

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0256595	(X3) Date Survey Completed 02/14/2018
Name of Provider or Supplier Perisseia Physicians Llc	Street Address, City, State 1655 Lebanon Rd Ste A, Lawrenceville, 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 February 14, 2018. 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:
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with testing personnel (TP # 4 on CMS 209), the lab failed to calibrate the Horizon Model 642 Mini E centrifuge per the procedure manual. Findings include: 1. Observation during the laboratory tour revealed the LabCorp Horizon model 642 Mini E centrifuge was last calibrated on April 2, 2015. 2. Interviews with TP #4 (CMS 209 form) and the laboratory director on February 14, 2018 in the surveyor review room at approximately 12:40 PM, confirmed the centrifuge had not been calibrated since 04/02/2015.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of personnel competency assessment records and staff interview, the Technical Consultant failed to include the six required competency assessment criteria when evaluating competency on testing personnel for testing performed on the Horiba Micros 60 Hematology analyzer in 2016 and 2017. The findings include: 1. Review of testing personnel competency assessment records for 2016 and 2017 on all testing personnel revealed the assessment did not include the six competency assessment criteria required by CLIA. 2. Interview with testing personnel # 4 (see CMS 209) and the Laboratory director in the office used by the surveyor on February 14, 2018 at 12:30 PM confirmed testing personnel performing testing on the Horiba Micros 60 Hematology analyzer and annual competency assessments did not contain the six required criteria by CLIA.