

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  09D0208490	<b>(X3) Date Survey Completed</b>  11/07/2024
<b>Name of Provider or Supplier</b>  Spring Valley Pediatrics	<b>Street Address, City, State</b>  4850 Massachusetts Ave Nw, Suite 200, Washington, DC	
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>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 written procedure manual, the technical consultant (TC) competency records, and interview with the TC, the laboratory director (LD) failed to perform annual competency procedures for the TC during the year 2023. Findings: 1. The LD failed to perform annual competency procedures for the TC during the year 2023. 2. The TC stated on the day of the survey 10/10/24 at 3:00 PM that he did have any competency procedures performed for him by the LD during the year 2023. 3. The TC confirmed on the day of the survey 10/10/24 at 3:00 PM that the LD failed to perform competency procedures for the TC during the year 2023</p>
<b>D5413</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> 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>

This STANDARD is not met as evidenced by:  
Based on observation of the hematology stains, review of the staining material package insert, and interview with the technical consultant (TC), the laboratory failed to ensure that hematology staining materials were stored according to the package insert. Finding: 1. Observation of the lab on 10/10/24 at 2:00 PM showed that the hematology Quik Stain II stains were stored under the lab sink. 2. The TC stated on 10/10/24 at 2:00 PM that stains were stored under the sink because there was no other place to store them. 3. Review of the manufactures package insert for the staining material showed that Quik Stain II is "is highly flammable, liquid and vapor". 4. The TC confirmed on the day of the survey on 10/10/24 at 2:00 PM that the lab failed to ensure that hematology staining materials were stored according to the package insert.

**D5445**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--  
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on review of the Alethia analyzer quality control (QC) procedure, the laboratory written procedure manual, and interview with the technical consultant (TC), the laboratory failed to run two levels of external QC each day of patient testing. Findings: 1. The laboratory failed to establish an IQCP when performing patient testing with the Alethia analyzer that was installed in June 2018 and uses internal QC. 2. The Alethia analyzer uses an internal QC that is included in the test device and ran with patient testing each day that lab testing is performed. 3. Record review of the Alethia analyzer QC procedure and the written procedure manual showed on 10/10/24 at 2:30 PM that when testing for Streptococcus, Pertussis, Mycoplasma, HSV using the Alethia analyzer. It is recommended by the manufacturer to run two levels of external QC to verify each new lot and each new shipment of test reagents prior to use, once per month, or during proficiency testing. 4. The TC confirmed on the day of the survey 10/10/24 at 3:00 PM that an Individualized Quality Control Plan was not performed when patients were tested each day using the Alethia analyzer with internal QC.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

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 the quality control program is established and maintained to assure the quality of laboratory services provided.

	<p>This STANDARD is not met as evidenced by: Based on review of the Alethia analyzer quality control (QC) procedure, the laboratory written procedure manual, and interview with the technical consultant, the laboratory director failed to establish and ensure that QC procedures were implemented when performing patient testing using the Alethia analyzer. Findings: Refer to D5445</p>
<p><b>D6021</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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 written procedure manual, laboratory logs, and interview with the technical consultant (TC), the laboratory director (LD) failed to maintain quality assessment (QA) procedures for the overall quality of laboratory testing. Findings: 1. Review of the laboratory written procedure manual and laboratory logs on 10/10/24 at 2:00 PM showed that the LD did not maintain QA procedures by reviewing and signing completed lab logs. 2. Review of the lab occurrence management log and the patient critical value log showed the LD failed to review and sign the logs during the year 2023. 3. The TC confirmed on the day of the survey 10/10/24 at 2:00 PM that the LD failed to maintain QA procedures for the overall quality of laboratory testing.</p>
<p><b>D6032</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(14)</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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the technical consultant (TC), the lab director failed to have written duties and responsibilities for all persons involved in laboratory testing. Findings: 1. The lab did not have written duties and responsible for the lab director. 2. The TC confirmed on the day of the survey 10/10/14 at 2:00 PM that the lab failed to have written duties and responsibilities for the lab director.</p>
<p><b>D6042</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b></p>

CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:

Based on review of the written procedure manual, quality control (QC) logs, and interview with the technical consultant (TC), the TC failed to review all lab QC records for the overall quality of laboratory testing. Findings: 1. Review of Levey Jennings charts from the year 2023 showed on the day of the survey 10/10/24 at 2:00 PM that the TC did not review the charts nor document a review was performed anywhere in QC records. 2. The TC stated on the day of the survey 10/10/24 at 2:00 PM that Levey Jennings charts were not reviewed. 3. The TC confirmed on the day of the survey 10/10/24 at 2:00 PM that a review all lab QC records for the overall quality of laboratory testing was not performed.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of the written procedure manual, testing personnel competency records, and interview with the technical consultant (TC), the TC failed to perform annual competency procedures during the year 2023. Findings: 1. The TC failed to perform annual competency procedures during the year 2023 for five out of five testing persons when performing Microbiology, Chemistry, Immunology, and Hematology testing. 2. The TC failed to perform the annual "Bloodborne Pathogen Training" during the year 2023 for five out of five testing persons. 3. The "Bloodborne Pathogen Training" procedure states on the day of the survey 10/10/24 at 2:00 PM that laboratory testing personnel must have annual training when performing infectious disease testing. 4. The TC confirmed during the survey on 10/10/ 24 at 2:00 PM that annual competency procedures nor the annual "Bloodborne Pathogen Training" were performed on TP during the year 2023 to ensure accurate and reliable patient testing.