

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0719555	<b>(X3) Date Survey Completed</b>  12/22/2022
<b>Name of Provider or Supplier</b>  Physicians Associates Pa	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey conducted from 12/20/2022 to 12/22/2022 found the PHYSICIANS ASSOCIATES PA clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories. Cited the following Conditions: -D2000 Enrollment and Testing of Samples. -D2016 Successful Participation. -D6000 Moderate Complexity Laboratory Director.
<b>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to enroll in a Proficiency Testing (PT) program approved by the Department of Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS) for the specialty of Hematology during first and second event of 2022. Findings include: -Review of College of American Pathologists (CAP) PT records revealed that the laboratory had no results for PT for the Hematology Specialty for the first and second events of 2022. During an interview on 12/20/2022 at 1:30 PM. the Office Manager confirmed that the facility failed to enroll in PT for 2022 for the events of reference.</p>
<b>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p>

The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

This STANDARD is not met as evidenced by:  
Based on record review and staff interview, the laboratory failed to have attestation signed by testing person (TP) and laboratory director (LD) for 1 out of 4 events reviewed for hematology specialty in 2021 and 2022. Findings include: -Review of College of American Pathologists (CAP) Proficiency Testing (PT) records for years 2021 and 2022 revealed that the laboratory failed to have a signed attestation for the second event of Hematology of 2021 During an interview on 12/20/2022 at 1:45 PM, the office manager confirmed that the laboratory failed to have a signed attestation for the event of reference.

**D2016**

**SUCCESSFUL PARTICIPATION**  
CFR(s): 493.803(a)(b)(c)

(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.

This CONDITION is not met as evidenced by:  
Based on review of the laboratory's Proficiency Testing records for 2022, the laboratory did not have successful performance in Proficiency Testing (PT) for analytes in the specialty of Hematology. Refer to D2130.

**D2127**

**HEMATOLOGY**  
CFR(s): 493.851(d)

Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

This STANDARD is not met as evidenced by:  
Based on review of College of American Pathologists (CAP) Hematology Proficiency Testing (PT) results and interview, the laboratory failed to submit PT results in the

	<p>specified timeframe for third event of 2021 for the specialty of Hematology resulting in a score of 0% for all Hematology analytes. Findings include: Review of CAP Hematology PT records revealed that the laboratory failed to submit the results for the third event of 2021 on time resulting in a score of 0 % for Hematology Specialty, Cell Identification or White Blood Differential, Red Blood Cell, Hematocrit, Hemoglobin, White Blood Cells and Platelets. During an interview on 12/20/2022 at 1:00 PM, the office manager confirmed that the laboratory failed to submit on time the results for the third event of 2021.</p>
<p><b>D2130</b></p>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of College of American Pathologists (CAP) Hematology Proficiency Testing (PT) results and interview, the laboratory did not have successful performance in PT for analytes in the specialty of Hematology. Findings include: Review of CAP Hematology PT records revealed that the laboratory had an unsatisfactory score of 0% for Hematology Specialty, Cell Identification or White Blood Differential, Red Blood Cell, Hematocrit, Hemoglobin, White Blood Cells and Platelets in the third event of 2021. The laboratory did not have results for first and second event of 2022 and for the third event of 2022 had 0% score for Hematocrit and Hemoglobin with an overall percentage of 67% in the Hematology specialty resulting in a unsatisfactory result for this event. The PT overall evaluation for the laboratory performance was Unsuccessful for Hematocrit, Hemoglobin and the Specialty of Hematology. Refer to D2127. During an interview on 12/20/2022 at 1:10 PM, the office manager confirmed that the laboratory had the unsuccessful result for PT 2022.</p>
<p><b>D3031</b></p>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with office manager, the laboratory failed to retain daily Quality Control (QC) records for 14 out of 24 months reviewed (2021 and 2022). Findings include: Review of QC records for 2021 and 2022 revealed that the laboratory failed to have the records for 2021 and for September and October 2022. During an interview on 12/20/2022 at 1:35 PM, the office manager confirmed that the laboratory failed to have onsite during the survey the daily QC records of reference.</p>
<p><b>D3033</b></p>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)(i)</p> <p>In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years.</p>

This STANDARD is not met as evidenced by:  
Based on record review and interview with office manager, the laboratory failed to retain daily maintenance for Coulter Ac T diff analyzer records for 18 out of 24 months reviewed (2021 and 2022). The laboratory failed to have room temperature and humidity records for 18 out of 24 months reviewed (2021 and 2022). Findings include: Review of Coulter Ac T diff analyzer maintenance records for 2021 and 2022 revealed that the laboratory failed to have the records of year 2021 and from January to July of year 2022. Review of room temperature and humidity records revealed that the laboratory failed to have on site the records for 2021 and for January to July of 2022. During an interview on 12/20/2022 at 1:40 PM, the office manager confirmed that the laboratory failed to have onsite maintenance, room temperature and humidity records of reference.

