

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0928015	(X3) Date Survey Completed 05/15/2025
Name of Provider or Supplier Fairway Pediatrics Llc	Street Address, City, State 7020 North Highway 190 Suite C, Covington, LA	
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	A Recertification survey was performed at Fairway Pediatrics, CLIA ID 19D0928015, on May 15, 2025. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of manufacturer's instructions and laboratory temperature records, as well as interview with personnel, the laboratory failed to define acceptable room temperature limits within the manufacturer's required range for supplies stored in the laboratory. Findings: 1. Observation by surveyor during the laboratory tour on May 15, 2025 at 9:05 a.m. revealed the following swabs stored in the laboratory at room temperature: a) Cultureswab Plus Collection and Transport System for aerobes and anaerobes - Manufacturer's required storage requirements 5 - 25 degrees Celsius 2. Review of the laboratory's room temperature records from January 2025 through April 2025 revealed the laboratory defined the acceptable room temperature limits as 65 - 95 degrees Fahrenheit (18.3 - 35 degrees Celsius) which exceeded the manufacturer's upper temperature limits. 3. In interview on May 15, 2025 at 10:50 a.m., Testing Personnel 1 confirmed the laboratory's acceptable room temperature limits exceeded the manufacturer's limits as identified above.</p>

<p>D6014</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)</p> <p>(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5413.</p>
<p>D6029</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>(e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and personnel records as well as interview with personnel, the Laboratory Director failed to ensure one (1) of three (3) testing personnel reviewed had appropriate training documentation prior to patient testing. Findings: 1. Review of the laboratory's policy "Laboratory Personnel Competency Assessment {sic}" revealed "An initial competency assessment will be done after training is complete, and again at 6 months, and annually thereafter, for all laboratory personnel." 2. Review of the laboratory's personnel records revealed the laboratory did not have documentation of an initial training for Personnel 5. 3. In interview on May 15, 2025 at 10:25 a.m., Testing Personnel 1 stated training was performed and documented for Personnel 5, but she could not find the documentation.</p>
<p>D6051</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v)</p> <p>(b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 (Laboratory Personnel Report), policies, and personnel records; as well as interview with personnel, the Technical Consultant failed to ensure the assessment of test performance through previously analyzed, internal blind samples, or external proficiency testing samples for two (2) of five (5) testing personnel reviewed. Findings: 1. Review of the laboratory's CMS-209 revealed the Laboratory Director also served as the Technical Consultant. 2. Review of the laboratory's form "Competency Assessment" revealed six (6) criteria for competency assessment which included "Assessment of test performance through previously analyzed specimens, internal blind samples, or external proficiency testing samples." 3. Review of the laboratory's personnel records revealed the laboratory documented competency assessments for the following personnel but failed to provide documentation to support the performance of blind sample testing: a) Testing</p>

Personnel 3 - 2024 annual competency b) Testing Personnel 6 - 2023 semiannual competency and 2024 annual competency 4. In interview on May 15, 2025 at 10:40 a. m., Testing Personnel 1 confirmed the personnel identified above did not have an assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples performed.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

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

(b)(9) 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 review of the laboratory's CMS-209 (Laboratory Personnel Report), policies, and personnel records; as well as interview with personnel, the Technical Consultant failed to perform a competency assessment semiannually for one (1) of two (2) testing personnel reviewed. Findings: 1. Review of the laboratory's CMS-209 revealed the Laboratory Director also served as the Technical Consultant. 2. Review of the laboratory's policy "Laboratory Personnel Competency Assessment {sic}" revealed "An initial competency assessment will be done after training is complete, and again at 6 months, and annually thereafter, for all laboratory personnel." 3. Review of the laboratory's personnel records revealed Personnel 5 began patient testing in December 2023 but a semiannual assessment was not performed in 2024. 4. In interview on May 15, 2025 at 10:25 a.m., Testing Personnel 1 stated a semiannual competency was performed and documented for Personnel 5, but she could not find the documentation.