

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0990585	<b>(X3) Date Survey Completed</b>  02/20/2020
<b>Name of Provider or Supplier</b>  Peachtree City Physicians Group Pc	<b>Street Address, City, State</b>  1401 Georgian Park Drive, Suite 200, Peachtree City, GA	
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 Provider Performed Microscopy (PPM) Clinical Laboratory Improvement Amendments (CLIA) survey was completed on February 20, 2020. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
<b>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on lack of quality control (QC) and temperature/humidity logs, observation during the laboratory tour, review of laboratory test package inserts, and staff interview, the laboratory failed to follow current manufacturer's instructions for all waived tests performed by the laboratory as required. Findings include: 1. Review of waived test package inserts and observation during the laboratory tour on 2/20/2020 at approximately 2:15 p.m. revealed there were no required QC logs available at the time of survey for the following waived tests: Urine Human Chorionic Gonadotropin (Consult Diagnostics), Strep A (Consult), Influenza A/B (Sofia), Hemaglobin A1C (Afinion), Urine analyzer (Consult) and TruMetrix ProGlucose (McKesson) for 2018, 2019 and January 2020. 2. Review of the Consult Urinalysis macroscopic analyzer manual, Afinion HBA1C operators guide, and lack of temperature/humidity log documents revealed there were no required temperature/humidity documents available at the time of survey for 2018, 2019 and 2020 thus far. 3. An interview with the nurse manager in the practice manager's office at approximately 2:35 p.m. on 2/20/2020</p>

	<p>confirmed the lack of temperature/humidity documents for the aforementioned waived tests for 2018, 2019 and 2020 thus far. During the same interview, the nurse manager confirmed the lack of QC for the aforementioned waived tests.</p>
<p><b>D5200</b></p>	<p><b>GENERAL LABORATORY SYSTEMS</b> CFR(s): 493.1230</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on lack of Provider Performed Microscopy (PPM) testing personnel (TP) peer review documents and subsequent staff interview, the laboratory failed to monitor and evaluate the overall quality of the general laboratory systems and correct identified problems for each specialty and subspecialty of testing performed as required. Findings include: For details refer to D5203, D5209, D5217</p>
<p><b>D5203</b></p>	<p><b>SPECIMEN IDENTIFICATION AND INTEGRITY</b> CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on review of a laboratory policy and procedure manual (SOP) and staff interview, the laboratory did not have a policy and procedure for positive identification and optimum integrity of a patient's specimen throughout all phases of testing as required.. Findings include: 1. Review of the SOP revealed there was no specimen identification policy and procedure available at the time of survey. 2. An interview with the nurse manager in the practice manager's office on 2/20/2020 at approximately 2:30 p.m. confirmed the lack of a positive specimen identification policy and procedure for the laboratory.</p>
<p><b>D5209</b></p>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory policy and procedure manual (SOP) review, personnel document review, and staff interview, the laboratory failed to establish and follow a policy and procedure to assess (TP) competency as required. Findings include: 1. SOP review</p>

	<p>revealed there was no policy and procedure to assess (TP) competency available at the time of survey. 2. Lack of TP competency documents revealed there was no annual competencies performed for the following TP(CMS 209) for 2018, 2019, and 2020 thus far: Staff #2, Staff #3. 3. An interview with the nurse manager in the practice manager's office on 2/20/2020 at approximately 1:30 p.m. confirmed the lack of a TP competency policy and procedure at the time of survey. During the same interview, the nurse manager confirmed there were no competency documents available at the time of survey for the aforementioned staff for 2018, 2019, and 2020 thus far.</p>
<p><b>D5217</b></p>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on testing personnel (TP) document review and staff interview, the laboratory failed to verify at least twice annually the accuracy of any test or procedure performed. Findings include: 1. TP document revealed there were no twice annual peer reviews performed on Staff #2 (CMS 209) and Staff #3 (CMS 209) for Potassium Hydroxide (KOH) testing in 2018, 2019, and 2020 thus far. 2. An interview with the nurse manager in the practice manager's office on 2/20/2020 at approximately 2:30 p. m. confirmed the lack of KOH TP peer reviews for the aforementioned dates.</p>
<p><b>D5400</b></p>	<p><b>ANALYTIC SYSTEMS</b> CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP), lack of microscopic qualitative quality control (QC) documents, and staff interview, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems as required. Findings include: For details refer to D5401, D5403, D5435, and D5449</p>
<p><b>D5401</b></p>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on (SOP) review and staff interview, the laboratory director (LD) failed to ensure an approved SOP was available for all procedures performed. Findings include: 1. SOP review revealed the LD did not provide written policy and procedure for Potassium Hydroxide (KOH) exams or urine microscopic exams. 2. An interview with the nurse manager in the practice manager's office on 2/20/2020 at approximately 3:00 p.m. confirmed the lack of the aforementioned procedures and the LD's approval of all procedures.

**D5403**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:  
Based on (SOP) review and staff interview, the laboratory failed to follow the SOP as written and approved. Findings include: 1. SOP review reveals the laboratory is not following written procedures for testing personnel competency, Quality Control (QC) of urine microscopics, KOH preparations, and equipment maintenance protocol. 2. An interview with the nurse manager in the practice manager's office on 2/20/2020 at approximately 2:40 p.m. confirmed the lack of following the laboratory SOP for the aforementioned procedures.

**D5435**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

	<p>Based on observation and staff interview, the laboratory failed to perform and document equipment function checks as required. Findings include: 1. Observation during the laboratory tour on 2/20/2020 at approximately 1:15 p.m. revealed the Quest Horizon Laboratory centrifuges were last calibrated on 08/29/2006 (mini B) and 01/29/2014 (642E). The PROPPER microscope (sn#171571) was last calibrated on 07/18/2013. 2. An interview with the nurse manager on 2/20/2020 in the practice manager's office at approximately 1:15 p.m. in the laboratory confirmed the lack of annual calibration for the laboratory centrifuges and microscope.</p>
<p><b>D5449</b></p>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on quality control (QC) document review and staff interview, the laboratory failed to perform and document QC on potassium hydroxide (KOH) slides and urine microscopic exams. Findings include: 1. No QC documents were available to review on KOH slides or urine microscopic exams at the time of survey. 2. An interview with the nurse manager in the lab on 02/20/2020 at 1:15 PM confirmed controls were not performed on KOH slides or urine microscopic exams.</p>
<p><b>D5891</b></p>	<p><b>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1299(a)</p> <p>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 postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory policy and procedure manual (SOP) review and staff interview, the laboratory failed to monitor, assess, and correct problems as required. Findings include: 1. SOP review revealed the laboratory failed to provide an established corrective action policy and procedure at the time of survey. 2. An interview with the nurse manager in the practice manager's office at approximately 2:45 p.m. confirmed the lack of a corrective action policy and procedure available at the time of survey. .</p>