

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D2033207	(X3) Date Survey Completed 11/23/2021
Name of Provider or Supplier America's Express Urgent Care, Llc	Street Address, City, State 7124 Commons Dr, Suite C, Cheyenne, WY	
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
D1001	<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: Based on review of the manufacturer's instructions, record review, and staff interview, the laboratory failed to perform quality control per manufacturer's instructions for 1 of 3 SARS-CoV-2 test systems (InBios Ag Detect) reviewed. The findings were: 1. Review of the InBios patient test logs from 8/5/21 to 11/23/21 showed 752 SARS-CoV-2 patient tests had been performed. There was no evidence quality control and been performed. 2. Review of the InBios manufacturer's instructions showed positive and negative controls should be run once per kit, upon opening, and once for each new operator. 3. Interview with nurse practitioner #1 on 11/23/21 at 9:15 AM revealed quality control was performed on each new kit lot number, however the results had not been documented.</p>
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results 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</p>

timing and frequency, as the Secretary may prescribe.

This CONDITION is not met as evidenced by:

Based on review of policy and procedure, record review, and staff interview, the laboratory failed to report 3,215 SARS-CoV-2 negative patient test results to the State Public Health Laboratory, as required, for 16 weeks of testing reviewed (8/3/21 to 11/23/21). The findings were: 1. Review of the laboratory's documentation from 8/27/21 to 11/23/21 showed 768 SARS-CoV-2 patient tests were performed using the Cepheid Xpert Xpress test system. There was no evidence the 673 SARS-CoV-2 negative patient results had been reported to the State Public Health Laboratory. 2. Review of the laboratory's documentation from 8/5/21 to 11/23/21 showed 2,341 SARS-CoV-2 patient tests were performed using the Sophia test system. There was no evidence the 1,950 SARS-CoV-2 negative patient results had been reported to the State Public Health Laboratory. 3. Review of the laboratory's documentation from 8/5/21 to 11/23/21 showed 752 SARS-CoV-2 patient tests were performed using the InBios test system. There was no evidence the 592 SARS-CoV-2 negative patient results had been reported to the State Public Health Laboratory. 4. Interview with medical assistant (MA) #1 and nurse practitioner #1 on 11/23/21 at 9:15 AM confirmed the negative SARS-CoV-2 patient test results had not been reported to the State Public Health Laboratory. In an additional interview with MA #1 on 11/23/21 at 11:10 AM revealed the laboratory had not developed a policy and procedure for reporting SARS-CoV-2 to the appropriate agencies.

D3009

FACILITIES

CFR(s): 493.1101(c)

The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.

This STANDARD is not met as evidenced by:

Based on review of Wyoming State Statute 35-4-107, review of the Wyoming Department of Health reportable Diseases and Conditions document, record review, and staff interview, the laboratory failed to report 3,861 SARS-CoV-2 patient test results to the State Public Health Laboratory in a timely manner for 16 weeks of testing reviewed (8/3/21 to 11/23/21). The findings were: 1. Review of the laboratory's documentation from 8/27/21 to 11/23/21 showed 768 SARS-CoV-2 patient tests were performed using the Cepheid Xpert Xpress test system. 2. Review of the laboratory's documentation from 8/5/21 to 11/23/21 showed 2,341 SARS-CoV-2 patient tests were performed using the Sophia test system. 3. Review of the laboratory's documentation from 8/5/21 to 11/23/21 showed 752 SARS-CoV-2 patient tests were performed using the In-Bios test system. 4. Interview with medical assistant (MA) #1 on 11/23/21 at 11:10 AM revealed she was responsible for reporting positive SARS-CoV-2 patient results to the State Public Health Laboratory. MA #1 stated she gathered the positive SARS-CoV-2 patient data throughout the week and reported to the State Public Health Department on Fridays. 5. The laboratory was open for patient care Monday through Sunday. 6. Review of the Wyoming Department of Health Reportable Diseases and Conditions document, revised April 2020, showed reporting an infectious disease was required by law (State Statute 35-4-107). "Immediate Notification" was required for all positive and negative SARS-CoV-2 patient test results. 7. Review of Wyoming State Statute 35-4-107 showed "(a) Pursuant to department of health rules and regulation, the state health officer or his designee shall

publish a list of communicable diseases or conditions to be reported by licensed physicians and laboratories in the state. It shall be the duty of every practicing or licensed physician or other health care provider as provided by department rules and regulations in the state of Wyoming to report immediately to the state health officer or his designee in the manner established by department rule and regulation through published reporting procedures provided to each licensed physician or laboratory..."