

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0876126	<b>(X3) Date Survey Completed</b>  10/21/2024
<b>Name of Provider or Supplier</b>  Crozer-Chester Medical Center-Cath Lab	<b>Street Address, City, State</b>  1 Medical Center Blvd, Upland, 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>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) proficiency testing (PT) records and interview with Testing Personnel (TP) (CMS 209 TP #15), the laboratory failed to provide 7 of 9 CAP PT attestation statements for chemistry and hematology testing events performed in 2023 and 2024. Findings include: 1. On the day of the survey, 10/21/2024 at 09:20am, the laboratory could not provide attestation statements for the following 7 of 9 CAP Chemistry and Hematology PT events: - 2023 Blood Oximetry 1st event (SO-A) and 3rd event (SO-C) - 2024 Blood Oximetry 1st event (SO-A) and 2nd event (SO-B) - 2023 Activated Clotting Time 1st event (CT2-A) and 2nd event (CT2-B) - 2024 Activated Clotting Time 1st event (CT2-A) 2. TP#15 confirmed the findings above on 10/21/2024 around 12:30 pm.</p>
<b>D5403</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test</p>

procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) 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. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedure manual, and interview with Technical consultant (TC) #1 (CMS 209 TC #1) and testing personnel #15 (CMS 209 TP #15) the laboratory failed to provide a complete procedural manual for Hematology and Chemistry testing performed from 11/22/2022 to the date of survey. 1. The laboratory's procedure titled "ACT LR Hemochron Signature Elite" stated the following "X. Results A. Expected Results. Normal ranges and therapeutic values are based on type of procedure getting done by Physician. B. Upon test completion, report all test results in Patient's Chart in Seconds." 2. On the day of the survey, 10/21/2024, review of the laboratory's Hematology procedure manual revealed, the laboratory failed to include the following applicable requirements under 493.1251 (b) for activated clotting time (ACT) performed on 2 of 2 Hemochron analyzers from 11/22/2022 to 10/21/2024: - 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. 3. Review of the laboratory's Chemistry procedure manual revealed, the laboratory failed to include the following applicable requirements under 493.1251 (b) for Blood Gas examinations performed on 2 of 2 Avoximeter analyzers from 11/22/2022 to 10/21/2024: - The reportable range for test results for the test system as established or verified in 493.1253. - 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. 4. TC #1 and TP #15 confirmed the findings above on 10/21/2024 at 11:00 am.

**D5415**

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:  
Based on observation of the laboratory and interview with testing personnel #15 (CMS 209 TP #15), the laboratory failed to label 2 of 2 quality controls with the pertinent information required for the proper use of the Avoximeter 1000E blood gas analyzer from 11/22/2022 to the day of survey. Findings Include: 1. On the day of survey, 10/21/2024, observation of control materials in use, revealed the laboratory did not label the following optical filters used to verify instrument calibration from 11/22/2022 to 10/21/2024: - 1 of 1 yellow optical filter. - 1 of 1 orange optical filter. 2. TP #15 confirmed the findings above on 10/21/2024 around 12:15 pm.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:  
Based on review of quality control records and interview with the technical consultant #1 (CMS 209 TC #1) and testing personnel #15 (TP #15), the Laboratory Director (LD) failed to ensure a quality control (QC) program was maintained to assure the quality of laboratory services provided for blood gas examinations performed on 2 of 2 Avoximeter 1000E analyzers from 11/22/2022 to the day of survey. Findings include: 1. The laboratory's Individualized Quality Control Plan (IQCP) for the Avoximeter 1000E stated the following: "Quality control testing for the AVOXimeter 1000E consists of the following operations: - Daily optical quality control. - Weekly testing of two levels of liquid controls." 2. On the day of survey, 10/21/2024, review of QC records revealed that the laboratory failed to perform two levels of liquid controls weekly: Avoximeter 1000E serial #7344: - 2023: October, and November. - 2024: January, February, March, April, May, June, and July. Avoximeter 1000E serial #7345: - 2023: July, August, October, November, and December. - 2024: January, March, April, May, June, August, and September. 3. TC #1 and TP #15 confirmed the findings above on 10/21/2024 at 11:30 am.

**D8103**

**BASIC INSPECTION REQUIREMENTS**  
CFR(s): 493.1773(b)(c)(d)

(b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact

duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with the technical consultant #1 (CMS 209 TC #1) and testing personnel #15 (TP #15), the laboratory failed to have the required records accessible during the laboratory survey performed on 10/21/2024. Findings Include: 1. On the day of the survey, 10/21/2024 at 12:00 pm, the laboratory could not provide the following records upon request: - Quality Assessment records from 11/22/2022 to 10/21/2024. - Maintenance records for 2 of 2 Avoximeters (s/n 7344 and s/n 7345) from 11/22/2022 to 10/21/2024. - Maintenance records for 2 of 2 Hemochrons (s/n 23313 and s/n 12276) from 11/22/2022 to 10/21/2024. - QC Logs for Avoximeter Serial #7344 January - July, October - November 2023. May 2024. - QC Logs for Avoximeter Serial #7345 January-June, August-September, December 2023. January and May 2024. 2. TC #1 and TP #15 confirmed the finding above on 10/21/2024 at 12:30 pm. \*Repeat deficiency.