Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0876126	11/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
Crozer-Chester Medical Center-Cath Lab	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that 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; 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 #1 (TP), the laboratory director (LD) failed to ensure that 5 of 5 CAP PT reports were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action from 10/15/2020 to 11/22/2022. Findings include: 1. On the date of the survey, 11/22/2022 at 10:01 am, the laboratory could not provide documentation that the following CAP PT results were reviewed and assessed by the LD for activated clotting time, oxyhemoglobin, and total hemoglobin testing from 10 /15/2020 to the date of the survey: - CAP CT2-B 2020: Activated Clotting Time - CAP CT2-A 2021: Activated Clotting Time - CAP CT2-B 2021: Activated Clotting Time - CAP SO-A 2022: Blood Oximetry Survey (Attestation not signed by testing personnel or LD) - CAP CT2-B 2022: Activated Clotting Time 2. TP # 1 confirmed the findings above on 11/22/2022 around 12:45 pm.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on a review of the laboratory's training and competency records and interview with testing personnel #1 (TP), the laboratory director failed to employ a sufficient number of laboratory personnel with the appropriate education and training to perfom competency assessments for 16 of 16 TP from 10/15/2020 to the date of the survey. Findings include: 1. On the date of the survey, 11/22/2022 at 09:30 am, review of competency and training records revealed that the laboratory failed to document the competency assesments of 16 of 16 TP that performed activated clotting time (ACT), oxyhemoglobin, and total hemoglobin from 10/15/2020 to 11/22/2022 for the following: - Hemochorn Signature Elite (ACT) competency assessments in 2020 were not reviewed or signed by the TC for 7 of 16 TP (CMS 209 TP # 1, 3, 4, 5, 10, 11). - Hemochron Signature Elite (ACT) competency assessments were not documented for 7 of 7 TP (CMS 209 TP #1, 2, 3, 4, 5, 10, 11) in 2021. - Hemochorn Signature Elite (ACT) training documentation was not reviewed or signed by the TC/Super-User for: - TP #12, training performed 10/1/2022 -TP # 11, training performed 11/18/2022 - Avoximeter 1000E (oxyhemoglobin and total hemoglobin) training documents and competency assessments for 10 of 16 TP (CMS 209 TP # 2, 3, 5, 7, 8, 9, 13, 14, 15, 16) were not reviewed or signed by the TC from 8/25/2021 to 11/22/2022. 2. Review of the competency assessment records revealed that TP # 8 and #11 who do not meet the qualification requirements of 493:1411 performed the evaluation of TP in 2022. TP # 8 and #11 are not listed on the CMS 209 form as a TC. 3. 500 chemistry and 1400 hematology tests were performed in 2021 (CMS 116 annual test volume). 4. TP #1 confirmed the findings above 11/22/2022 around 12:45 pm.
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 testing personnel #1 (TP), the laboratory failed to have the required records accessible during the course of the laboratory survey performed on 11/22/2022. Findings Include: 1. On the day of the survey, 11/22/2022, the laboratory could not provide the following records upon request: - Quality assessment records from 10/15/2020 to 11/22/2022. - Biannual comparison of test results for: -2 of 2 Hemochron Signature Elite analyzers (ACT) from 10/15/2020 to 11/22/2022. - 2 of 2 Avoximeter 1000E analyzers (oxyhemoglobin, total hemoglobin) from 08/25/2021 to 11/22/2022. - Calibration verification records for: - 2 of 2 Hemochorn Signature Elite analyzers from 10/15 /2020 to 11/22/2022. - 2 of 2 Avoximeter 1000E analyzers from 08/25/2021 to 11/22 /2022. - Quality control records for 2 of 2 Avoximeter 1000E analyzers from 08/25 /2021 to 11/22/2022. - Quality control corrective action logs for 2 of 2 Hemochron Signature Elite analyzers from 10/15/2020 to 11/22/2022. - Verification of performance specifications for 2 of 2 Avoximeter 1000E analyzers approved by the laboratory director (LD). - Technical Consultant (TC) yearly competency for their supervisory responsibilities signed by LD from 10/15/2020 to 11/22/2022. - Competency assessment procedure to assess the TC for their supervisory responsibilities. - Credentials for 3 of 16 TP (CMS 209 TP # 14, 15, and 16) that were previously employed at the facility. 2. TP #1 confirmed the findings above on 11/22 /2022 around 12:45 pm.