Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0930416	05/23/2023
Name of Provider or Supplier	**Street Address, City, State**	
Forest Park Pediatrics	4488 Forest Park Avenue, Suite 230, Saint Louis, MO	

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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the temperature log sheet, policies and interview with the practice manager, the laboratory failed to follow policy for room temperature for 113 out of 292 days. Findings: 1. Review of the policy, "Temperature Checklist 2023," states "correct temperature range in between 10C - 25C." 2. Review of the temperature log sheets from January 2022 to date May 26, 2023, showed the temperature did not fall within the stated parameters on log sheet. For the following days: 2022 February 17 March 2, 8, 10, 16, 18, 19, 23, 25, 29, and 31 April 9, 22, and 28 May 5, 11, 13, 14, 19, 28, and 31 June 4, 6, 7, 8, 9, 11, 12, 13, 15, 16, 17, 18, 23, 28, and 30 July 2, 5, 6, 7, 8, 9, 11, 12, 13, 14, 18, 19, 20, 21, 22, 28, 29, and 30 August 1, 2, 3, 8, 9, 12, 15, 19, 20, and 30 September 2, 3, 4, 5, 6, 10, 13, 14, 19, 20, 21, 22, 23, 24, 26, 27, and 28 October 1, 2, 4, 5, 6, 7, 13, 15, 24, 26, 27, and 31 November 1, 9, 15, 21, 23, 25, and 26 April 29 May 1, 2, 3, 4, 6, 8, 9, 10, 11, 19, 20, and 22 3. Interview with the practice manager on May 23, 2023 at 10:30 AM, confirmed the laboratory failed to follow policy for room temperature for 113 out of 292 days.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and

	shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of TSA II 5% SB agar, Taxo A disc, policies, and interview with practice manager , the laboratory failed to check new lot numbers and shipments of TSA, Taxo A discs for positive and negative reactivity from 2021 to date May 23, 2023. findings: 1. Policy Comprehensive Quality Assurance Program states "inspect culture media on arrival of each shipment. Check plates from each batch or shipment of blood agar plates for signs of hemolysis, cracking, drying, contamination, freezing, excessive bubbles, and leaking. Record on TSA Media Quality Control Log the lot number, expiration date, and finding of media check. If media is visually acceptable upon arrival, store properly and use within expiration date. Let Lab Assistant know there are plates to QC. Once QC has been performed and is acceptable, Lab Assistant will write "QC" on stacks of plates to let everyone know they can now be used. 2. Laboratory had no documentation for positive and negative reactivity for Taxo A discs or TSA logs available for 2021 to date May 23, 2023. 2. Interview with the practice manager on May, 23, 2023 at 10:30 AM confirmed the laboratory failed to check new lot numbers and shipments of TSA, Taxo A discs for positive and negative reactivity from 2021 to date May 23, 2023.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on the lack of an approved corrective action plan for proficiency testing (PT) results, review of PT records for 202 and 2023 and interview with the practice manager, the laboratory director failed to establish a corrective action plan for PT results found to be unacceptable or unsatisfactory. Findings: 1. The laboratory did not have a corrective action plan for the following unacceptable PT results: 2022 MLE M2 and M3. 3. Interview with the practice manager on May 23, 2023 at 10:30 AM confirmed the laboratory director failed to ensure an approved corrective action plan was followed for PT results found to be unacceptable or unsatisfactory.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

	This STANDARD is not met as evidenced by: Based on lack of performance evaluations, review of policies, and interview with the practice manager, the technical consultant (TC) failed to perform and document initial performance evaluations which included direct observation of testing personnel (TP) in 2022. Findings: 1. Lack of performance evaluations showed no initial performance evaluation on testing for 1 of 1 TP in 2022. 2. The Comprehensive Quality Assurance Program Policy states "New employees will be evaluated prior to performing any patient sample testing." 3. Interview with practice manager on May 23, 2023 at 10:30 AM confirmed the TC failed to perform and document initial performance evaluation on TP #5.
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on lack of the performance evaluations and interview with practice manager, the technical consultant (TC) failed to evaluate and document performance evaluations at least semiannually during the first year for one of one testing personnel. Findings: 1. Review of performance evaluations showed no semiannual performance evaluation was documented for testing personnel #5. 2. Interview with practice manager on May 23, 2023 at 10:30 AM confirmed the technical consultant did not evaluate and document the semiannual performance evaluation for testing personnel #5.