

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 09D0867243	(X3) Date Survey Completed 05/13/2025
Name of Provider or Supplier Some Health Service	Street Address, City, State 60 O Street Nw, Washington, DC	
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	Based on the complaint concerning tests performed on the CLIA 116 application in the Provider Performed Microscopy Lab (PPM) and the onsite inspection, the lab failed to obtain a certificate of registration before performing and reporting patient test results for nonwaived testing with the iStat Analyzer. It was determined that the lab was not in compliance with the specific requirements for the certification type issued
D1000	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(c)</p> <p>(c) Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others: (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: (i) Bilirubin; (ii) Glucose; (iii) Hemoglobin; (iv) Ketone; (v) Leukocytes; (vi) Nitrite; (vii) pH; (viii) Protein; (ix) Specific gravity; and (x) Urobilinogen. (2) Fecal occult blood - non-automated (3) Ovulation tests visual color comparison tests for human luteinizing hormone; (4) Urine pregnancy tests - visual color comparison tests; (5) Erythrocyte sedimentation rate-non-automated; (6) Hemoglobin-copper sulfate-non-automated; (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; (8) Spun microhematocrit; and (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout. (d) Revisions to criteria for test categorization and the list of waived tests. HHS will determine whether a laboratory test meets the criteria listed under paragraph (b) of this section for a waived test. Revisions to the list of waived tests approved by HHS will be published in the FEDERAL REGISTER in a notice with opportunity for comment.</p> <p>This STANDARD is not met as evidenced by: Based on the complaint concerning tests performed on the CLIA 116 application in</p>

	<p>the Provider Performed Microscopy Lab (PPM) and the onsite inspection, the lab failed to obtain a certificate of registration before performing and reporting patient test results for nonwaived testing with the iStat Analyzer. It was determined that the lab was not in compliance with the specific requirements for the certification type issued. Refer to 8201</p>
<p>D8100</p>	<p>INSPECTION REQUIREMENTS CFR(s): 493.1771</p> <p>(a) Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. (b) All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable.</p> <p>This CONDITION is not met as evidenced by: Based on the complaint concerning tests performed on the CLIA 116 application in the Provider Performed Microscopy Lab (PPM) and the onsite inspection, the lab failed to obtain a certificate of registration before performing and reporting patient test results for nonwaived testing. It was determined that the lab was not in compliance with the specific requirements for the certification type issued. Refer to 8201</p>
<p>D8201</p>	<p>INSPECTION OF COW OR PPMP LABS CFR(s): 493.1775(b)</p> <p>(b) If necessary, CMS or a CMS agent may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for provider-performed microscopy procedures at anytime during the laboratory's hours of operation to do the following: (b)(1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health. (b)(2) Evaluate a complaint from the public. (b)(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory. (b)(4) Collect information regarding the appropriateness of tests specified as waived tests or provider-performed microscopy procedures.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory, i-STAT1 Analyzer supply website, and interview with the Senior Director who is a testing person (TP), the lab failed to obtain a certificate of registration before performing and reporting patient test results for nonwaived testing with the i-STAT1 Test System Analyzer. Findings: 1. The lab has a Provider Performed Microscopy Certification (PPM) and submitted a CLIA 116 application on April 14, 2025, to the State Agency to update the lab director. 2. Review of the application under waived testing showed that the lab was performing General Chemistry with the i-STAT analyzer, which is a Moderate Complex analyzer and test by CLIA classification. 3. On May 13, 2025, at 10:30 AM, an onsite complaint survey was performed and the TP stated that she was unaware that the lab was performing nonwaived patient testing and that the lab has been performing i-STAT testing since she was hired over eight years ago. 4. Review of the i-STAT1 Analyzer website on May 13, 2025, at 11:30 AM with the TP where reagents are ordered for Chem8+ testing showed under product specifications that General Chemistry Reagent i-STAT1 Chem8+ for performing Sodium, Potassium, Chloride, Ionized Calcium, Glucose, Blood Urea Nitrogen, Total Carbon Dioxide, Creatinine,</p>

Hematocrit, and Anion Gap Hemoglobin testing is CLIA Classified as Non Waived and CLIA Classification is Moderate Complex. 5. The TP confirmed on May 13, 2025, at 11:30 AM that the i-STAT1 Test System Analyzer for performing i-STAT1 Chem 8+ testing is nonwaived and is a moderately complex patient test. 6. It was determined on May 13, 2025, at 1:00 PM that the lab was performing patient testing beyond the PPM certification. 7. On May 14, 2025, the lab director sent a notification to all lab staff to cease performing nonwaived i-STAT patient testing