

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D2154354	<b>(X3) Date Survey Completed</b> 09/11/2020
<b>Name of Provider or Supplier</b> Ted Pharmacy	<b>Street Address, City, State</b> 24585 Stone Carver Dr Suite 175, Aldie, VA	
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 unannounced, on-site and off-site CLIA complaint survey was conducted at Ted Pharmacy on August 31, 2020 to September 10, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The deficiency is as follows:
<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: A. Based on an on-site tour, document review and interviews, the laboratory performed moderate complexity testing for one hundred eighty four (184) patients utilizing the Healgen Scientific COVID-19 IgG/IgM Rapid Test and Zhejiang Orient Gene Biotech Co. Ltd. COVID-19 IgG/IgM Rapid Test not authorized under the laboratory's Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver from April 14, 2020 until August 13, 2020. The findings include: 1. During the on-site tour, the surveyor observed the following test kits: a. Healgen Scientific</p>

COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) - lot # 2004173 exp. 04/2022 - 2 boxes of 25 tests/box and 1 box with 5 tests remaining. b. Zhejiang Orient Gene Biotech Co COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) - lot # 2005213 exp. 04/30/2022 - 2 boxes of 25 tests/box. 2. Review of the laboratory's invoices from Paragon Enterprises, Inc revealed the purchase of one (1) case of "COVID-19 IgG/IgM RAPID TEST 25/BOX (1 BUFFER PER 25 PPK, EUA APPROVED) CONFIRM BIOSCIENCE" purchased on 08/21/2020 and two (2) cases purchased on 08/27/2020. 3. Review of the website for Confirm Bioscience revealed a listing for the Healgen COVID-19 IgG/IgM Rapid Test Kit as available for purchase. 4. Review of the instructions for use (IFU) for the Healgen Scientific COVID-19 kit and Zhejiang Orient Gene Biotech Co. Ltd. COVID-19 kit revealed the statement, "The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) should not be used to diagnose acute SARS-CoV-2 infection. Testing is limited to laboratories certified under the Clinical Laboratory Amendments of 1988 (CLIA), 42 U.S.C. 263a, to perform moderate or high complexity tests." 5. Review of the laboratory's Center for Medicaid and Medicare (CMS) Automated Survey Processing Environment (ASPEN) WEB database WEB-116 revealed the laboratory possesses a CLIA Certificate of Waiver. 6. On September 1, 2020, a review of the U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) "In Vitro Diagnostics EUA" website revealed a listing for an EUA granted for the Healgen Scientific COVID-19 IgG/IgM Rapid Test and Zhejiang Orient Gene Biotech Co. Ltd. COVID-19 IgG/IgM Rapid Test for use in laboratories certified under the Clinical Laboratory Amendments of 1988 (CLIA), 42 U.S.C. 263a, to perform moderate or high complexity tests 7. Review of patient test logs revealed the laboratory tested 184 patients using the Healgen Scientific COVID-19 IgG/IgM Rapid Test and Zhejiang Orient Gene Biotech Co. Ltd. COVID-19 IgG/IgM Rapid Test between April 14, 2020 and August 13, 2020. 8. In an exit interview on September 11, 2020 at 9:40 AM, the Lab Director (LD) confirmed the above findings. B. Based on document review and interviews, the laboratory performed high complexity testing for two hundred eighteen (218) patients utilizing the Lungene SARS-COV-2 Virus (COV-19) IgG/IgM Rapid Test Kits not authorized under the laboratory's Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver from May 23, 2020 until August 31, 2020.. The findings include: 1. Review of the laboratory's invoices from Paragon Enterprises, Inc revealed the purchase of following COVID-19 IgG/IgM RAPID TEST 25/BOX LUNGENE test kits from Paragon Enterprises Inc.: a. 5 cases on 04/30/2020; b. 2 cases on 05/08/2020; c. 2 cases on 05/11/2020; d. 2 cases on 05/19/2020; e. 1 case on 06/08/2020; f. 1 case on 06/30/2020; g. 2 cases on 6/30/2020; h. 1 case on 07/07/2020; i. 4 cases on 07/10/2020; j. 2 cases on 07/22/2020; k. 1 case on 07/27/2020; l. 5 cases on 07/28/2020; m. 5 cases on 07/30/2020; n. 6 cases on 08/04/2020; o. 2 cases on 08/11/2020; p. 2 cases on 08/27/2020. 2. Review of the IFU for the Lungene COVID-19 IgG/IgM Rapid test kit revealed the following statements, "This test has not been reviewed by the FDA." The IFU listed Hangzhou Clongene Biotech Co., Ltd as the manufacturer. 3. Review of the laboratory's CMS ASPEN WEB-116 revealed the laboratory possesses a CLIA Certificate of Waiver. 4. On September 1, 2020, review of the "FDA EUA In Vitro Diagnostics EUA", website revealed no listing for the Lungene COVID-19 IgG/IgM Rapid test kit 2. Review of the "FDA FAQs (Frequently Asked Questions) on Testing for SARS-CoV-2" website revealed the following: a. A statement "What Tests Should No Longer Be Used and/or Distributed for COVID-19?...The commercial manufacturers in the list below provided notification to the FDA that they validated and intended to distribute a serology test as set forth in Section IV.D of the Policy for Coronavirus Disease-2019 Tests. The FDA had previously included them on the website notification list of commercial manufacturers distributing serology test kits under that policy, but they

have now been removed from that notification list and placed on the list below. As noted in the guidance, if an EUA request is not submitted by a commercial manufacturer of a serology test within a reasonable period of time, or if significant problems are identified with such a test that cannot be or have not been addressed in a timely manner, the FDA intends to remove the manufacturer and test from the notification list. Commercial manufacturers may also voluntarily withdraw their test notification, and such tests are noted with an asterisk." b. A listing for COVID-19 IgM /IgG Rapid test manufactured by Hangzhou Clongene Biotech Co., Ltd. 5. Review of patient test logs revealed the laboratory tested 218 patients using the Lungene SARS-COV-2 Virus (COV-19) IgG/IgM Rapid Test Kits. 6. In an exit interview on September 11, 2020 at approximately 9:40 AM, the LD confirmed the above findings.