| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 11D0264233 | 06/21/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Piedmont Physicians Urology Macon | 330 Hosptial Drive, Bldg C, Cuite 315, Macon, GA | |

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 |
|---|---|
| **D0000** | A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on June 21, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited: |
| **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 Proficiency Testing (PT) documentation and staff interview, the laboratory was not rotating the performance between ALL testing personnel listed on the CMS 209 form. Findings: 1. Review of the PT documentation the laboratory was not rotating testing with all testing personnel: 2016 3rd event was performed by staff #2, #3, #7(CMS 209 form) 2017 1st event was performed by staff #2, #7 2017 2nd event was performed by staff #2, #3, #7 2017 3rd event was performed by staff #2, #7 2018 1st event was performed by staff, #2, #3, #7 Staff #4, #5, and #6, never performed PT samples. 2. Interview with the billing manager, and staff #3, and #7, (CMS form 209) on June 21, 208 at approximately 2:42 pm in the office manager's office, confirmed that PT testing was not being performed by all testing personnel listed on the CMS 209 form. |
| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Proficiency Testing (PT) Documentation, the laboratory failed to provide signed attestation documents stating that the PT samples were handled the same manner as patient samples for all testing events. Findings: 1. Review of the PT documents showed that the attestation statement was not signed both the testing personnel(TP) an the lab director (LD). 2016 3rd event, was signed by TP and LD 2017 1st event, was signed by TP only 2017 2nd event, was signed by TP only 2017 3rd event, was NOT signed 2018 1st event, was signed by TP only 2. Interview with the billing office manager, and staff #3, and #7, (CMS form 209) confirmed that the attestation statements were not being signed appropriate as indicated above. |
| **D5213** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(b)(1)<br><br>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Proficiency Testing(PT) documents and staff interview, the laboratory failed to perform a self evaluation on the Prostate Specific Antigen testing that was not submitted for evaluation. Findings: 1 Review of the PT documents showed that the 2nd event for 2017 results were not graded due to not being submitted by the deadline. The results were not self evaluated. 2 Interview with the billing manager, and staff #3 and #4 (CMS 209 form) on June 21, 2018 at approximately 2: 35 pm in the office manager's office, confirmed that the unsubmitted results had not been self evaluated. |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the proficiency testing(PT) documentation, and staff interview, the laboratory failed to verify the accuracy of the provider performed (PPM) urine microscopic procedure performed. Findings: 1. Review of the proficiency testing documentation the laboratory was not participating in a PT evaluation for the urine microscopic procedure. 2. Staff interview with the billing manager, and staff #3, and staff #7 (CMS form 209) on June 21, 2018 at approximately 2:48 pm in the office manager's office, confirmed the laboratory was not performing PT evaluation for the PPM urine microscopic procedure and was not performing peer review for the PPM urine microscopic procedure. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a) |

