

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0887654	(X3) Date Survey Completed 12/13/2019
Name of Provider or Supplier Crozer Chester Medical Ctr - Poc	Street Address, City, State One Medical Center Boulevard, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedure manuals and interview with the point of care testing (PoCT) coordinator and PoCT educator, the laboratory failed to establish a competency assessment procedure to assess the competency of 2 of 2 technical consultants from 2018 to the date of survey. Findings Include: 1. On the day of survey, 12/13/219, the laboratory could not provide a written procedure to assess the competency of 2 of 2 clinical consultants from 11/06/2019 to 12/13/2019. 2. The PoCT coordinator and PoCT educator confirmed the finding above on 12/13/2019 around 8:45 am.</p>
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the point of care testing (PoCT) coordinator and PoCT educator, the laboratory failed to provide a written or electronic request for patient creatinine testing performed in the MRI department in 2018 and 2019. Finding Include: 1. On the day of survey, 12/13/2019, review of patient records revealed, the laboratory did not have a written or electronic requests</p>

for creatinine tests ordered in the MRI department in 2018 and 2019. 2. The PoCT coordinator interviewed at the time of survey said, "there was a standing order policy". 3. The "Administration of Gadolinium - Based Contrast Agents procedure manual provided to the surveyor (discontinued 7/1/2019) by the MRI department, was unclear regarding the laboratory's process for standing orders. 4. The procedure was not signed by the CLIA laboratory director. 5. The PoCT coordinator confirmed the findings above on 12/13/2019 around 10:00 am. **** MRI = Magnetic Resonance Imaging.

D5433

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

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory and interview with the point of care testing (PoCT) coordinator, the laboratory failed to establish and perform maintenance protocols for 3 of 3 thermometers used to monitor a mini refrigerator in the radiology department from 2017 to the date of survey. Findings Include: 1. On the day of survey, 12/13/2019, while on tour of the laboratory, observation of a mini refrigerator stored in the Radiology department, revealed 3 thermometers, were in use to monitor the refrigerator temperature. 2. The mini refrigerator stored quality control material for nova state sensor, used to perform creatinine tests from 11/06/2017 to 12/13/2019. 3. The PoCT coordinator was unable to provide the calibration and maintenance records for the 3 of 3 thermometers. 4. The laboratory could not provide a maintenance protocol for the thermometers. 5. The PoCT coordinator confirmed the findings above on 12/13/2019 around 10:15 am.

D5785

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:
Based on review of temperature logs and interview with point of care testing (PoCT) coordinator, the laboratory failed to document corrective actions for refrigerator temperatures outside acceptable range from 01/01/2018 to the 12/31/2019. Findings Include: 1. According to the laboratory's temperature log, "Maintain a refrigerator temperatures between 36 - 46 degrees fahrenheit at all times." "If refrigerator temperature is found to be outside of range, please document action taken and also notify appropriate personnel." 2. On the day of survey, 12/13/2019, a review of refrigerator temperature records revealed, the dates below were outside of the 36 - 46 degrees fahrenheit range and no corrective actions were documented: In 2018 (8 out

of 365 days) - January 01st, 2018 - 47 degrees - January 10th, 2018 - 48 degrees - January 15th, 2018 - 48 degrees - May 09th, 2018 - 48 degrees - May 10th, 2018 - 48 degrees - May 11th, 2018 - 48 degrees - May 19th, 2018 - 48 degrees - July 09th, 2018 - 47 degrees In 2019 (01/01/2019 to 12/13/2019) (5 out of 346 days) - January 05th, 2019 - 48 degrees - January 12th, 2019 - 48 degrees - February 17th, 2019 - 48 degrees - April 24th, 2019 - 47 degrees - May 15th, 2019 - 47 degrees 3. The PoCT coordinator confirmed the findings above on 12/13/2019 around 10:15 am.

D6049

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

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:
Based on review of temperature records and interview of the point of care testing (PoCT) coordinator, the laboratory failed to ensure personnel were qualified to review preventive maintenance records as a technical consultant from 2017 to the date of survey. Findings Include: 1. On the day of survey, 12/13/2013, review of refrigerator temperature records revealed, a radiology personnel not listed on the "CMS 209 Personnel Form" performed and signed off on the refrigerator monthly log reviews from 11/2017 to 11/2019. 2. Interview with the radiology personnel revealed, the individual did not meet the minimal requirements to be a technical consultant. 3. The PoCT coordinator confirmed the findings above on 12/13/2019 around 10:20 am.