

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0185429	(X3) Date Survey Completed 12/16/2025
Name of Provider or Supplier Tan & Garcia Pediatrics Pc	Street Address, City, State 2020 Good Hope Road, Suite 120, Enola, PA	
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
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by:</p> <p>A. Based on record review, lack of documentation, and interview with the Office Manager (OM), the laboratory failed to ensure manufacturer's performance instructions and laboratory procedures were followed when quality control (QC) was performed on 1 of 1 Alere Cholestech LDX chemistry analyzer from 2/28/2025 to 12/11/2025. Findings include: 1. Manufacturer instructions for the Alere Cholestech LDX system stated, "Controls should be tested with each new lot of cassettes". 2. The laboratory's Cholesterol Machine Info stated, "Controls are to be done at every new lot number. Controls - Quality Control is to be documented in the big lab book at the beginning of every new kit." 3. On the day of survey, 12/16/2025 at 10:03 am, review of the laboratory's Cholestech QC records revealed the laboratory failed to document QC performed for the following new lots of cassettes used to perform cholesterol testing on 1 of 1 Alere Cholestech LDX chemistry analyzer from 2/28/2025 to 12/11/2025: - Cassette lot # 441556, expiration date 11/30/2025. 4. The laboratory performed 30 Cholesterol examinations from 2/28/2025 to 12/11/2025 (Cholesterol Patient Result Logs, dated 3/31/2025 to 11/18/2025). 5. The OM confirmed the findings above on 12/16/2025 at 12:10 pm. B. Based on observation in the laboratory, review of laboratory temperature records, and interview with the Office Manager (OM), the laboratory failed to monitor and document temperatures to ensure acceptable reagent storage conditions were met on weekends and holidays for 191 of 630 days from 3/26/2024 to 12/16/2025. Findings include: 1. On the day of survey, 12/16/2025, at 11:30 am, during the tour of the laboratory, the surveyor observed the following reagents stored in the laboratory: - Consult Covid-19/Flu A&B Antigen test kits. Manufacturer storage requirements 2C to 30C. - Status Covid-19/Flu A&B test</p>

kits. Manufacturer storage requirements 2C to 30C. - Leadcare II Blood Lead test kits. Manufacturer storage requirements 15C to 27C. - Sofia RSV FIA test kits. Manufacturer storage requirements 15C to 30C. 2. Review of the laboratory's temperature records revealed the laboratory failed to monitor and document temperatures to ensure acceptable reagent storage conditions were met on weekends and holidays for 191 of 630 days from 3/26/2024 to 12/16/2025. 3. The laboratory reported an estimated annual test volume of 653 RSV/Covid/Flu and 362 Blood Lead examinations in 2024 (CMS 116, dated 11/17/2025). 4. The OM confirmed the findings above on 12/16/2025 at 12:10 pm.

D5213

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(1)

(b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:
Based on review of the Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) results, lack of documentation, and interview with the Office Manager (OM), the laboratory failed to verify the accuracy of the PT results obtained for 2 of 5 WSLH PT Performance Evaluation reports reviewed for toxicology and microbiology testing performed from 03/26/2024 to date of the survey. Findings Include: 1. The WSLH Proficiency Testing performance Evaluation form stated, "NC = Non-consensus, self -assessment needed." 2. On the day of survey, 12/16/2025 at 10:39 am, review of the laboratory's WSLH PT Performance Evaluation records revealed the laboratory failed to verify the accuracy or perform a self-evaluation for analytes that were not graded by the PT agency for the following 2 of 5 WSLH PT Performance Evaluation reports reviewed onsite for toxicology and microbiology testing performed from 03/26/2024 to 12/16/2025: - WSLH 2025-Bacti_Viral1: 2025 Event #1 - WSLH 2025-Chem/Endo 1x1: 2025 Event #1 3. The laboratory failed to provide a comprehensive policy for the PT testing performance and evaluation performed by the laboratory in 2025. 4. The laboratory reported an estimated annual test volume of 458 Throat Cultures, 110 Urine Cultures and 362 Blood Lead examinations in 2024 (CMS 116, dated 11/17/2025). 5. The OM confirmed the findings above on 12/16/2025 at 12:10 pm.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

(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.

This STANDARD is not met as evidenced by:
Based on observation in the laboratory, review of laboratory temperature records, and

interview with the Office Manager (OM), the laboratory failed to monitor and document temperatures to ensure acceptable reagent and microbiology patient culture specimens storage conditions were met on weekends and holidays for 191 of 630 days from 3/26/2024 to 12/16/2025. Findings include: 1. On the day of survey, 12/16/2025, at 11:30 am, during the tour of the laboratory, the surveyor observed the following reagents stored in the laboratory: - Uricult test paddles. Manufacturer storage requirements 2C to 30C. 2. During an interview with the OM on 12/16/2025, at 9:39 am, the OM stated, "urine and throat cultures collected on Saturday are kept in the incubator and are read when the laboratory opens on Monday." 3. Review of the laboratory's temperature records revealed the laboratory failed to monitor and document room temperatures (laboratory acceptable range: 45 to 77 F) and incubator temperatures (laboratory acceptable range: 35 to 37 C) to ensure acceptable reagent and microbiology patient culture specimens (throat/urine) storage temperatures were maintained on weekends and holidays for 191 of 630 days from 3/26/2024 to 12/16/2025. 4. The laboratory reported an estimated annual test volume of 458 Throat Cultures and 110 Urine Cultures for 2024 (CMS 116, dated 11/17/2025). 5. The OM confirmed the findings above on 12/16/2025 at 12:10 pm.

D5435

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(2)

(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
Based on record review, lack of documentation, and interview with the Office Manager (OM), the laboratory failed to establish and maintain a maintenance/function check policy for 1 of 1 thermometers used to ensure acceptable storage and operating temperatures were met in the laboratory from 3/26/2024 to 12/16/2025. Findings include: 1. On the day of the survey, 12/6/2025 at 11:30 am, the surveyor observed the following thermometer used in the laboratory to monitor the storage temperatures of reagents, supplies, calibrators, and quality control: - ThermPro room temperature /humidity thermometer. 2. Review of laboratory procedures revealed the laboratory failed to establish and maintain a maintenance/function check policy for 1 of 1 thermometers used to ensure acceptable storage and operating temperatures were met in the laboratory for microbiology testing performed from 3/26/2024 to 12/16/2025. 3. The OM confirmed the findings above on 12/16/2025 at 12:10 pm.