| | |
|---|---|
| | A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the procedure manuals and staff interview the laboratory failed to provide a written procedure for the definition of critical values for patient results. Findings: 1. Review of the procedure manuals revealed that there was not a procedure for listing the critical values for patient results and the procedure to follow when a critical value resulted and notifying the provider. 2. Staff interview with the billing manager, and staff #3, and #7 (CMS form 209) on June 21, 2018 at approximately 2: 42 pm, in the office manager's office confirmed that the laboratory did not have a procedure for the reporting of critical values for patient results. |
| **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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Nano Entek Frend System (Frend System) specifications and staff interview, the laboratory failed to monitor the room temperature and the humidity in the laboratory area where the Frend system is located. Findings: 1. Review of the Frend System specifications revealed that the laboratory failed to follow manufacturer's recommendations for monitoring the optimal operating room temperature (15 to 30 degrees Celsius), and optimal operating humidity (10 % to 80%) for 2017 and 2018 up to the date of the survey. 2. An interview with the billing manager, and Testing Personnel (PT) #3 and #7, in the Office Manager's office, on June 21, 2018 at approximately 2:20 pm, confirmed that there were no laboratory room temperature records and no room humidity records in the testing area. Based on review of the maintenance logs and staff interview the laboratory failed to provide a log for the maintenance on the eyewash, the microscope, and the centrifuges. Findings: 1. Review of the maintenance logs revealed that the lab was not performing the daily or weekly maintenance on the eyewash station, also revealed the lab was not performing the maintenance on the microscope, or the centrifuges (the Lab Corp Horizon miniE was last calibrated 01/22/2008, and the Quest Vanguard V6500 was last calibrated on 04/24/1997). 2. Staff interview with the billing manager, and staff #3, and #7 (CMS form 209) on June 21, 2018 at approximately 2:42 pm, in the office manager's office confirmed that the laboratory was not performing maintenance on the eyewash, the microscope maintenance, or centrifuge maintenance. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation and interview with testing personnel (TP), the lab failed to calibrate the LabCorp Horizon Mini E , Quest VanGuard V6500, or Stat Spin Express 2 centrifuges per the manufacturer. Findings include: 1. Observation during the lab tour revealed the LabCorp Horizon Mini E centrifuge was last calibrated on 1/22/18, Quest VanGuard V6500 was last calibrated on 4/24/97, StatSpin Express 2 was last calibrated in the factory - no calibration noted on the centrifuge. 2. Interviews with TP #--- (CMS 209 form) on 06/21/18 in the practice manager's office at approximately 230 PM, confirmed the centrifuges had not been calibrated as required. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of the Nano Entek Frend System (Frend System) specifications, and staff interview, the laboratory failed to perform Verification of Linearity and Precision as required in the Frend System Procedure. Findings: 1. Based on review of the Frend System Procedure, Verification of Linearity and Precision should be performed when a new analyzer is put into use and every 6 months thereafter, and documented on the Monthly Maintenance Log. There was no documentation that the Verification of Linearity and Precision was performed after January 2017 up until June 21, 2018, the date of the survey. 2. Interview with the billing manager, and Testing Personnel #3 and #7 (CMS form 209), in the Office Manager's office, on June 21, 2018 at approximately, 2:15 pm, confirmed that there was no documentation that the Verification of Linearity and Precision had been performed after January 2017 up until the date of the survey, June 21, 2018. |
| | |

| | |
|---|---|
| **D5447** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(i)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Quality Control (QC) documents and staff interview, the laboratory failed to perform QC as required ,at least once a day patient specimens are assayed using two control materials of different concentrations, on the NanoEntek Frend System (Frend System). Findings: 1. Review of the QC documents for the Frend System, showed that two levels of liquid controls were not being performed once a day patient specimens were assayed. 2. Interview with the billing manager, and staff #3 and #7 (CMS form 209), at approximately 2:40 pm, on June 21, 2018, in the Office Manager's office, confirmed that two levels of liquid controls were not being performed once a day on days patients specimens were being assayed. |
| **D5789** | TEST RECORDS<br>CFR(s): 493.1283(b)<br><br>Records of patient testing including, if applicable, instrument printouts, must be retained.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the proficiency testing (PT) documents and staff interview the laboratory failed to save the instrument printout from the the Prostate Specific Antigen (PSA) analyzer used for testing the PT samples. Findings: 1. Review of the PT documents for the 2016 - 3rd event , and 2017 - 1st, 2nd, and 3rd event, there were no instrument printouts for the analyte PSA attached to each event. 2. Interview with the billing manager, and staff #3, and #7, (CMS 209 form) on June 21, 2018 at approximately 2:33 pm, in the office manager's office, confirmed that there were no instrument printouts attached to the events listed above. |
| **D5793** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(b)(c)<br><br>(b) The analytic 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 analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Quality Assessment(QA) policy and procedure, and staff interview, the laboratory failed to monitor the effectiveness of corrective actions taken to resolve problems, to prevent recurrence of problems, and discuss analytic systems quality assessment reviews with appropriate staff. Findings: 1. Review of the Quality |

