Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0213084	01/27/2021
Name of Provider or Supplier	**Street Address, City, State**	
Potomac Physician Associates-Chevy Chase	8401 Connecticut Ave Penthouse Suite, Chevy Chase, MD	

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
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on remote survey record review and phone interview with the testing person and technical consultant, the laboratory failed to document all components of the investigation of failed proficiency testing (PT) results and the corrective actions taken to prevent recurrence of PT failures (D5221).
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: I. Based on remote survey record review and phone interview on 01/27/2021 with the testing person (TP) and technical consultant (TC), the laboratory failed to document all corrective actions taken to prevent recurrence of the proficiency testing (PT) failures for Vitamin D and Carbon Dioxide (CO2) testing. Findings: 1. The PT investigation records provided by the laboratory on 01/13/2021 showed the following results for the Vitamin D analyte: a) 2019 MLE-M1 (Medical Laboratory Evaluation-

	Module 1), Vitamin D- 0%. The investigation identified that the specimens were switched, but failed to address the potential that switching PT specimens would have on actual patient results. b) 2019 MLE-M2, Vitamin D- 50%. The investigation stated that the specimen was re-run and the result was within the acceptable range. The quality control (QC) results were acceptable on the day the specimen was initially run. The investigation failed to mention if there was a high or low bias with the QC results. There was no mention of how these failures might affect patient test results. At this point, the laboratory had 2 consecutive failures for a non-regulated analyte and the investigations failed to resolve the problem. c) 2019 MLE-M3, Vitamin D- 50%. The investigation stated that the specimens were re-run and the result was within the acceptable range. The QC results were acceptable on the day the specimen was initially run. The investigation failed to mention if there was a high or low bias with the QC results. There was no mention of how these failures might affect patient test results. At this point, the laboratory had 3 consecutive failures for a non-regulated analyte and the investigations failed to resolve the problem. d) 2020 MLE-M3, Vitamin-D 50%. The investigation identified a "mixing issue." The investigation did not include reviewing proper mixing of the PT specimen with the testing personnel. The laboratory had a recurrence with Vitamin D failure. 2. The PT records provided by the laboratory on 01/13/2021 showed the following results for the CO2 analyte: a) 2020 MLE-M1, CO2 60%. The investigation stated that the specimens were brought to room temperature and re-run and the values were within acceptable range. b) 2020 MLE-M2, CO2 60%. The investigation implied that the specimens were re-run and one of the values was still unacceptable. At this point, the laboratory had 2 consecutive failures for a non-regulated analyte and the investigations failed to resolve the problem. 3. Each investigation failed to identify the root cause of the failures and evaluate the potential for patient test results to be affected. II. Based on remote survey record review and phone interview on 01/27/2021 with the testing person (TP) and technical consultant (TC), the laboratory failed to document all corrective actions when investigating the PT failures for the first Medical Laboratory Evaluation (MLE) event in 2020. Findings: 1. The PT documentation submitted on 01 /13/2021 showed that there were failures for phosphorous, CO2, lactate dehydrogenase and sodium. 2. In the "Quality System Assessment" section, the laboratory circled "No" for the question "Did the reason for the error affect patient results?" There was no investigation into the root cause of the failures and the laboratory did not explain why patient results would not have been affected nor did they note whether a review of patient results at the time of the PT failure was performed. 3 The laboratory failed to complete the "MLE Corrective Action Record" with all the corrective actions taken to prevent recurrence of the failed PT results.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by: Based on review of maintenance logs and phone interview on 01/27/2021 with the testing personnel (TP), the laboratory failed to perform and document maintenance as defined by the manufacturer for multiple analyzers. Findings: 1. Routine maintenance logs for Beckman AU480, Sysmex XS-1000i and Beckman Access 2 analyzers for December 2018 through February 2019, November 2019 through March 2020, and

