

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0048776	(X3) Date Survey Completed 08/22/2022
Name of Provider or Supplier Louisiana State Penitentiary	Street Address, City, State 911 Warehouse Rd, Angola, LA	
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	An recertification survey was performed on August 21-22, 2022 at Louisiana State Penitentiary, 19D0048776, was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.803 CONDITION: Successful Participation 42 CFR 493.1403 CONDITION: Laboratory Director, Moderate Complexity
D2016	<p>SUCCESSFUL PARTICIPATION 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 review of proficiency testing results from the CMS-153D, CMS-155D and American Proficiency Institute (API) and interview with laboratory personnel, the laboratory failed to achieve a score of at least 80% for two consecutive events,</p>

resulting in initial unsuccessful performance as evidenced by: 1. The laboratory failed to achieve overall satisfactory performance for Routine Chemistry for two consecutive events. Refer to D2097. 2. The laboratory failed to achieve overall satisfactory performance for Endocrinology for two consecutive events. Refer to D2108. 3. The laboratory failed to achieve overall satisfactory performance for Toxicology for two consecutive events. Refer to D2119. 4. The laboratory failed to achieve overall satisfactory performance for Hematology for two consecutive events. Refer to D2131.

D2097

ROUTINE CHEMISTRY
CFR(s): 493.841(g)

Failure to achieve an overall testing event score of satisfactory performance for 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 a review of laboratory proficiency testing results and CMS reports, the laboratory failed to achieve overall satisfactory performance for Routine Chemistry for two consecutive events. Findings are: 1. Review of American Proficiency Institute (API) proficiency testing results and CMS Report 0153D and 0155D revealed the laboratory received unsatisfactory performance for the following two events resulting in the first unsuccessful participation for Routine Chemistry: Event 3 of 2021 with an overall score of 0% Event 1 of 2022 with an overall score of 0% 2. Review of patient testing records and instrument logs revealed patient testing and laboratory operation ceased from May 2021 - April 2022. 3. Interview with the laboratory director, technical consultant and testing personnel confirmed the laboratory did not notify the proficiency testing agency that the laboratory was not patient testing or operational for PT performance. Interview with the technical consultant stated they laboratory thought API was notified and they were not being graded during the period of PT failures.

D2108

ENDOCRINOLOGY
CFR(s): 493.843(g)

Failure to achieve an overall testing event score of satisfactory performance for 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 a review of laboratory proficiency testing results and CMS reports, the laboratory failed to achieve overall satisfactory performance for Endocrinology for two consecutive events. Findings are: 1. Review of American Proficiency Institute (API) proficiency testing results and CMS Report 0153D and 0155D revealed the laboratory received unsatisfactory performance for the following two events resulting in the first unsuccessful participation for Endocrinology: Event 3 of 2021 with an overall score of 0% Event 1 of 2022 with an overall score of 0% 2. Review of patient testing records and instrument logs revealed patient testing and laboratory operation ceased from May 2021 - April 2022. 3. Interview with the laboratory director, technical consultant and testing personnel confirmed the laboratory did not notify the proficiency testing agency that the laboratory was not patient testing or operational for PT performance. Interview with the technical consultant stated they laboratory

	<p>thought API was notified and they were not being graded during the period of PT failures.</p>
D2119	<p>TOXICOLOGY CFR(s): 493.845(g)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory proficiency testing results and CMS reports, the laboratory failed to achieve overall satisfactory performance for Toxicology for two consecutive events. Findings are: 1. Review of American Proficiency Institute (API) proficiency testing results and CMS Report 0153D and 0155D revealed the laboratory received unsatisfactory performance for the following two events resulting in the first unsuccessful participation for Toxicology: Event 3 of 2021 with an overall score of 0% Event 1 of 2022 with an overall score of 0% 2. Review of patient testing records and instrument logs revealed patient testing and laboratory operation ceased from May 2021 - April 2022. 3. Interview with the laboratory director, technical consultant and testing personnel confirmed the laboratory did not notify the proficiency testing agency that the laboratory was not patient testing or operational for PT performance. Interview with the technical consultant stated they laboratory thought API was notified and they were not being graded during the period of PT failures.</p>
D2131	<p>HEMATOLOGY CFR(s): 493.851(g)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory proficiency testing results and CMS reports, the laboratory failed to achieve overall satisfactory performance for Hematology for two consecutive events. Findings are: 1. Review of American Proficiency Institute (API) proficiency testing results and CMS Report 0153D and 0155D revealed the laboratory received unsatisfactory performance for the following two events resulting in the first unsuccessful participation for Routine Chemistry: Event 3 of 2021 with an overall score of 0% Event 2 of 2021 with an overall score of 0% 2. Review of patient testing records and instrument logs revealed patient testing and laboratory operation ceased from May 2021 - April 2022. 3. Interview with the laboratory director, technical consultant and testing personnel confirmed the laboratory did not notify the proficiency testing agency that the laboratory was not patient testing or operational for PT performance. Interview with the technical consultant stated they laboratory thought API was notified and they were not being graded during the period of PT failures.</p>
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</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.

This CONDITION is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Refer to D6016

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 review of the CMS-153D and CMS-155D reports and the American Proficiency Institute (API) proficiency testing records, the laboratory director failed to ensure that proficiency testing samples are satisfactory as required. Findings: 1. The laboratory failed to achieve overall satisfactory performance for Routine Chemistry for two consecutive events. Refer to D2097. 2. The laboratory failed to achieve overall satisfactory performance for Endocrinology for two consecutive events. Refer to D2108. 3. The laboratory failed to achieve overall satisfactory performance for Toxicology for two consecutive events. Refer to D2119. 4. The laboratory failed to achieve overall satisfactory performance for Hematology for two consecutive events. Refer to D2131.