

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2199484	(X3) Date Survey Completed 11/09/2020
Name of Provider or Supplier Universal Wellness	Street Address, City, State 251 Rochelle Ave, Rochelle Park, NJ	
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
D1000	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(c)</p> <p>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; (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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of the laboratory and interview with the Practice Owner (PO) and Office Manager (OM), the laboratory performed COVID tests without a CLIA Certificate of Waiver at the time of the survey. The findings include: 1. The Laboratory had a Sophia 2 instrument and BD Veritor instrument. 2. The PO stated patients had been tested with the instruments above. 4. The PO confirmed at 11: 40 am on 11/9/2020 that the laboratory tested for COVID-19 without a CLIA certificate.</p>