

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2208117	<b>(X3) Date Survey Completed</b>  11/19/2021
<b>Name of Provider or Supplier</b>  Phytogenics Specialty Pharmacy	<b>Street Address, City, State</b>  4501 Nw 31st Ave, Oakland Park, FL	
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>	An onsite complaint visit, #2021014174, conducted on 11/19/2021 at PHYTOGENICS SPECIALTY PHARMACY found the laboratory was not in compliance with 42 CFR 493, Requirements for Clinical Laboratories.
<b>D1000</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> 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 observation, record review and interview, the laboratory performed tests under their Certificate of Waiver that were not within the waived category. Findings include: -During the laboratory tour on 11/19/2021, the surveyor observed at 1:40 PM that there was a box of Biohit SARS-CoV-2 IgM/IgG ANTIBODY TEST KIT and a box of SARS-CoV-2 ANTIGEN RAPID TEST KIT, both from the Biohit Healthcare manufacturer. -Review of U.S. Food and Drug Administration (FDA) web site revealed: a) Biohit SARS-CoV-2 IgM/IgG antibody test kit had Emergency Use Authorization (EUA) and was classified as a moderate complexity test. b) SARS-CoV-</p>

2 ANTIGEN RAPID TEST KIT had no EUA, which makes this test to be classified as a High Complexity test. - Patient record review revealed the laboratory used: a) Biohit SARS-CoV-2 IgM/IgG ANTIBODY TEST KIT from 01/27/2021 to 08/27/2021 and performed 36 tests. b) SARS-CoV-2 ANTIGEN RAPID TEST KIT from 02/08/2021 to 08/27/2021 and performed 53 tests. During an interview on 11/19/2021 at 1:45 PM, the owner explained that she was not aware that the tests used were not under the category of waived tests, she stopped using them since August 2021.