

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0670316	(X3) Date Survey Completed 06/27/2023
Name of Provider or Supplier Valley Pediatric Assoc Pa	Street Address, City, State 201 East Franklin Tpke, Ho Ho Kus, 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
D5409	<p>PROCEDURE MANUAL CFR(s): 493.1251(e)</p> <p>The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to record a discontinuance date on the procedure not performed in the laboratory on the date of survey. The finding includes: 1. There was no discontinuance date on the Throat culture procedures in the PM. 2. The TP #8 as listed on the CMS-209 form confirmed on 6/27/23 at 10:45 am that a discontinuance date was not documented.</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to establish a Quality Assurance (QA)</p>

program for verifying manually entered results into the Electronic Media Record (EMR) from 5/4/21 to the date of survey. The TP#8 as stated on CMS-209 form confirmed on 6/27/23 at 11:45 AM that a QA program was not established.

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 Testing Personnel (TP), the Laboratory Director (LD) failed to have appropriate education documentation for Testing Personnel (TP) performing laboratory testing on the date of survey. The findings include: 1. The laboratory did not have education records for TP #11 and TP #12 listed on the CMS form 209. 2. The TP confirmed on 6/27/23 at 11:00 am the above records were not on file.