| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 10D0719555 | 09/26/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Physicians Associates Pa | 10860 Sw 88th St, Miami, 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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| **D2007** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods<br><br>This STANDARD is not met as evidenced by:<br>Based on review of CAP (College of American Pathologists) proficiency testing for two-year period (2016 to 2018), and interview with testing person #1, the laboratory failed to rotate proficiency testing (PT) events to include all testing personnel who perform patient testing, for 6 of 6 events reviewed for hematology and urine hCG (Human chorionic gonadotropin) tests. The findings include: On September 26, 2018 at 12:30pm surveyor reviewed CAP proficiency testing record for six events (2016- 3rd event, 2017-1st, 2nd, 3rd events, 2018-1st and 2nd event). 1) Hematology PT showed that testing person #1 performed PT for 2016- 3rd event, 2017-1st, 2nd, 3rd events. For 2018-1st and 2nd event, two testing personnel (#1 and #2) had signed the CAP attestation forms for each test event, indicating testing personnel #1 and #2 both participated in same testing events. 2) Urinalysis and urine hCG PT showed that testing person #1 performed proficiency tests for year 2016 and 2017-1st event. For 2017 2nd event, 2018 1st and 2nd events two testing personnel (#1 and #2) had signed the CAP attestation forms for each test event, indicating testing personnel #1 and #2 both participated in same testing events. During an interview on September 26, 2018, at 4:45pm, the testing person#1 confirmed that: a) the testing person #1 and #2 performed both hematology, urinalysis, urine hCG patient testing but only testing person #1 performed hematology PT tests for 2016- 3rd event, 2017-1st, 2nd, 3rd events and performed urinalysis and urine hCG proficiency tests for year 2016 and 2017-1st event. b) For 2018-1st and 2nd event- hematology and for 2017 2nd, 2018 1st and 2nd events-urinalysis, urine hCG, two testing personnel (#1 and #2) had signed the CAP attestation forms for each test event, indicating testing personnel #1 |

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| | and #2 both participated in same testing events. c) Testing person #1 did not perform hematology proficiency testing independently for 1st and 2nd event 2018 and urinalysis, urine hCG proficiency testing independently for 2nd event 2017, 1st and 2nd event of 2018. d) Testing person #2 did not perform hematology, urinalysis, urine hCG proficiency testing independently from year 2016 to 2018. |
| **D2121** | HEMATOLOGY<br>CFR(s): 493.851(a)<br><br>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of CAP (College of American Pathologists) proficiency testing for two-year period (2016 to 2018), and interview with testing person #1, the laboratory failed to score at least 80% for cell identification (white blood cell differential) in the specialty of hematology in one (2017, 1st event) out of six (2016-3rd, 2017-1st, 2nd, 3rd, 2018-1st, 2nd) testing events reviewed. The findings include: On September 26, 2018 at 12:30pm surveyor reviewed CAP proficiency testing records for six test events (2016-3rd event, 2017-1st, 2nd, 3rd events, 2018-1st and 2nd event). It showed that laboratory scored 80% for cell identification (white blood cell differential) for the 1st event-2017. During an interview on September 26, 2018, at 4:45pm, the testing person #1 confirmed the cell identification (white blood cell differential) proficiency testing failure. |
| **D3011** | FACILITIES<br>CFR(s): 493.1101(d)<br><br>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation and the interview with the testing person #1, the laboratory failed to provide the safety and sanitary conditions to the testing personnel. The findings include: Observation on September 26, 2018 at 1) 10:30am surveyor observed the laboratory personnel - used gloves in regular trashcan. 2) 3:30pm surveyor observed another pair of the laboratory personnel - used gloves in regular trashcan. During an interview on September 26, 2018, at 4:45pm the testing person#1 confirmed both the findings that the regular trashcan had laboratory personnel - used gloves from hematology specialty at 10:30am and again at 3:30pm. |
| **D5221** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(d)<br><br>All proficiency testing evaluation and verification activities must be documented.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of CAP (College of American Pathologists) proficiency testing results for two-year period (2016 to 2018) and interview with testing person #1, the |

