

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0213084	(X3) Date Survey Completed 06/20/2018
Name of Provider or Supplier Potomac Physician Associates-Chevy Chase	Street Address, City, State 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
D2094	<p>ROUTINE CHEMISTRY CFR(s): 493.841(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, interview with the laboratory manager, and the technical consultant, the laboratory did not perform corrective action procedures for failed PT. Findings: 1. The laboratory failed BUN for the 2017 1st event chemistry, score 40%. 2. The laboratory did not perform an investigation for the failed result. 3. The laboratory PT procedure states that all PT failures will be investigated and corrective action procedures will be performed. 4. The laboratory manager and the TC confirmed that corrective actions procedures were not performed for the failed BUN result for the 2017 1st event chemistry.</p>
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p>

	<p>This STANDARD is not met as evidenced by: Based on observation of the hematology staining materials at 10:30 AM and interview with the laboratory manager, the laboratory did ensure that flammable materials were stored according to the manufacturers instructions. Findings: 1. The laboratory staining reagents for performing peripheral smears were not stored in a flammable proof cabinet. 2. The reagents manufacturers instructions states that the reagents are flammable and should be stored accordingly. 3. The laboratory manager stated that she was not aware that the materials were flammable.</p>
D3031	<p>RETENTION REQUIREMENTS 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 review of laboratory test results, interview with the laboratory manager, and the testing person, the laboratory did not maintain all laboratory quality control (QC) results for two years after completion of the test. Findings: 1. The laboratory performed the Vitamin B12 QC level one on February 22, 2018. 2. The Vit B12 level one control was out of range. A new set of controls were opened to repeat the QC and the Vit B12 Level one was in acceptable range. 3. The laboratory did not maintain the out of range QC result along with the repeated in range QC result. 4. The laboratory confirmed that the Vit B12 QC result that was out of range was not maintained by the laboratory.</p>
D3041	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6)</p> <p>Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting.</p> <p>This STANDARD is not met as evidenced by: Based on review of preliminary patient results, interview with the laboratory manager, and the testing person, the laboratory did not maintain all original reports obtained through laboratory testing. Findings: 1. The laboratory did not maintain the original preliminary patient report for endocrinology testing at least two years after patient testing was completed. 2. The laboratory manager stated that the patient results and test orders are in the electronic medical record but the instrument printout is keep for two weeks with the physician order than discarded. 3. The laboratory manager stated that she was not aware that preliminary results needed to be maintained for two years.</p>
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</p>

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.

This STANDARD is not met as evidenced by:

Based on review of humidity logs, interview with the laboratory manager, and the technical consultant (TC), the laboratory did not ensure that humidity levels were maintained for the overall acceptability of performing laboratory testing. Findings: 1. The humidity levels were out of range on January 9-10, 2017. 2. The range for humidity is 20-80% and on 1/9/17 and 1/10/17 the level was 19%. 3. The humidity log was reviewed and signed by the laboratory manager and monthly by the TC. 4. The humidity level was not checked again throughout the day shift. 5. The laboratory manager confirmed that the humidity level was out of range January 9-10, 2017 and a recheck was not performed.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(14)

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.

This STANDARD is not met as evidenced by:

Based on review of the technical consultant duties, interview with the laboratory manager, and the technical consultant (TC), the laboratory director (LD) failed to provide a schedule for the TC to report to the lab and contact information. Findings: 1. The LD did not provide in the written duties a recurring schedule for the TC to follow when reporting to the laboratory and contact information when problems occur. 2. The laboratory manager confirmed that the TC did not have a schedule documented in the duties for reporting to the laboratory and contact information was not available.

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:

Based on review of the quality control (QC) records and interview with the technical

consultant (TC), the TC failed to review all QC to ensure the overall acceptability of performing laboratory testing. Findings 1. The TC did not review and sign the hematology QC levels 2/3 from August 1-25, 2017. 2. The TC did not review and sign the chemistry QC from July 3-31, 2017. 3. The TC did not document in the TC notes that the review was performed. 4. The TC confirmed that she did not review all QC to ensure the acceptability of performing laboratory testing.

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on review of competency records, interview with the laboratory manager, and the technical consultant (TC), the TC did not ensure that all testing personnel performed proficiency testing (PT) procedures. Findings; 1. Review of testing personnel competency procedures showed the PRN testing person did not perform PT. 2. The laboratory manager stated that the testing person is only here a few times a year. 3. The proficiency testing procedure states that PT will be rotated for testing personnel. 4. The laboratory manager confirmed that all persons performing laboratory testing did not receive PT competency assessment procedures.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as 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 result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of the written procedure manual and interview with the laboratory manager, the laboratory director failed to establish the duties and responsibilities of testing personnel performing high complexity testing. Findings: 1. Review of the written procedure manual stated that laboratory techs perform review and reporting of abnormal peripheral smears. 2. The duties and responsibilities of laboratory personnel did not state that high complexity testing of abnormal smear reviews were performed. 3. The laboratory manager stated that she was unaware that when laboratory technologist perform abnormal peripheral smear reviews were considered high complexity testing.