	July 2020 through October 2020 were reviewed. 2. Review of the Beckman AU480 Maintenance Logs showed that no monthly maintenance activities were checked off for July and August 2020 and for February 2019, the daily activity "Replace the DI Water in the Pre-dilution Bottle" was not checked off 19 of 20 days. 3. Review of the Sysmex XS-1000i Maintenance Logs showed that no monthly maintenance was performed for February and March 2020. 4. Section 8.2 titled "Daily Maintenance" of the Beckman Access 2 Operator's Guide (C42384) states that daily maintenance should be performed every 24 hours and is made up of 5 procedures performed in sequence. Number 4 in the sequence is "Prime the Substrate". 5. Review of the Beckman Access 2 Maintenance Logs showed that the "Prime Substrate" was not checked off for 8 of 14 days in December 2018; 11 of 14 days in January 2019; 6 of 9 days in February 2019; 12 of 13 days in November 2019; 12 of 14 days in December 2019, February 2020, July 2020 and August 2020; 15 of 17 days in January 2020; 11 of 13 days in March 2020; 11 of 15 days in September 2020 and 13 of 18 days in October 2020. 6. During a phone interview on 01/27/2021 at 10:30 AM, the TP stated that the laboratory primes the substrate only when the bottle is replaced in the instrument. The laboratory failed to performed the required maintenance defined in the Beckman Access 2 Operator's Guide. 7. Review of the records show that the laboratory failed to perform routine maintenance on the multiple analyzers used in the laboratory as defined by each of the manufacturers.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on remote survey record review and phone interview with the testing person and technical consultant, the laboratory director failed to ensure that the laboratory implemented correctives action to prevent continued failures of the proficiency testing samples for Vitamin D and carbon dioxide testing. Cross refer to D5211 for details.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on remote survey record review and phone interview on 01/27/2021 with the testing person (TP) and technical consultant (TC), the TC failed to ensure that technical oversight was provided during the investigation of proficiency testing (PT) failures. Findings: 1. Review of the PT investigations for 2019 and 2020 submitted on 01/13/2021 showed that the TP performed the investigations but the TC failed to provide technical oversight. Cross refer to Tag D5221 for details. 2. The "Proficiency Testing" element of the "Quality Assessment Review" documents from 2019 and

	2020 were reviewed. 3. The "Proficiency Testing" element from 04/17/2019 stated "All results received as acceptable. One Iron assay (CH2) and one CO2 (CH5) assay were just out of acceptable range; samples will be repeated to determine if due to random error, or if further action needs to be taken. Vitamin D assay failed, but upon investigation is seems to be a transcription error (results attached to incorrect specimen - would be 100% if reported correctly)." 4. The "Proficiency Testing" element from 07/23/2019 stated "Received all results at 100% except for one Vitamin D result which was slightly under required value. Corrective Actions documented showed random error likely as repeated value was acceptable." At this point, the laboratory had 2 consecutive failures for the non-regulated analyte Vitamin D. 5. The "Proficiency Testing" element from 11/06/2019 stated "All results were received as acceptable. One Vitamin D and one Retic were just slightly out of Acceptable Range. Any actions taken for investigative purposes will be documented and kept in Proficiency Testing file." At this point, the laboratory had 3 consecutive failures for the non-regulated analyte Vitamin D. 6. The "Proficiency Testing" element from 05/06 /2020 stated "Phosphorous at 40%; CO2 at 60%; Sodium and LDH at 80% and one Urinary Sediment cast was misidentified. Any actions taken for investigative purposes will be documented and kept in Proficiency Testing file." The PT investigations that were reviewed failed to include re-education of the TP who perform microscopic urinalysis. 7. The "Proficiency Testing" element from 11/12/2020 stated "All regulatory assays were received at 100%. Assays that did not receive 100% are non-regulated, but must still be investigated and addressed for Corrective Actions. (Reticulocytes, A1c, CO2 and Vitamin D). Any actions taken for investigative purposes will be documented and kept in Proficiency Testing file." At this point, the laboratory had 2 consecutive failures for the non-regulated analyte CO2 (2020 MLE-M1, 60% and 2020 MLE-M2, 60%). The laboratory had a recurrence with Vitamin D failure. 8. The documented QA reviews performed by the TC failed to address whether the testing personnel were given training and technical assistance as a corrective action to prevent recurrence of PT failures.