

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2196666	(X3) Date Survey Completed 08/30/2024
Name of Provider or Supplier Physicians Lab Services, PLLC	Street Address, City, State 3786 Fm 1488, Suite 150a, Conroe, TX	
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 announced survey of the laboratory was conducted on 08/30/2024. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
D2111	<p>TOXICOLOGY CFR(s): 493.845(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's proficiency testing (PT) records and staff interview, the laboratory failed to participate in 1 of 4 reviewed PT events from 2022, 2023 and 2024, resulting in an unsatisfactory performance. Findings included: 1. Review of laboratory's PT records from 2022, 2023 and 2024 revealed the laboratory was enrolled in the American Proficiency Testing Institute (API) PT for its toxicology testing. 2. Further review of the above PT records revealed the laboratory received a score of "0% (percent) - Failure to Participate" for Event 1 of 2024. There was no documentation of alternate PT testing and/or self-evaluation for that event, nor documentation of notification to API within the time frame for submitting proficiency</p>

testing results about the circumstances associated with failure to perform PT. 3. In an interview on 08/30/2024 at 0940 hours in the breakroom, the Laboratory Director (as indicated on submitted Form CMS 116) confirmed the findings.

D5213

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(1)

The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:
Based on review of laboratory's proficiency testing (PT) records and staff interview, the laboratory failed to document evaluation of "Not Graded" results for 1 of 6 analytes in 4 Chemistry-Miscellaneous PT events reviewed from 2022, 2023 and 2024. Findings included: 1. Review of laboratory's PT records revealed the laboratory used American Proficiency Institute (API) as its PT provider. Review of API's instructions revealed: "Laboratories are responsible for documenting and performing corrective action for failures and must perform self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 2. Review of the PT records from 2022, 2023 and 2024 revealed the following analyte's "Not Graded" performance results did not have documentation of self-evaluation: 2022 Chemistry-Miscellaneous - 2nd Event Analyte: UDS Oxycodone (qual) Sample: UDS-04 Expected Results: See Data Summary Performance: Not Graded 3. In an interview on 08/30/2024 at 0940 hours in the breakroom, the Laboratory Director (as indicated on submitted Form CMS 209) confirmed the findings.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of a random sampling of laboratory's reports, review of laboratory's policies/procedures and staff interview, the laboratory failed to ensure 1 of 7 required report components was documented on final patient's report, specimen source. Findings included: 1. Review of a random sampling of laboratory's reports from June 2024 revealed the final report did not have documentation of 1 of the 7 required report components, specimen source. 2. Review of laboratory's policies/procedures revealed the policies/procedures did not specify the requirements for documentation of specimen source. 3. In an interview on 08/30/2024 at 1040 hours in the breakroom, the Laboratory Director (as indicated on submitted Form CMS 209) confirmed the findings.