

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D0012808	<b>(X3) Date Survey Completed</b> 01/30/2025
<b>Name of Provider or Supplier</b> Crozer Chester Med Ctr Blood Gas Lab	<b>Street Address, City, State</b> One Medical Center Boulevard, Chester, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A validation survey was conducted by the Pennsylvania State Agency at Crozer Chester Med Ctr Blood Gas Lab on 01/30/2025. The laboratory was found out of compliance with the following conditions: 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director. 493.1409 Condition: Laboratories performing moderate complexity testing: technical consultant.
<b>D3009</b>	<p><b>FACILITIES</b> 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: Based on review of the Pennsylvania (PA) clinical laboratory permit, record review, and interview with the Respiratory Therapy Director (RTD), the laboratory director (LD) failed to ensure the laboratory was in compliance with PA Department of Health (DOH) regulatory requirements for notifying the DOH of changes in Directorship and physical facilities of the laboratory from 2020 to day of the survey. Findings Include: 1. On the day of the survey, 01/30/2025 at 09:15 am, review of the Pennsylvania Department of Health Clinical Laboratory Permit revealed Laboratory Director A listed as the current Director and physical address as 15th &amp; Upland Ave Chester, PA 19013. 2. Review of the CMS-116 provided by the laboratory listed the physical address as One Medical Center Boulevard Chester, PA 19013. and new laboratory director, LD B. 3. Review of the CMS-209 provided by the laboratory listed LD B current LD on 01/30/2025. 4. During an interview, 01/30/2025 at 09:20 am, the RTD confirmed the laboratory did not notify the PA DOH of change of Directorship and address change.</p>
<b>D5405</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(c)</p>

(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedures, operator manuals, and interview with the Respiratory Therapy Director (RTD), the laboratory failed to have a complete written procedure manual for blood gas testing performed on 2 of 2 Siemens analyzers that met the requirements of 493.1251 from 1/30/2023 to the date of the survey.

Findings include: 1. On the day of the survey, 1/30/2025, at 11:30 am, review of the procedure manuals for blood gas testing revealed the operator's manuals were used to perform testing on 2 of 2 Siemens 500 blood gas analyzers from 1/30/2023 to 1/30/2025. 2. Review of the operator's manual revealed that the test system instructions used failed to include the following requirements of 493.1251 that are specific to the laboratory: - Step by step performance of the procedure including test calculations and interpretation of results - Preparation of slides, solution, calibrators, controls, reagents, stains, and other material used in testing. - Control procedures - Calibration and calibration verification procedures. - Corrective action to take when calibrations or control results fail to meet the laboratory criteria for acceptability. - Limitations in the test methodology, including interfering substances. -The reportable range for test results for the test system as established or verified in 493.1253. - Reference intervals (normal values). - Imminently life-threatening test results, or panic or alert values. - The laboratory 's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. - Description of the course of action to take if a test system becomes inoperable. 3.The operators manuals were not approved for use by the current laboratory director prior to the start of patient testing. 4. The RTD confirmed the findings on 1/30/2025 at 01:00 pm.

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**

CFR(s): 493.1255(b)

(b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:  
 Based on review of calibration verification records and interview with the Respiratory Therapy Director (RTD), the laboratory failed to perform calibration verification at least every six months for the 1 of 2 Siemens 500 blood gas analyzers from 1/30/2023 to the date of survey. Findings include: 1. On the date of survey, 1/30/2025, review of laboratory policy titled "Analytical Measurement Range (AMR) Validation" stated "Our lab currently utilizes 2 instruments. SN 57076 and 57068. Verification of the AMR will include analysis of all reportable analytes on both of these instruments. The AMR will be re-verified every 6 months and following changes in major system components or lots of analytically critical reagents." 2. Review of the laboratory's AMR records revealed that Siemens 500 SN 57068 had one validation performed in June 2024. 3. The RTD confirmed the finding above on 1/30/2025 at 1:00 pm.

**D5775**

**COMPARISON OF TEST RESULTS**

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

This STANDARD is not met as evidenced by:  
 Based on review of the Siemens 500 analyzer records and interview with the Respiratory Therapy Director (RTD), the laboratory failed to evaluate the relationship between 2 of 2 Siemens 500 blood gases analyzers at least twice a year in 2023 and 2024. Findings include: 1. The laboratory's "Comparability of Instrument/Methods" policy states, "instrument/methods are checked against each other at least twice a year". 2. On the day of survey, 1/30/2025, the laboratory could not provide comparison studies performed on 2 of 2 Siemens 500 analyzers used for blood gas analysis in 2023 and 2024. 3. For 2023 and 2024, 13618 patient specimens were analyzed on the Siemens 500 blood gases analyzers (CMS 116 estimated annual volume). 4. The RTD confirmed the findings above on 1/30/2025 at 12:30 pm.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**

CFR(s): 493.1403

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.

