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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 04D2042678 | (X3) Date Survey Completed 01/31/2019 |
| Name of Provider or Supplier Physicians Laboratories Of America Llc | Street Address, City, State 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 |
|---------------------------|---|
| D5413 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Through a review of the laboratory policy and procedure manual, a review of 2018 Temperature/Humidity Record, and interviews with staff it was determined the laboratory criteria for storage of Cerilliant Calibration Standards was not consistent with the manufacturer's instructions. Survey findings include: A. A review of Certificates of Analysis for four Standards used in liquid chromatography / mass spectrophotometry (LC/MS) urine drug confirmations, revealed that three of four Standards (Ketamine Primary Standard, Nordiazepam Primary Standard, and Oxycodone Primary Standard) included storage instructions to "Store unopened in Freezer (-10 degrees to -25 degrees Celsius)". B. The policy and procedure manual for LC/MS states that the laboratory will store Standards at -80 +/- 5 degrees Celsius (not the (-10 to -25 degrees Celsius required by the manufacturer). C. A review of the 2018 Temperature/Humidity Record showed that the acceptable range for the freezer in which the Standards were stored was listed as -70 to -90 degrees Celsius instead of -10 to -25 degrees Celsius required by the manufacturer. D. In an interview, at 1:28 p. m. on 1/31/2019, laboratory employee #2 (as listed on the form CMS-209) confirmed the laboratory criteria for storage of Cerilliant Calibration Standards was not consistent with the manufacturer's instructions.</p> |

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Through a review of competency assessment documentation on two of two testing personnel, through lack of documentation, and through interviews with laboratory staff, it was determined the technical supervisor failed to evaluate the competency of testing personnel using the required six elements for evaluation. Survey finding follow: A. The competency assessments for three of three testing personnel were documented on a form with columns to indicate the methods of evaluation. B. The 2018 competency assessments for two of two personnel failed to include documentation of evaluation by direct observation, monitoring of recording and reporting of test results, review of records, direct observation of maintenance and function checks, assessment of blind samples, or assessment of problem solving skills as listed at 493.1451(b)(8). C. The 2017 competency assessments for two of two testing personnel included documentation of evaluation by direct observation, but did not include monitoring of recording and reporting of test results, review of records, direct observation of maintenance and function checks, assessment of blind samples, or assessment of problem solving skills as listed at 493.1451(b)(8). D. In an interview, on 1/31/2019 at 3:00 p.m., laboratory employee #2 (listed as the technical supervisor on the form CMS-209) confirmed the methods of competency assessment had not been documented as listed above.