| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br>04D2042678 | (X3) Date Survey Completed<br>07/25/2023 |
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| **Name of Provider or Supplier**<br>Physicians Laboratories Of America Llc | **Street Address, City, State**<br>10 Corporate Hill Drive Suite 180, Little Rock, AR | |

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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| **D6032** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(14)<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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Through a review of the CMS-209 form presented at the time of the survey, a review of personnel records for five personnel listed on the form CMS-209, and through interviews with laboratory staff, it was determined five of five testing personnel failed to have written authorization to perform testing without direct supervision. Survey findings include: A. Through a review of the CMS- 209 form, it was determined laboratory personnel # 2, # 3, # 4, # 5, and # 6, were designated as testing personnel. B. A review of personnel records for five testing personnel listed on the form CMS-209 revealed that five of five failed to have written authorization to perform testing without direct supervision. Laboratory personnel # 2, # 3, # 4, # 5, and # 6, did not have a written authorization to perform testing without direct supervision. C. In an interview at 11:13 a.m. on 7/25/2023, laboratory personnel # 3 (listed on the form CMS-209) confirmed that the laboratory did not have documented authorization for testing for employees performing moderate or high complexity testing. |
| **D6054** | TECHNICAL CONSULTANT RESPONSIBILITIES |

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| | CFR(s): 493.1413(b)(9)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Through a review of personnel records for two testing personnel performing general laboratory procedures, liquid chromatograph mass spectrometer (LCMS) operations, V-Twin operation, and technical/general supervisor assessment operations in the laboratory, and through lack of documentation, it was determined the laboratory failed to document competency annually. Survey findings include: A. A review of the personnel file for employee # 2 (listed on the CMS-209 Form) revealed the annual Competency Assessment for Technical Supervisors and Competency Assessment for General Supervisors dated 1/25/2022 and the next date 7/24/2023 was six months late. General Lab Competency and LCMS Operation Competency for emplyee # 2 was last documented 1/26/2022 which was due and is currently six months late. B. A review of the personnel file for employee # 3 (listed on the CMS-209 Form) revealed the annual General Lab Competency and V-Twin Operation Competency dated 1/17/2022 and the next date 4/5/2023 which was due by 1/17/2023 was three months late. C. In an interview, at 13:13 p.m. on 7/25/2023, laboratory employee # 3 confirmed there were no other competency assessments available. |