

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1032456	(X3) Date Survey Completed 09/13/2018
Name of Provider or Supplier Augusta State Medical Prison	Street Address, City, State 3001 Gordon Highway, Grovetown, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on September 13, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D6017	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii)</p> <p>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)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of the 2018 AAB (American Association of Bioanalysts) Proficiency Testing (PT) documents and an interview with the laboratory's supervisor (TP # 2 CMS 209) and the Clinic's administrator, the laboratory director failed to ensure Proficiency Testing results were submitted within the timeframes established by the PT program. Findings include: 1.) A review of the 2018 AAB PT records revealed Events # Q1 and Q2 of the Chemistry survey received a score of 0% "Failure to Participate" because results were not submitted to AAB on a timely basis. 2.) An interview with the laboratory's Supervisor (TP# 2 CMS 209) and the Clinic's administrator at approximately 03:50 pm on September 13, 2018 in the conference room confirmed the laboratory failed to submit AAB PT Chemistry events Q1 and Q2 results before the cut off dates.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p>

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of personnel competency assessment records and an interview with the laboratory's supervisor (TP# 2 CMS 209) and the Clinic's administrator, the laboratory failed to include the six required competency assessment criteria when evaluating annual competency on testing personnel for the Sysmex Hematology analyzer and Vitros 250 Chemistry analyzer. The findings include: 1. Review of testing personnel (TP # 2, 3, 4 and 5 CMS 209) competency assessment records for 2017 and 2018 revealed the assessment did not include the six competency assessment criteria required by CLIA. 2. An interview with the laboratory's supervisor TP (#2 CMS 209) and Clinic's administrator in the conference room on September 13, 2018 at approximately 03:55 PM confirmed that annual competency assessment for testing personnel (TP# 2, 3, 4 and 5 CMS 209) did not contain the six required criteria by CLIA.