| | |
|---|---|
| | Assessment documentation showed that the laboratory had not documented any QA assessments since December 2016. 2. Interview with the billing manager, and staff #3, and #7 (CMS 209 form), on June 21, 2018 at approximately 2:50 pm in the office manager's office, confirmed that they laboratory had not performed any QA assessments since December 2016. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of a test report and staff interview, the laboratory does not have all of the required information on the report that is sent to another provider. Findings: 1. Review of a copy of at patient report that is sent to another provider, the report shows the patient name, the date the test was ordered, the name of the test, which machine it was ran on, who was the technician, venipuncture, and venipuncture site. The report does not have: The name and address of the testing lab, The units of measurement The Reference Range 2. Interview with the billing manager and staff #3 and #7 (CMS form 209), on June 21, 2018, at approximately 2:30pm confirmed that the test report did not have all of the required information listed. |
| **D6007** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(1)<br><br>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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of the Nano Entek Frend System implementation and installation documents, and staff interview, there was no documentation that the Laboratory Director(LD) reviewed and approve the use of the Nano Entek Frend System for the testing of Prostate Specific Antigen (PSA) on patient samples. Findings: 1. Review of the implementation and installation documents showed that the Calibration, Precision, Reproducibility, Comparison studies, had been completed but the data obtained had not been evaluated and approved by the LD, before patient testing began. 2. Interview with the billing manager, and Staff #3, and #7 (CMS 209 form) on June 21, 2018, at approximately 2:35 pm in the office manager's office, confirmed that the LD had not |

| | |
|---|---|
| | documented review or acceptance of the Nano Entek Frend System before patient testing was started. |
| **D6014** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(3)(iii)<br><br>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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Testing Personnel (TP) training and competency documents and staff interviews, the Laboratory Director failed to meet the requlatory requirements for Competency Assessment of Testing Personnel. Findings: 1. Review of the TP competency assessment documents showed that the Yearly Employee Competency Testing consisted of a checklist. The minimal six procedures for regulatory requirements for assessment of competency for all TP was not met. 2. Interview with the billing manager, and staff #3 and #7 (CMS form 209), on June 21, 2018 at approximately 2:55pm in the office manager's office, confirmed that the competency assessment consisted of the Yearly Employee Competency Testing Checklist. |
| **D6020** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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 the quality control program is established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Quality Control (QC) documents for the Nano Entek Frend System, and staff interview the Laboratory Director (LD) failed to document review and oversight of the QC for the Nano Entek Frend System. Findings: 1. Review of the QC document showed that the laboratory was not performing external QC, using two levels of controls each day of patient sample testing. There was no documentation of LD review of the QC documents. 2. Interview with the billing manager, and staff #3, and #7 (CMS 209 form), on June 21, 2018, at 2:50 pm in the office manager's office confirmed that the lab was not performing two levels of controls each day of patient testing, and that there were no documented reviews by the LD. |
| **D6064** | TESTING PERSONNEL QUALIFICATIONS<br>CFR(s): 493.1423(a)<br><br>Each individual performing moderte complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. |

| | |
|---|---|
| | This STANDARD is not met as evidenced by:<br>Based on Testing Personnel (TP) training documents, the laboratory failed to provide training and 6 month evalution documents for the new employees hired. Findings: 1. Review of the TP training and evaluation documents showed that two new employees (TP #4 and #6, CMS 209 form) did not have intial training documents or 6 month evaluation documents. 2. Interview with the billing manager, and staff #3, and #& (CMS 209 form) on June 21, 2018 at approximately 2:30 pm in the office manager's office, confirmed that there were no initial training and 6 month training documents for TP #4 and #6 (CMS 209 form) available. |
| **D6065** | TESTING PERSONNEL QUALIFICATIONS<br>CFR(s): 493.1423(b)(1)(2)(3)(4)(i)<br><br>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and<br><br>This STANDARD is not met as evidenced by:<br>Based on review of testing personnel records(TP), and staff interview, the laboratory failed to have documentation of an earned high school diploma or equivalent for two of their testing personnel. Findings: 1. Based on review of the testing personnel records, TP #4 and TP #6 (CMS form 209) did not have a copy of their high school diploma or equivalent in their personnel record. 2. Interview with the billing manager, and staff #3 and #7, on June 21, 2018 at approximately 2:50pm, in the office manager's office, confirmed that there was not a copy of their high school diploma or equivalent in their personnel record. |