/19 at 12:15 pm that the laboratory did not have the procedure mentioned above.