Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D0208490	04/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Spring Valley Pediatrics	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on observation, the review of the laboratory's policies and procedure, patient test results and hematology analyzer instrument print outs and confirmation by interview with Employee #1 on April 26, 2018 at approximately 3:00 PM, the laboratory failed to develop a mechanism for retaining instrument printouts. There was no evidence that the laboratory retained results from repeat sample analysis of abnormal Complete Blood Count (CBC) for eight (8) of the eight (8) patient samples that were verified by repeat sample testing (Patient Numbers 1- dated 3/24/18, 4- dated 4/5/18, 5- dated 4/12/18, 8 - dated 4/16/18, 8- dated 4/19/18, 1 and 6 - dated 4/24 /18 and 3 - dated 4/25/18). The findings included: 1. Review of the laboratory's policy for abnormal CBC revealed that "Abnormal CBC's will be verified by repeating the sample run. If the second test result is similar to the first, the first sample result will be used, unless there are flags that disappear on the second run." 2. Review of Patients Number (#) 1- dated 3/24/18, #4- dated 4/5/18, #5- dated 4/12/18, #8 - dated 4/16/18, #8- dated 4/19/18, #1 and #6 - dated 4/24/18 and #3 - dated 4/25/18 CBC results were documented as being verified. Although at the time of the survey, results of the repeat testing for the aforementioned samples can be retrieved from the analyzer, according to Employee #1 the instrument does not have the capability to retain results for two (2) years as required by the regulation. 3. On April 25, 2018 at approximately 11: 00 AM, a staff member was observed discarding the print out for the repeat sample testing of Patient #3 specimen dated 4/25/18.

D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: A. Based on the review of patients test results, the manufacturer's instructions for Coulter ACT Diff 2 TM, and the laboratory's policies and procedures manual, the laboratory failed to develop a procedure for addressing flagged results for two (2) of the two (2) patients with flagged white cell automated differentials (Patient Numbers 8 dated 4/19/18 and 6 dated 4/24/18). The findings included: 1. Review of the manufacturer's instructions for Coulter ACT Diff 2 TM, revealed that flags such as "1,2,3,4,M" appear next to the white cell deferential, when internal regional distributional criteria fails at one specific region (1,2,3,4) or multiple regions M. Further review revealed instructions to verify results according to the laboratory's protocol. 2. Review of the laboratory's policies and procedures manual failed to provide a protocol for verifying the flagged white cell differentials. 3. Review of Patient Number (#) 8 dated 4/19/18 revealed a white cell differential with a "3" flag Patient # 6 dated 4/24/18 revealed a white cell differential with "M" flag. Although the staff performed manual differential and a repeat analysis was performed, the result was reported without a notation to indicate that the flagged parameters were verified. 4. Interview with the Employee #1 on April 26, at approximately 2:30 PM confirmed the lack of a written protocol to address flagged white cell differentials. B. Based on the review of the laboratory's procedure manual and confirmation by staff interview on April 25, 2018 at approximately 4:00 PM, the laboratory's procedure manual failed to include quality control procedures for four (4) of the four (4) procedures that require a microscope for analysis (microscopic urinalysis, potassium hydroxide preparation wet preparation and pinworm). The findings included: 1. Review of the laboratory's procedure for analyzing urine sediment did not include procedure for daily quality control. 2. Review of laboratory's procedure for potassium hydroxide preparation (KOH Prep) for analyzing skin scrapings, hair, nails, and vaginal fluids for presence and absence of fungal elements did not include procedure for daily quality control. 3. Review of the laboratories procedure for wet preparation for analyzing vaginal samples for the presence or absence of epithelia cells, white blood cells, bacteria, trichomonas, yeast, and clue cells did not include procedure for daily quality control. 4. Review of the laboratories procedure for examining specimens for

	pinworm did not include procedure for daily quality control. 5. Interview with Employee #1 confirmed the lack of daily quality control procedures for microscopic urinalysis, potassium hydroxide preparation wet preparation and pinworm.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policies and procedures and Quality Control records, and confirmation by staff interview on April 25, 2018 at approximately 11:30 AM, the laboratory failed to provide a documented evidence that the hematology stain quality control is performed each day of use for one (1) of the one (1) stain the laboratory uses to perform manual white blood cell (WBC) differential (HEMA-QUICK II stain). The findings included: 1. Review of the laboratory's policies and procedures for performing HEMA-QUICK II (a Wright Gimesa) stain revealed instructions to check and document the quality of the stain once a week by observing a stained blood smear. 2. Review of the laboratory's quality control log for HEMA-QUICK II stain revealed a weekly quality control documentation. 3. Interview with the Employee #1 revealed that although the stain quality is reviewed for each smear, quality control is documented once a week. It should be noted that the laboratory did not implement individual quality control plan (IQCP) to perform a weekly quality control.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on observation, the review of instrument printouts and confirmation by interview with Employee #1 on April 26, 2018 at approximately 11:00 AM, the laboratory failed to have a systems that twice a year evaluates and defines the relationship between the two (2) analyzers used for testing Respiratory Syncytial Virus (RSV) (SN 00011612 and SN 00010102). Findings include: 1. During a tour of the laboratory, two (2) Quidel Sofia analyzers were observed in the lab. According to interview with Employee #1, the two analyzers were used for assaying RSV. 2. Review of instrument printouts for both Quidel Sofia analyzers (SN 00011612 and SN 00010102) revealed that the laboratory used the two analyzers to test patient specimens. 3. Further interview with Employee #1 confirmed the lack of protocol to compare the results obtained from the two analyzers.

D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: A. Based on the review of patients test results, the manufacturer's instructions for Coulter ACT Diff 2 TM and the laboratory's policies and procedures manual, the Laboratory Director failed to develop procedure for addressing flagged results for two (2) of the two (2) white cell automated differentials with flags (Patient Numbers 8 dated 4/19/18 and 6 dated 4/24/18). Cross reference D5403A. B. Based on the review of the laboratory's procedure manual and confirmation by staff interview on April 25, 2018 at approximately 4:00 PM, the laboratory's Director failed to ensure that policies and procedures were developed for daily quality control for four (4) of the four (4) microscopic procedures (microscopic urinalysis, potassium hydroxide preparation wet preparation and pinworm). Cross reference D5403B.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES 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: A. Based on the review of the laboratory's procedure manual and confirmation by staff interview on April 25, 2018 at approximately 4:00 PM, the laboratory's Technical Consultant failed to ensure that daily quality control procedures were developed for four (4) of the four (4) microscopic procedures (microscopic urinalysis, potassium hydroxide preparation wet preparation and pinworm). Cross reference D5403B. B. Based on the review of the laboratory's policies and procedures and Quality Control records and confirmation by staff interview on April 25, 2018 at approximately 11:30 AM, the laboratory's Technical Consultant failed to develop a daily quality control procedure for one (1) of the one (1) stain the laboratory uses to perform manual white blood cell (WBC) differential (HEMA-QUICK II stain). Cross reference D5473.