

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D1032456	<b>(X3) Date Survey Completed</b>  02/22/2022
<b>Name of Provider or Supplier</b>  Augusta State Medical Prison	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A proficiency testing desk review was completed on February 22, 2022. At the time of the review, the laboratory was not in compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two of three consecutive events (3rd event of 2020 and 1st event of</p>

2021), resulting in the first unsuccessful occurrence for Hematology # 760 including: cell ID or WBC differential (DIFF) # 765, red blood cell count (RBC) #775, hematocrit(HCT) # 785, hemoglobin (HGB) # 795, white blood cell count (WBC) # 805 and platelets (PLT) # 815, PTT #835, PT #845; Chemistry #245 including: ALT (SGPT) #255, albumin #265, alk phos #275, AST (SGOT) #295, TOTAL BILIRUBIN (TBIL) #305, Calcium (CA) #345, Chloride (CL) #355, creatine #405, glucose #415, Potassium (K) #465, Sodium (Na) #475, total protein #485, BUN #505. Findings include: Refer to D 2130

**D2096**

**ROUTINE CHEMISTRY**  
CFR(s): 493.841(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:  
Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two of three events (3rd event of 2020 and 1st event of 2021), resulting in the first unsuccessful performance for Chemistry #245 including: ALT (SGPT) #255, albumin #265, alk phos #275, AST (SGOT) #295, TOTAL BILIRUBIN (TBIL) #305, Calcium (CA) #345, Chloride (CL) #355, creatine #405, glucose #415, Potassium (K) #465, Sodium (Na) #475, total protein #485, BUN #505. Findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed analytes Chemistry #245 including: ALT(SGPT) #255, albumin #265, alk phos #275, AST (SGOT) #295, TOTAL BILIRUBIN (TBIL) #305, Calcium (CA) #345, Chloride (CL) #355, creatine #405, glucose #415, Potassium (K) #465, Sodium (Na) #475, total protein #485, BUN #505. on event 3 of 2020 with a score of 0% and event 1 of 2021 with a score of 0%. 2. Desk review of the laboratory's proficiency testing reports from American Association of Bioanalysts (AAB) confirmed the laboratory failed the aforementioned analytes on Event 3 of 2020 and Event 1 of 2021 resulting in the first unsuccessful performance.

**D2130**

**HEMATOLOGY**  
CFR(s): 493.851(f)

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:  
Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports from the American Association of Bioanalysts (AAB), the laboratory failed to maintain satisfactory performance in two consecutive events (3rd event of 2020 and 1st event of 2021), resulting in the first unsuccessful occurrence for Hematology # 760 including: Cell ID or white blood cell differential (WBC DIFF) # 765, red blood cell count (RBC) #775, hematocrit (HCT) # 785, hemoglobin (HGB) # 795, white blood cell count (WBC) # 805, platelets (PLT) # 815, PT #845, and PTT #835. Findings include: 1. Desk review of Casper Reports 153

and 155 disclosed the laboratory failed with the following scores: Hematology #760 Event 3 of 2020 and 1 of 2021 a score of 0% on both events WBC DIFF # 765 Event 3 of 2020 and 1 of 2021 a score of 0% on both events RBC # 775 Event 3 of 2020 and 1 of 2021 a score of 0% on both events HCT # 785 Event 3 of 2020 and 1 of 2021 a score of 0% on both events HGB # 795 Event 3 of 2020 and 1 of 2021 a score of 0% on both events WBC # 805 Event 3 of 2020 and 1 of 2021 a score of 0% on both events PLT # 815 Event 3 of 2020 and 1 of 2021 a score of 0% on both events PT #845 Event 3 of 2020 and 1 of 2021 a score of 0% on both events PTT #835 Event 3 of 2020 and 1 of 2021 a score of 0% on both events 2. Desk review of the laboratory's proficiency testing reports from AAB confirmed the laboratory failed event 3 of 2020 and 1 of 2021 resulting in the first unsuccessful performance.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

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.

This CONDITION is not met as evidenced by:  
Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports, the laboratory director failed to ensure the laboratory maintained satisfactory performance in two of three consecutive events (3rd event of 2020 and 1st event of 2021), resulting in the first unsuccessful occurrence for Hematology # 760 including: cell ID or WBC differential (DIFF) # 765, red blood cell count (RBC) #775, hematocrit(HCT) # 785, hemoglobin (HGB) # 795, white blood cell count (WBC) # 805 and platelets (PLT) # 815, PTT #835, PT #845; Chemistry #245 including: ALT(SGPT) #255, albumin #265, alk phos #275, AST (SGOT) #295, TOTAL BILIRUBIN (TBIL) #305, Calcium (CA) #345, Chloride (CL) #355, creatine #405, glucose #415, Potassium (K) #465, Sodium (Na) #475, total protein #485, BUN #505. Findings include: Refer to D 6016

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(i)

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:  
Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports, the laboratory director failed to ensure the laboratory maintained satisfactory performance in two of three consecutive events (3rd event of 2020 and 1st event of 2021), resulting in the first unsuccessful occurrence for Hematology # 760 including: cell ID or WBC differential (DIFF) # 765, red blood cell count (RBC) #775, hematocrit(HCT) # 785, hemoglobin (HGB) # 795, white blood

cell count (WBC) # 805 and platelets (PLT) # 815, PTT #835, PT #845; Chemistry #245 including: ALT(SGPT) #255, albumin #265, alk phos #275, AST (SGOT) #295, TOTAL BILIRUBIN (TBIL) #305, Calcium (CA) #345, Chloride (CL) #355, creatine #405, glucose #415, Potassium (K) #465, Sodium (Na) #475, total protein #485, BUN #505. Findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed analytes Hematology # 760 including: cell ID or WBC differential (DIFF) # 765, red blood cell count (RBC) #775, hematocrit(HCT) # 785, hemoglobin (HGB) # 795, white blood cell count (WBC) # 805 and platelets (PLT) # 815, PTT #835, PT #845; Chemistry #245 including: ALT(SGPT) #255, albumin #265, alk phos #275, AST (SGOT) #295, TOTAL BILIRUBIN (TBIL) #305, Calcium (CA) #345, Chloride (CL) #355, creatine #405, glucose #415, Potassium (K) #465, Sodium (Na) #475, total protein #485, BUN #505. on event 3 of 2020 with a score of 0% and event 1 of 2021 with a score of 0%. 2. Desk review of the laboratory's proficiency testing reports from American Association of Bioanalyts (AAB) confirmed the laboratory failed the aforementioned analytes on Event 3 of 2020 and Event 1 of 2021 resulting in the first unsuccessful performance.

**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 testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports, the laboratory director (LD) failed to ensure PT results are returned within the timeframes established by the proficiency testing program. Findings include: 1. Review of PT records for 2020 event 3 and 2021 event 1 revealed the laboratory received a score of 0% for "no results received". 2. Desk review of the laboratory's proficiency testing reports from American Association of Bioanalyts (AAB) confirmed the laboratory failed the aforementioned analytes on Event 3 of 2020 and Event 1 of 2021 resulting in the first unsuccessful performance due to "no results received".