

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0670316	(X3) Date Survey Completed 03/19/2025
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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on survey review of the Procedure Manual (PM), Test Reports and interview with Testing Personnel (TP), the laboratory did not establish written policies and procedures for specimen referral for Bacteriology tests performed from 6/28/23 to 3/19/25. The findings include: 1. The PM lacked written procedures for specimen referral. 2. There was no established criteria to send specimens for identification and susceptibility testing based on Urine Colony Count results in the PM. 3. The TP #1 as listed on the CMS 209 form confirmed on 3/19/25 at 11:40 am, the laboratory did not establish written policies and procedures for specimen referral.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test</p>

reports.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Temperature Logs (TL) and interview with Testing Personnel (TP), the laboratory failed to have a defined range for the incubator on the TL from 10/26/23 to 3/19/25. The finding includes: 1. There was no defined range for the incubator on the TL logs. 2. The TL did not state if the temperature was recorded in degrees Fahrenheit or degrees Celsius. 3. The TP #1 as stated on the CMS 209 form confirmed on 3/19/25 at 11:05 am, the TL did not have a defined range or state if recorded in degrees Fahrenheit or Celsius.

D5805

TEST REPORT

CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on surveyor review of Test Reports (TR) and interview with the Testing Personnel (TP), the laboratory failed to ensure the TR included all required information for Urine Colony Count tests performed from 2/13/23 to 3/19/25. The findings include: 1. Specimen identification number 3990 performed on 12/13/23 was sent to a reference laboratory for identification and susceptibilities. 2. The TR did not state the name and address of the laboratory where the identification and susceptibilities were performed. 3. TP #1 as listed on the CMS confirmed on 3/19/25 at 11:30 am, the laboratory failed to ensure the TR included all the required information.