| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 10D0270276 | 05/10/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Florida State Hospital Clinical Laboratory | 100 N Main St, Chattahoochee, FL | |

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 |
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| **D0000** | A desk review survey of the laboratory's proficiency test results was performed on May 10, 2022 for Florida State Hospital Clinical Laboratory. The Florida State Hospital Clinical Laboratory is not in compliance with the Code of Federal Regulations (CFR), Part 493, Laboratory Requirements. |
| **D2016** | SUCCESSFUL PARTICIPATION<br>CFR(s): 493.803(a)(b)(c)<br><br>(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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of the laboratory's proficiency testing records for 2021 and 2022, the laboratory did not have successful performance in proficiency testing in the subspecialty of routine chemistry. Refer to D2096. Findings include: Review of the College of American Pathologists (CAP) proficiency testing records and the review of |

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| | the Centers for Medicare & Medicaid Services (CMS) 153 and 155 reports, on May 10, 2022 on or about 11:00 AM, showed that the laboratory had unsatisfactory testing scores for the analyte, blood urea nitrogen (BUN) for two out of three testing events in 2021 and 2022. |
| **D2096** | ROUTINE CHEMISTRY<br>CFR(s): 493.841(f)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of the Centers for Medicare & Medicaid Services (CMS) 153 and 155 reports and the laboratory's proficiency testing records, the laboratory did not have successful performance in proficiency testing in the sub specialty of routine chemistry. Findings include: On may 10, 2022 on or about 11:00 AM the College of American Pathologists (CAP) proficiency testing records and the CMS 153 and 155 reports were reviewed. The review showed that the laboratory failed to achieve satisfactory performance for the analyte, blood urea nitrogen, (BUN), as shown below. Event #2, 2021 BUN-0% Event #1, 2022 BUN-60% |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on the review of the laboratory's proficiency testing records, the laboratory director failed to ensure that the laboratory maintained a satisfactory score for proficiency testing in the subspecialty of routine chemistry. Findings include: On May 10, 2022, on or about 11:00 AM, the College of American Pathologists (CAP) proficiency records and the Centers for Medicare & Medicaid Service (CMS) 153 and 155 reports were reviewed. The review showed that the laboratory had unsatisfactory testing scores for two out of three testing events for the analyte, blood urea nitrogen (BUN), in the sub-specialty of routine chemistry. The laboratory director is responsible for ensuring that the laboratory maintains successful participation in proficiency testing. Refer to D2096. |
| **D6016** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(i)<br><br>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; |

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| | This STANDARD is not met as evidenced by:<br>Based on the review of the laboratory's proficiency testing scores, the laboratory director failed to ensure that the laboratory performed proficiency testing in such a manner as to achieve and maintain successful participation in proficiency testing in the subspecialty of routine chemistry. Findings Include: The review of the College of American Pathologists (CAP) proficiency testing records and the Centers for Medicare & Medicaid Services (CMS) 153 and 155 reports on May 10, 2022, on or about 11:00 AM showed that the laboratory received unsatisfactory proficiency testing scores for two out of three testing events as shown below. Event #2, 2020 BUN-0% Event #1, 2022 BUN-60% |