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| | laboratory failed to have documentation for corrective action for unsatisfactory test scores in cell identification ( white blood cell differentiation) for one (2017, 1st event) out of six (2016-3rd, 2017-1st, 2nd,3rd, 2018-1st, 2nd). The findings include: On September 26, 2018 at 12:30pm surveyor reviewed CAP proficiency testing records for six test events (2016-3rd event, 2017-1st, 2nd, 3rd events, 2018-1st and 2nd event). It showed that laboratory scored 80% for cell identification (white blood cell differentiation) for the 1st event-2017, and there was no documentation for the corrective action. During an interview on September 26, 2018, at 4:45pm, the testing person #1 confirmed that the laboratory scored 80% for cell identification (white blood cell differentiation) for 1st event- 2017, and did not have the corrective action and did not have the documentation of it. |
| **D5293** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(b)(c)<br><br>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review and the interview with the testing person #1, the laboratory had 1- CLIA certificate of compliance -only for hematology. 1- CLIA moderate complexity rapid test kit Sofia hCG (human chorionic gonadotropin) FIA ( fluorescence immunoassay) 50 tests in use. 2- Yearly competency evaluation questionnaire forms were signed and dated without answering Y for YES, N for NO or N/A for not applicable. 3- No corrective action taken. 4- No other quality assessment review records. The findings include: A) CLIA certificate of compliance showed only hematology specialty. B) Waived test records review on September 26, 2018 at12:00pm revealed that Sofia hCG FIA 50 test kit insert for urine pregnancy did not state if it was a waived test kit. Kit box had no 'CLIA waived' on it. C) McKesson product information had CLIA classification as CLIA moderate complexity for the test kit. D) Yearly competency evaluation record review at 3:30 pm from year 2016 to 2018 revealed that competency evaluation questionnaire forms for testing personnel were signed and dated without answering Y for YES, N for NO or N/A for not applicable for meeting the criteria of evaluations. E) Record review did not reveal any corrective action and laboratory had no other quality assessment review records. During an interview on September 26, 2018, at 4:45pm, the testing person#1 confirmed findings A to E. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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. |

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| | This STANDARD is not met as evidenced by:<br>Based on observation, record review and the interview with the testing person #1, the laboratory failed to monitor and record the humidity from 9/2016 to 9/26/2018 (for two-year review period) for hematology specialty. The findings include: On 9/26 /2018 at 2:30pm, surveyor did not see daily humidity check records in the instrument maintenance and temperature record logs. Beckman Coulter AcT Diff 2 hematology analyzer manual- ambient temperature and humidity stated, 'keep room temperature between 16*C and 35*C (61*F and 95*F) and humidity to between 20 and 85 percent without condensation'. During an interview on September 26, 2018, at 4:45pm, testing person # 1 confirmed that the laboratory did not monitor daily humidity as part of the environmental requirement for Beckman Coulter AcT Diff 2 Hematology analyzer. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review and interview with testing person, laboratory failed to have 1) The manufacturer's instructions -operator's manual for the recommended maintenance and function checks, and maintenance for Atherotech Diagnostics Lab centrifuge. 2) The biennial calibration and earth ground testing for three Quest Diagnostics Horizon Model 642E centrifuges for the two year (9/2016 to 9 /26/2018) record review period. The findings include: During a laboratory tour on 9/26 /18 at 2:30 pm, surveyor observed -a) Atherotech Diagnostics Lab centrifuge with no manufacturer's instructions or operator's manual for the recommended maintenance and function checks and no maintenance records. b) Three Quest Diagnostics Horizon Model 642E centrifuges, with inspection dates as 4/28/14, 1/23/15 and 9/1/15. Calibration and earth ground testing recommended as 'top speed, ground continuity and line leakage be tested every two years for continued safe operation'. Maintenance record review did not show records for centrifuge maintenance from year 2016 to 2018. During an interview on September 26, 2018, at 4:45pm, testing person #1 confirmed that the laboratory I) Did not have manufacturer's instructions or operator's manual for the recommended maintenance and function checks, no maintenance, no maintenance records for Atherotech Diagnostics Lab centrifuge. II) Did not perform biennial recommended maintenance on three Quest Diagnostics Horizon Model 642E centrifuges for two-year record review period from 2016 to 2018 and had no records. |