

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0890532	(X3) Date Survey Completed 04/25/2019
Name of Provider or Supplier Crozer Chester Med Ctr Operating Room	Street Address, City, State 1 Medical Center Blvd, 4th Floor Or, 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 the Laboratory procedure manuals and interview with the laboratory director (LD), point of care testing (PoCT) coordinator and technical consultant (TC) #2, the laboratory failed to establish a procedure to assess the competency for all testing personnel TP who performed Activated clotting time (ACT), Blood Gases Analysis and 2 of 3 TCs from 07/28/2017 to the date of survey. Findings include: 1. On the day of survey, 04/25/2019, the laboratory could not provide a competency assessment policy. 2. The laboratory could not provide documentation of competency assessment for 2 of 3 TC from 07/28/2017 to 04/25/2019. 3. The LD, PoCT coordinator and TC#2 confirmed the findings above on 04/25/2019 around 09:45 am.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality assessment (QA) documents and interview with the</p>

laboratory director (LD), point of care testing (PoCT) coordinator and technical consultant (TC) #2, the laboratory failed to establish a quality assurance policy from 07/28/2017 to the date of survey. Findings Include: 1. On the day of survey, 04/25/2019, the laboratory could not provide a policy for monitoring its pre-analytical, analytical, and post analytic programs from 07/28/2019 to 04/25/2019. 2. On 04/25/2019 around 11:00, the LD provided QA activities performed on a monthly basis from July of 2017 to March of 2019, but could not produce a policy describing how quality systems are assessed.