Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D2267432	03/13/2024
Name of Provider or Supplier	**Street Address, City, State**	
Versailles Pediatrics	360 Amsden Avenue Suite 200, Versailles, KY	

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
D0000	An initial certification survey was conducted on 03/13/2024. The laboratory was found to be out of compliance with the following condition: 493.801 Enrollment and Testing of Samples.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of laboratory policy, document review, and confirmed in staff interview, the laboratory failed to enroll in a Centers for Medicare and Medicaid Services (CMS) approved proficiency testing (PT) program as required by Clinical Laboratory Improvement Amendments (CLIA) for the specialty of hematology for 5 of 7 events. Findings included: The laboratory policy, signed by the Laboratory Director (LD) on 08/29/2023, included "Proficiency Testing Instructions" that revealed, "11. This laboratory will abide by all rules of the proficiency testing agency and all rules under CLIA '88 [1988] regarding successful participation in, and sanctions resulting from any failure of proficiency testing, as deemed by HCFA [health care financing administration] or any other government, or accrediting agency." Review of the untitled document signed by the LD, undated, revealed, "This is being written to disclose our failure to promptly enroll in proficiency testing during the opening of [name of laboratory] in July of 2022 and to serve as a plan of action to

	correct the error. On April 24, 2023 our purchasing director sent out an email to the administration inquiring about the purchase of the API-PT testing. At that time, it was recognized that the clinic had failed to be enrolled in the API-PT testing. The emails are included in the action plan to show the quick response and attempt to correct the error. The clinic was enrolled in API-PT testing the next day on April 25, 2023. Due to clinical staffing issues in those first few months after the clinic opened it was not evidence that the proficiency testing was absent from our normal clinical standards. Once the error was realized the order was placed and the first shipment was set up to be delivered. Now that our clinic is enrolled in the API-PT testing the account will auto re-new with no concern for further missed cycles. To disclose we did miss the October 2022 event and March 2023 event. The API-PT testing was delivered in July 2023 for the second event of the year. Missing API-PT testing should never be a problem in the future from here on out." In an interview on 03/13/2024 at 12:15PM, the Regional Director (RD) acknowledged the laboratory did not enroll in proficiency testing (PT) when the laboratory first opened. Per the RD, the oversight was first discovered in April of 2023. The RD stated the laboratory enrolled in PT on 04/23 /2023 and missed the third event of 2022, and the first event of 2023.
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: Based on direct observation, review of laboratory policy, and confirmed in staff interview, the laboratory failed to establish a policy and procedure for the reporting of critical values for complete blood count (CBC) to medical providers for 6 of 6 analytes. Findings included: During an observation on 03/13/2024 at 11:45 AM Testing Personnel (TP) #2 demonstrated how she performed a CBC on the Sysmex XP-300 hematology analyzer. The laboratory policy signed by the Laboratory Director (LD) on 08/29/2023, revealed the manual did not include a list of critical CBC values or a procedure for the reporting of critical values to medical providers. In a confirmed interview on 03/13/2024 at 11:45 AM, TP #2 and the Regional Director (RD) stated the laboratory did not have a written policy for the reporting of critical values.

D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation, package insert review, record review, and confirmed in staff interview, the laboratory failed to ensure expired quality control (QC) material was not used for 4 of 6 patient records reviewed. Findings included: During a laboratory tour on 03/13/2024 at 11:05 AM, the surveyor noted the QC material in use had an expiration date of 03/06/2024 and was not labeled with an opened vial stability date. Review of the package insert for the "Sysmex Eighcheck-3WP X-TRA," dated March 2023, revealed "Storage and shelf lift after first opening Opened and recapped vials and vials whose caps have been pierced will retain stability for 14 days if stored at 2-8 [degrees] C [Celsius] after being re-capped." Review of patient records revealed the laboratory staff used expired QC materials when they performed complete blood count (CBC) testing for four patients, Patient #1 on 03/07/2024 at 12:06 PM, Patient #2 on 03/11/2024 at 8:47 AM, Patient #3 on 03/11/2024 at 11:03 AM, and Patient #4 on 03/11/2024 at 11:51 AM. In an interview on 03/13/2024 at 11:15 AM, Testing Personnel (TP) #2 and the Regional Director (RD) stated they were unaware of the manufacturer's opened vial stability requirements, and they were unaware the QC were expired.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on document review and confirmed in staff interview, the laboratory failed to ensure proficiency testing (PT) was performed for 7 of 7 events reviewed. Findings included: Review of the untitled document signed by the LD, undated, revealed, "This is being written to disclose our failure to promptly enroll in proficiency testing during the opening of [name of laboratory] in July of 2022 and to serve as a plan of action to correct the error. On April 24, 2023 our purchasing director sent out an email to the administration inquiring about the purchase of the API-PT testing. At that time, it was recognized that the clinic had failed to be enrolled in the API-PT testing. The emails are included in the action plan to show the quick response and attempt to correct the error. The clinic was enrolled in API-PT testing the next day on April 25, 2023. Due to clinical staffing issues in those first few months after the clinic opened it was not evidence that the proficiency testing was absent from our normal clinical standards. Once the error was realized the order was placed and the first shipment was set up to be delivered. Now that our clinic is enrolled in the API-PT testing the account will auto re-new with no concern for further missed cycles. To disclose we did miss the

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