

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1032456	(X3) Date Survey Completed 01/13/2021
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 January 13, 2021. 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:
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to document corrective action for unsatisfactory PT scores as required. Findings include: 1. American Association of Bioanalysts PT document review revealed corrective action was not performed and documented for 2020 First Event Hematology score of 98 percent. 2. An interview with Staff #2 (CMS 209) on 1/13 /2021 in a conference room at approximately 12:00 p.m. confirmed the lack of corrective action for the aforementioned PT event.</p>
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by:</p>

Based on proficiency test (PT) document review and staff interview, the laboratory director/technical consultant (LD/TC) failed to ensure PT results were returned within the timeframe established by the PT program as required. For details refer to D6017.

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on testing personnel (TP) document review and staff interview, the laboratory director/technical consultant (LD/TC) failed to delegate TP competency performance responsibility to qualified TP as required. Findings include; 1. TP competency document review revealed the following annual TP competencies were performed by unqualified TP in 2019 and 2020 for Staff #2 (CMS 209) and Staff #3 (CMS 209). 2. TP competency document review revealed the initial competency in 2020 for Staff #4 (CMS 209) was performed by unqualified TP. 3. An interview with Staff #2 (CMS 209) in the conference room on 1/13/2021 at approximately 11:00 a.m. confirmed the aforementioned TP competencies were performed by unqualified TP.

D6017

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(ii)

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.

This STANDARD is not met as evidenced by:

Based on proficiency test (PT) document review and staff interview, the laboratory director/technical consultant (LD/TC) failed to ensure PT results were returned within the timeframe established by the PT program as required. Findings include: 1. American Association of Bioanalysts (AAB) PT document review revealed the laboratory received a score of 0 percent for 2020 First Event (Hematology /Coagulation, Chemistry, and Prothrombin/Partial Thromboplastin Time) for failure to submit PT results in a timely manner. 2. An interview in the conference room with Staff #2 (CMS 209) on 1/13/2021 at approximately 12:30 p.m. confirmed the lack of timely PT result submission for the aforementioned PT event. This is a REPEAT DEFICIENCY.

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 proficiency test (PT) document review and staff interview, the laboratory director/technical consultant (LD/TC) failed to ensure all PT reports received were reviewed by appropriate staff as required. Findings include: 1. American Association of Bioanalysts (AAB) PT document review revealed the LD/TC failed to review the following PT reports; 2019 Third Event -- Chemistry and Hematology/Coagulation; 2020 First Event -- Hematology/Coagulation. 2. An interview with Staff #2 (CMS 209) in a conference room on 1/13/2021 at approximately 11:45 a.m. confirmed the lack of ld/TC review of the aforementioned PT reports.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on testing personnel (TP) document review and staff interview, the technical consultant/laboratory director (/TC/LD) failed to evaluate and document the performance of TP responsible for moderate complexity testing at least annually after the first year as required. Findings include: 1. TP competency document review revealed the lack of 2019 annual competency documents available at the time of survey for Staff #2 (CMS 209). 2. An interview in the conference room with Staff #2 (CMS 209) on 1/13/2021 at approximately 11:30 a.m. confirmed the lack of annual competency documents for the aforementioned TP for 2019.