This CONDITION is not met as evidenced by:  
 Based on observation of the laboratory, review of laboratory records, and interview with the Respiratory Therapy Director (RTD), the LD failed to provide overall management and direction of the laboratory in accordance with 493.1407 for a moderate complexity laboratory. Refer to 6018, 6020, 6031.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(iii)

(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require

corrective action; and

This STANDARD is not met as evidenced by:

Based on review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) records and interview with the Respiratory Therapy Director (RTD), the laboratory director (LD) failed to ensure that 2 of 6 CAP PT reports were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action in 2023 and 2024. Findings include: 1. The Laboratory Policies & Procedure for Proficiency Testing states, " If a proficiency testing result is ungraded, the following will be done according to the reason the result is ungraded. Refer to the Exception Reason codes provided by the College of American Pathologists to document response." 2. The CAP's actions laboratories should take when a PT result is not graded document states, "the laboratory is required to review participant summary for comparative results and document performance accordingly. Evaluation criteria is not established for educational challenges. Laboratories should determine their own evaluation criteria approved by their laboratory director for self-evaluation." 3. On the day of survey, 1 /30/2025, at 10:00 am, review of the laboratory's CAP PT records revealed the laboratory failed to verify the accuracy for the following 2 of 6 CAP FLD testing events for 2023 and 2024 that were not graded by the PT agency: - CAP FLD-A 2023 - CAP FLD- A 2024 4. The RTD confirmed the findings above on 1/30/2025 at 11:30 am

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:

A. Based on record review, lack of documentation, and interview with the Respiratory Therapy Director (RTD), the Laboratory Director (LD) failed to ensure a quality control (QC) program was established and maintained to assure the quality of laboratory services provided for Blood Gas analyses performed on 2 of 2 Siemens 500 analyzers from 1/30/2023 to 1/30/2025. Findings include: 1. The laboratory Blood Gas Laboratory Quality Management Program policy states: "The Quality Control results along with Temperature verification, maintenance results and assayed QC analyzed post Cartridge change are evaluated by the designated department manager. The report is signed and dated indicating review and any discrepancies are investigated." 2. On the day of survey, 1/30/2025 at 12:20 pm, review of the laboratory's procedures revealed the LD failed to establish a QC program to assure the quality of laboratory services provided for Blood Gas analyses performed on the 2 of 2 Siemens 500 analyzers from 1/30/2023 to 1/30/2025. 3. The laboratory failed to provide documentation for the corrective actions taken by the laboratory when the QC failed to meet acceptable performance. 4. The laboratory failed to provide documentation of the monthly QC reports review and evaluation for 2023 and 2024. 5. The RTD confirmed above findings on 1/30/2025 at 1:00 pm B. Based on record review, lack of documentation, and interview with the Respiratory Therapy Director (RTD), the Laboratory Director (LD) failed to ensure a Quality Assessment(QA) program was established and maintained to assure the quality of laboratory services

provided for Blood Gas analyses performed from 1/30/2023 to 1/30/2025. Findings include: 1. On the day of survey, 1/30/2025, review of the laboratory's "Blood Gas Laboratory Quality Management Program" policy revealed that the LD "oversees the execution of this program and will meet on site at a minimum of not less than four times per year to review laboratory quarterly reports as well as annually via a laboratory annual report:. 2. The laboratory failed to provide copies of the QA quarterly reports showing oversight and review of the laboratory quality activities. 3. The laboratory failed to provide documentation of the LD review of the annual report showing the LD review and approval. 4. The RTD confirmed above findings on 1/30/2025 at 1:00 pm.

**D6031**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(13)

(e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

This STANDARD is not met as evidenced by:  
Based on review of Procedure Manuals and interview with the Respiratory Therapy Director (RTD), the Laboratory Director failed to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process from 1/30/2023 to 1/30/2025. Finding Include: 1. On the date of survey, 1/30/2025, review of the 2 of 2 procedure manuals revealed that the laboratory director did not approve procedures in use. 2. The RTD confirmed the finding above on 1/30/2025 at 1:00 pm.

**D6033**

**TECHNICAL CONSULTANT-MODERATE COMPLEXITY**  
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:  
Based on review of personnel qualification records and interview with the Respiratory Therapy Director (RTD), the laboratory failed to ensure that 1 of 2 Technical Consultants (TC) met the requirements to perform technical consultation for moderate complexity blood gas examinations performed from 01/30/2024 to the date of the survey. Refer to 6035

**D6035**

**TECHNICAL CONSULTANT QUALIFICATIONS**  
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant 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 at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(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)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for 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 qualification records, review of laboratory documents and interview with the Respiratory Therapy Director (RTD), the laboratory failed to ensure 1 of 2 Technical Consultants (TC) met the requirements to perform technical consultation for blood gas examinations performed from 2023 to the day of the survey. Findings include: 1. On the date of survey, 01/30/2025, review of the General Policy Delegations of Functions revealed TC#2 performed the following supervisor responsibilities from 2023 to 2025. a). Review laboratory Policy and procedures. b). Review and Evaluate Quality Control Data c). Review Proficiency Testing performance d). Review laboratory maintenance 2. The laboratory provided the following personnel credentials for TC#2 on 01/30/2025: - Associate in respiratory therapy from Delaware County Community College 3. The RTD confirmed findings on 01/30/2025 at 01:00pm.

**D6190**

**TESTING PERSONNEL QUALIFICATIONS**

(b)(7) For blood gas analysis, the individual must- (b)(7)(i) Be qualified under paragraph (b)(1), (2), (3), (4), (5), or (6) of this section; or (b)(7)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(7)(ii)(B) Have at least 1 year of laboratory training or experience, or both, in blood gas analysis; or (b)(7)(iii)(A) Have earned an associate

degree related to pulmonary function from an accredited institution; and (b)(7)(iii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis.

This STANDARD is not met as evidenced by:

Based on lack of documentation, review of the CLIA laboratory Personnel Report (Form CMS-209), review of Personnel Qualification records, and interview with the Respiratory Therapy Director (RTD), the laboratory failed to ensure that of 1 of 33 testing personnel (TP) met the requirements to perform moderate complexity blood gas examinations from 2023 to date of survey were qualified. Findings include: 1. On the day of survey, 01/30/2025 at 11:40 am, the laboratory failed to provide personnel qualification records for 1 of 33 TP (CMS 209 TP #33) who performed moderate complexity blood gas testing from 2023 to the day of survey. 2. The RTD confirmed the finding above on 01/30/2025 at 12:00 pm.