

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0930416	(X3) Date Survey Completed 03/11/2025
Name of Provider or Supplier Forest Park Pediatrics	Street Address, City, State 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
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of lab director qualifications, and review of proficiency testing (PT), the laboratory failed to meet the condition of laboratory director (LD). The LD failed to ensure the required documentation to qualify the individual serving as laboratory director (Refer to D6003); and the LD failed to ensure an approved corrective action plan when PT results were unacceptable. (Refer to D6019).</p>
D6003	<p>LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406</p> <p>The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have had laboratory training or</p>

experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; and (b)(2)(ii)(B) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in 493.1407; or (b)(3)(i)(A) Hold an earned doctoral degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or (b)(3)(i)(B) Hold an earned doctoral degree; and (b)(3)(i)(B)(1) Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); or (b)(3)(i)(B)(2) An approved thesis or research project in biology/chemistry /MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (b)(3)(ii) Have at least 20 CE credit hours in laboratory practice that cover the laboratory director responsibilities defined in 493.1407; and (b)(3)(ii)(A) Be certified and continue to be certified by a board approved by HHS; and (b)(3)(ii)(B) Have had at least 1 year of experience directing or supervising nonwaived laboratory testing; or (b)(4)(i)(A) Have earned a master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B)(1) Meet bachelor's degree equivalency; and (b)(4)(i)(B)(2) Have at least 16 semester hours of additional graduate level coursework in biology, chemistry, medical technology, clinical or medical laboratory science; or (b)(4)(i)(C)(1) Meet bachelor's degree equivalency; and (b)(4)(i)(C)(2) Have at least 16 semester hours in a combination of graduate level coursework in biology, chemistry, medical technology, clinical or medical laboratory science coursework and an approved thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (b)(4)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing; and (b)(4)(iii) Have at least 1 year of supervisory laboratory experience in nonwaived testing; and (b)(4)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1407; or (b)(5)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(5)(i)(B) At least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either- (b)(5)(i)(B)(1) 48 semester hours of medical laboratory science or medical laboratory technology courses; or (b)(5)(i)(B)(2) 48 semester hours of science courses that include- (b)(5)(i)(B)(2)(i) 12 semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry; and (b)(5)(i)(B)(2)(ii) 12 semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and (b)(5)(i)(B)(2)(iii) 24 semester hours of chemistry, biology, or medical laboratory science or medical laboratory technology in any combination; and (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing; and (b)(5)(iii) Have at least 2 years of supervisory laboratory experience in nonwaived testing; and (b)(5)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1407. (b)(6) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of moderate complexity testing under this section if they were qualified and serving as a laboratory director of moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview with the office manager, the laboratory failed to have documentation to qualify the individual serving as the

	<p>laboratory director for moderate complexity testing. Findings: 1. The laboratory failed to have documentation to qualify the individual serving as the laboratory director for the moderate complexity laboratory. The laboratory has been operating without an approved laboratory director since October 2024. 2. Interview with the office manager on March 11, 2025 at 10:30 AM confirmed, the laboratory failed to have the required documentation to qualify the individual serving as laboratory director.</p>
<p>D6019</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</p> <p>(e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory;</p> <p>This STANDARD is not met as evidenced by: Based on review of 2023 and 2024 proficiency testing (PT) and interview with the office manager, the laboratory director (LD) failed to ensure an approved corrective action plan is followed when any PT result is found to be unacceptable or unsatisfactory for two of three testing events in 2024. Findings: 1. Review of Medical Laboratory Evaluation (MLE) PT results Nonchemistry M1 event 2024 showed: Throat Culture 80% with no corrective action plan. 2. Review of Medical Laboratory Evaluation (MLE) PT results Nonchemistry M3 event 2024 showed: Throat Culture 40% with no corrective action plan. 2. Interview with the office manager on March 11, 2025 at 10:30 AM confirmed the LD failed to ensure an approved corrective action plan when PT results were unacceptable.</p>
<p>D6054</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>(b)(9) Thereafter, evaluations must be performed at least annually</p> <p>This STANDARD is not met as evidenced by: Based on review of performance evaluations and interview with the office manager, the technical consultant (TC) failed to evaluate and document the annual performance evaluation for six of six testing personnel (TP) in 2023 and 2024. Findings: 1. Review of performance evaluations showed no annual performance evaluation for TP #1, TP #2, TP #3, TP #4, TP #5 and TP #6 in 2023 and 2024. 2. Interview with the office manager on March 11, 2024 at 11:00 AM confirmed the technical consultant failed to evaluate and document the annual performance evaluation for six testing personnel.</p>