Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D2278006	01/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Total Point Urgent Care	590 Birch Rd, Hollister, MO	

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	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 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. This STANDARD is not met as evidenced by: Based on review of the operator's guide for the Cepheid Genexpert Xpress PCR analyzer, review of laboratory temperature logs, and interview with the testing personnel (TP) #1, the laboratory failed to follow manufacturer's instructions for acceptable operating temperature and humidity for the Cepheid Genexpert Xpress PCR analyzer for 288 of 288 days from January 23, 2023 to date November 7, 2023. Findings: 1. Review of the operator's guide for the Cepheid Genexpert Xpress PCR analyzer states, "Your laboratory must meet the following requirements: Operating Temperature: 15 - 30 degrees Celsius. Relative Humidity: 20% - 80%, non-condensing." 2. Review of laboratory temperature logs from January 23, 2023 to date November 7, 2023 showed no documented room temperature or humidity for the PCR testing room for 288 of 288 days. 3. The laboratory was unable to provide the number of PCR tests performed from January 23, 2023 to date November 7, 2023 while the room temperature and humidity were not documented. 4. Interview with the TP #1 on November 7, 2023 at 11:00 AM confirmed the laboratory failed to follow manufacturer's instructions for acceptable operating temperature and humidity for the Cepheid Genexpert Xpress PCR analyzer 5. Interview with the TP #1 on January 3, 2024 at 11:00 AM confirmed the laboratory failed to follow manufacturer's instructions for acceptable operating temperature and humidity for the Cepheid Genexpert Xpress PCR analyzer. **This was cited on tag D5413 from the initial survey performed on November 7, 2023.
D3000	FACILITY ADMINISTRATION

	CFR(s): 493.1100 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 timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of waived tests, the laboratory failed to follow manufacturer's instructions for Cepheid Genexpert Xpress PCR analyzer (Refer to D1001).