

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0110124	(X3) Date Survey Completed 10/25/2023
Name of Provider or Supplier Valley Pediatric Associates	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor observation of COVID test results and interview with the Office Manager (OM) the laboratory failed to report COVID test results to the state of New Jersey (NJ) under the NJ requirements for a NJ State Clinical Laboratory License (NJCLL) under New Jersey Statutes Annotated: N.J.A.C. 8:44-2.11(a) Reporting by laboratory supervisors in the calendar year 2023.. The finding includes: 1. There was no documented evidence that the laboratory reported positive and negative COVID test results run on the Cepheid genexpert to the State of NJ. 2. The OM confirmed on 10/25/23 the laboratory was not following the state statute. .</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Temperature Logs (TL) and interview with the</p>

Office Manger (OM), the laboratory failed to define a range for the Incubator on the TL from 8/03/21 to the date of the survey. The OM confirmed on 10/25/23 at 11:30 am that a temperature range wasn't defined.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Personnel Files (PF) and interview with the Office Manager (OM), the Laboratory Director (LD) failed to have appropriate education and training documentation on all TP performing laboratory testing on the date of survey. The findings include: 1. The laboratory did not have education records for five out of ten TP listed on the CMS form 209. 2. The OM confirmed on 10/25/23 at 10:40 pm the laboratory did not have education records on all TP.