

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0690451	(X3) Date Survey Completed 06/25/2025
Name of Provider or Supplier Fulton County Medical Center	Street Address, City, State 214 Peach Orchard Road, Mcconnellsburg, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with the Technical Consultant (TC), the Laboratory Director (LD) failed to sign 1 of 8 API PT attestation statements for Blood Gas testing performed from 5/8/2023 to 6/25/2025. 1. The API PT instructions stated, "For all PT results, an attestation statement must be signed by testing personnel and the laboratory director and retained for a minimum of 2 years." 2. On the day of the survey, 6/25/2025 at 10:30 am, the laboratory failed to provide an attestation statement signed by the LD/designee for 1 of 8 API Chem Core PT Events (API 3-2023) performed from 5/8/2023 to 6/25/2025. 3. The TC confirmed the findings above on 6/25/2025 at 11:30 am.</p>
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>

This STANDARD is not met as evidenced by:
 Based on observation in the laboratory, lack of documentation, and interview with the Technical Consultant (TC), the laboratory failed to monitor the humidity of the blood gas laboratory to ensure proper operating conditions were met for 1 of 1 Werfen GEM 5000 blood gas analyzer used for chemistry testing from 8/5/2023 to 6/25/2025. Findings include: 1. On the day of survey, 4/14/2025, at 10:00 am, review of the laboratory's GEM Premier 5000 Requirements procedure stated: "GEM Premier 5000 machine: Relative Humidity - 15% to 85%." 2. The laboratory failed to provide documentation of humidity monitoring for 1 of 1 Werfen GEM 5000 blood gas analyzer from 8/5/2023 to 6/25/2025. 3. The laboratory performed 348 blood gas examinations in 2024 (CMS 116 estimated annual volume). 4. The TC confirmed the findings above on 6/25/2025 at 12:30 pm.

D5429

MAINTENANCE AND FUNCTION CHECKS
 CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
 Based on observation of the laboratory, lack of documentation, and interview with the Technical Consultant (TC), the laboratory failed to perform and document the maintenance and function checks as defined by the manufacturer for 1 of 1 Traceable thermometer used for monitoring refrigerator temperatures in the Blood Gas laboratory from 08/5/2023 to 6/25/2025. Findings include: 1. On the day of the survey, 06/25/2025 at 12:30 pm, observation of the laboratory revealed the following thermometer used for refrigerator temperature monitoring in the Blood Gas laboratory was due for maintenance: - 1 of 1 Traceable Thermometer (S/N 160145507) due 1/22 /2018. 2. The laboratory failed to provide maintenance/functions checks records for the Traceable thermometer from 08/5/2023 to 06/25/2025. 3. The laboratory performed 348 blood gas examinations in 2024 (CMS 116, estimated annual volume). 4. The TC confirmed the findings above on 06/25/2025 at 12:30 pm.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(8)

(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. The procedures for evaluation of the competency of the staff must include, but are not limited to--

This STANDARD is not met as evidenced by:
 Based on lack of documentation and interview with the Technical Consultant (TC), the TC failed to assess the competency of 5 of 13 testing personnel (TP) that performed blood gas examinations on the Werfen Gem Premier 5000 analyzer from 8 /5/2023 to 6/25/2025. Findings include: 1. On the day of survey, 6/55/2025 at 11:30 am, the laboratory failed to provide competency assessment records for the following 5 of 13 TP (CMS 209 TP #7-10 and 12) that performed blood gas analyses from 8/5 /2023 to the date of the survey: -TP #7 missing initial competency -TP #8 missing

2023 and 2024 annual competency -TP #9 missing 2024 and 2025 annual competency
-TP #10 missing 2023 annual competency -TP # 12 missing 2024 annual competency
2. The laboratory performed 348 blood gas analyses in 2024 (CMS 116, estimated
annual volume). 3. The TC confirmed the findings above on 6/55/2025 at 1:30 pm.