

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D2200827	<b>(X3) Date Survey Completed</b>  12/09/2022
<b>Name of Provider or Supplier</b>  Live Urgent Care Llc	<b>Street Address, City, State</b>  3490 Us 1, Princeton, NJ	
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>D1001</b>	<p>CERTIFICATE OF WAIVER TESTS 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:</p> <p>a) Based on surveyor review of the Sienna COVID-19 Antigen Rapid Test Cassette Instructions For Use (IFU), interview with the Testing Personnel (TP) the laboratory failed to follow the Information For Use (IFU) when performing Covid tests from 11 /17/20 to the date of the survey. The findings include: 1. The IFU stated " Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate. " but the laboratory did not report test results to relevant public health authorities. 2. The laboratory performs approximately 15 COVID tests per day. 3. The TP confirmed on 12/9/22 at 12:14 that the laboratory did not follow the IFU. b) Based on surveyor review of the Cepheid Xpert Xpress CoV-2 Plus test system, interview with the TP on 12/9/22 the laboratory failed to follow the IFU when performing Covid tests from 11 /17/20 to the date of the survey. The findings include: 1. The IFU stated " Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate. " but the laboratory did not report test results to relevant public health authorities. 2. The laboratory performs approximately 15 COVID tests per day. 3. The TP confirmed on 7 /28/22 at 12:14 that the laboratory did not follow the IFU. c) Based on surveyor review of the Cepheid Xpert Xpress CoV-2 Plus test system, and interview with the TP the laboratory failed to follow the IFU when performing Flu and RSV tests from 11 /17/20 to the date of the survey. The findings include: 1. The IFU stated "RX only". 2.</p>

	<p>There was no documented evidence that Flu and RSV were prescribed. 3. The TP confirmed on 12/9/22 at 12:30 pm there was no documented evidence that Flu and RSV were prescribed</p>
<p><b>D1002</b></p>	<p><b>REPORTING OF SARS-CoV-2 TEST RESULTS</b></p> <p>During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of the Sienna COVID-19 Antigen Rapid Test Cassette Test system, Cepheid Xpert Xpress CoV-2 Plus test system and interview with the Testing Personnel (TP) the laboratory failed to report all SARS-CoV-2 test results from August 2021 to the date of the survey. The findings include: 1. The laboratory did not report positive COVID-19 Antigen test results to the State of New Jersey. 2. The laboratory did not report all Polymerase Chain Reaction (PCR) SARS-CoV-2 test results to the State of New Jersey. 3. The laboratory performs approximately 15 COVID tests per day. 4. The TP confirmed on 12/9/22 at 12:30 pm the laboratory failed to report the aforementioned test results.</p>
<p><b>D5417</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of Sienna COVID-18 Antigen Rapid Test Cassette boxes and interview with the Tetin Peronnlle (TP), the laboratory failed to discard expired Cassette boxes from 9/25/22 to the date of survey. The finding include: 1. Sienna COVID-18 Antigen Rapid Test Cassette boxes lot # 21101403 expired 9/25/22 2. Sienna COVID-18 Antigen Rapid Test Cassette boxes lot # 21102104 expired 9/29/22 3. Sienna COVID-18 Antigen Rapid Test Cassette boxes lot # 21102901 expired 10/7/22 4. Sienna COVID-18 Antigen Rapid Test Cassette boxes lot # 21102902 expired 10/11/22 5. Sienna COVID-18 Antigen Rapid Test Cassette boxes lot # 21111002 expired 10/18/22 6. Sienna COVID-18 Antigen Rapid Test Cassette boxes lot # 21121601 expired 10/26/22 7. The TP confirmed on 12/9/22 at 12:30 pm that the laboratory failed to discard expired Cassette boxes.</p>
<p><b>D5805</b></p>	<p><b>TEST REPORT</b> CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units</p>

of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of the Final Report (FR) and interview with the Testing Personnel (TP), the laboratory failed to ensure that FR had accurate information from 11/17/20 to the date of survey. The findings include: 1. The FR stated the manufacturer of the test system was CareStart but the test kits being used stated Sienna. 2. There were no reference ranges for virology tests. 3. The TP on 12/9/22 at 1:00 pm that the laboratory failed to ensure that FR had accurate information.