**D5417**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:  
Based on observation, record review and interview, the laboratory had expired controls in use from 12/05/2022 to 12/20/2022. Findings include: -During the laboratory tour on 12/20/2021 at 11:30 AM, the surveyor observed that the laboratory was using Coulter 4C-ES Cell Control with Lot numbers: 069000, 079000 and 089000 and the vials were labeled with open date of 10/24/2022. The open vials have been in use for 50 days. -Review of the Coulter 4C-ES Cell Control user instructions revealed that used controls had an expiration date of 35 days after opening. -Review of patient records revealed that the laboratory tested patients using the expired controls in the following dates: 12/05/2022 tested 1 patient, 12/06/2022 tested 1 patient, 12/13/2022 tested 2 patients, 12/14/2023 tested 2 patients, 12/15/2022 tested 1 patient and on 12/19/2022 tested 3 patients. In total 10 patients were tested with the expired controls. During an interview on 12/20/2022 at 12:30 PM the officer manager confirmed the use of the expired controls for the days listed above.

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected

by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:  
Based on record review and interview with office manager, the laboratory failed to have documentation of the calibration verification for the Coulter Ac T Diff complete blood counter at least every 6 months from 01/01/2021 to 12/19/2022. Findings include: -Review of the Coulter Ac T Diff Analyzer records during 2021 and 2022 revealed that the laboratory performed calibration on 12/15/2021 and 09/27/2022. No other calibration records found. During an interview on 12/20/2022 at 12:30 PM, the office manager confirmed that the laboratory failed to have documentation of calibration verification at least every six month for 2021 and 2022.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:  
Based on lack of records and interview, the Quality Assessment (QA) failed to document the deficiency of failure to submit Proficiency Testing (PT) results for third event of 2021 and to review the results. Failed to do corrective action for no enrollment in PT in 2022 first and second event. Failed to do corrective action for the failure in the PT in third event of 2022. Failed to correct missing calibrations verifications to the Coulter Ac T diff during 2021 and 2022. Failed to do corrective action for the incomplete documentation of required maintenance for the Coulter Ac T diff. Failed to identify and correct the lack of records for room temperature and humidity requirement. Failed to identify the lack of records for daily quality control for year 2022 and September and October 2022. Findings include: Review of laboratory records for 2021 and 2022 revealed the following: -No documentation of the results review for the third event of PT of 2021 that the laboratory failed to submit results to CAP. No corrective action documented. Refer to D2127. -No documentation of corrective action for the failure to enroll in PT for first and second event of 2022. Refer to D2000. -No documentation of corrective action for the failure in PT in the third event of 2022. Refer to D2016 and D2130. -No corrective action for missing calibrations verification for Coulter Ac T Diff. Refer to D5439. -No corrective action for missing documentation for Quality Control, maintenance and temperature records. Refer to D3031, D3033. During an interview on 12/20/2022 at 2:00 PM, the office manager confirmed that the QA failed to correct the deficiencies listed above.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

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 staff interview, the laboratory director failed to effectively oversee the laboratory. Findings include: -Failed to ensure the laboratory enrolled in an approved Proficiency Testing program in first and second event of 2022. Refer to D6015. -Failed to ensure the laboratory review Proficiency Testing results. Refer to D6018. -Failed to ensure the laboratory followed the Quality Control and Quality Assurance. Refer to D6022.

**D6015**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)

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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on review of College of American Pathologists (CAP) Proficiency Testing records (PT) and interview with office manager, the laboratory director (LD) failed to ensure that the facility enrolled in a PT program approved by the Department of Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS) for Hematology Specialty during the first and second event of 2022. Findings include: Review of CAP PT evaluation results for 2022 revealed blank results in the first and second event of 2022. Refer to D2000. During an Interview on 12/20/2022 at 12.30 PM, the office manager confirmed that the LD failed to ensure the facility to enroll PT program for first and second events of 2022.

**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 proficiency testing records (PT) and interview with office manager, the laboratory director (LD) failed to ensure the laboratory performed PT in such a manner as to achieve and maintain successful participation in PT for analytes found in the specialty of Hematology. Finding included: Review of College of American Pathologists (CAP) CAP PT evaluation results revealed the laboratory received unsatisfactory score for two out of three events for the analytes listed below:

-2021 third event revealed 0% results for: Cell ID, Red Blood cells, Hematocrit, Hemoglobin, White Blood Cells and Platelets. -2022 first and second event of 2022 had no results. No enrollment in PT. -2022 third event: 0% results for Hematocrit and Hemoglobin. During an Interview on 12/20/2022 at 12.30 PM, the office manager confirmed that the LD failed to ensure the laboratory performed PT in such a manner to achieve and maintain successful participation in Hematology specialty.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iii)

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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:  
Based on review of College of American Pathologists (CAP) Proficiency Testing (PT) records and interview with officer manager (OM), the laboratory director failed to review the results for two out of four PT events reviewed (2021 and 2022). Review of CAP PT records revealed the following: -The laboratory failed to submit results for third event of Hematology 2021. Refer D2127. No review of the results documented. - The laboratory failed the third event of Hematology in 2022. Refer to D2130. No review of the results documented. During an interview on 12/20/2022 at 12:30 PM, the OM confirmed that the laboratory director failed to review the PT results of reference.

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:  
Based on record review and interview with office manager, the Laboratory Director failed to ensure the Quality Assessment (QA) corrected the laboratory deficiencies. Refer to D5791.