

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D2167154	<b>(X3) Date Survey Completed</b>  10/18/2023
<b>Name of Provider or Supplier</b>  Progressive Healthcare & Diagnostics, Llc	<b>Street Address, City, State</b>  4646 North Shallowford Road, Atlanta, 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>	On November 07, 2023 an off site follow-up review was completed for Complaint investigation survey GA00237528. The report revealed that the plan of correction was found to be acceptable. The facility is now in compliance with CLIA regulations.
<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) logs during the laboratory tour, review of laboratory test package inserts and staff interviews, the laboratory failed to follow current manufacturer's instructions for all waived tests performed by the laboratory as required by Clinical Laboratory Improvement Amendments (CLIA) in 2021, 2022 and 2023. Findings: 1. Review of waived test package inserts and observation during the laboratory tour on 10/18/2023 at approximately 10:44 a.m. revealed there were NO required/ requested QC logs available at the time of survey for the following waived test: Dip Stick Urinalysis test using the 120 Consult Diagnostics Urine Analyzer by McKesson. Per manufacturer's instructions on page 30, a known Positive and Negative controls were suppose to be run when a new canister of Strips are opened, new shipment is received, new operator running test and when controls fail in 2021, 2022 and 2023. 2. No instrument cleaning maintenance logs and no maintenance and calibration logs for Horizon 642-E Centrifuges ( 2 in total with Calibration dates of 3 /19/ 2021 and March /2016 ) at the time of survey. 3. No training, competencies or educational records were available for Testing Personnel (TP) #s 1 - 3 (CMS 209) at the time of survey. 4. No Room Temperature, Humidity and refrigerator logs from 2021 to 2023 were available during the survey. 5. Solidary Iodine testing (Uncategorized) was being performed in the clinic by QFA 1500 analyzer during the</p>

time of survey but, a "Stop testing letter" was issued by the lab director and office manager during the survey. 6. An interview with the office manager and laboratory director in the conference room at approximately 1:30 p.m. on 10/18/2023 confirmed the lack of QC documents and the aforementioned maintenance logs for the waived test performed in 2021, 2022 and 2023.