Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D1077619	01/23/2023
Name of Provider or Supplier	**Street Address, City, State**	
Total Access Urgent Care	9556 Manchester Road, Saint Louis, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of quality control, patient records, and interview with the technical consultant (TC), the laboratory failed to retain records documenting all analytical systems activities, including instrument printouts for two years for the Triage, iStat and Sysmex XP-300 analyzers. Findings: 1. Review of quality control records and patient results from the Triage, iStat, and Sysmex XP-300 showed the laboratory failed to retain instrument printouts for two years. 2. Interview with the TC on January 18, 2023 at 10:00 AM confirmed the instrument printouts are not being retained for two years for the Triage, iStat, and Sysmex XP-300 analyzers.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control records and interview with the technical consultant (TC), the laboratory failed to perform, two control materials of different

	concentrations for d-dimer, BNP, cardiac panel and chemistry 8 panel in 2021 to date January 18, 2023. Findings: 1. Review of quality control records showed the laboratory failed to perform two levels of quality control material every day of patient testing following tests in 2021 to date January 18, 2023: d-dimer (Triage) BNP (Triage) troponin I, CKMB and myoglobin (Triage) Chemistry 8 panel- potassium, chloride, sodium, ionized calcium, glucose, creatinine, CO2, hematocrit and hemoglobin (iStat) 2. Interview with the TC on January 18, 2023 at 10:00 AM confirmed that the laboratory failed to perform two control materials of different concentrations for d-dimer, BNP, cardiac panel and chemistry 8 panel.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on lack of records and interview with the technical consultant (TC), the laboratory failed to have a system that evaluates the same test using different instruments twice per year. Findings: 1. Lack of records showed the laboratory failed to perform test evaluations between the three Triage testing systems. There is no record of test evaluations twice per year for the following tests; D-dimer, troponin I, CKMB myoglobin, and BNP. 2. Interview with the TC on January 18, 2023 at 10:00 AM confirmed the laboratory failed to have a system that evaluates the same test using different instruments twice per year for the following tests: troponin I, CKMB, myoglobin, D-dimer, and BNP.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of employee competencies and interview with the technical consultant (TC), the TC failed to perform semiannual performance evaluation during the first year of employment for 1 of 3 testing personnel (TP). Findings: 1. Review of employee performance evaluations showed the TC failed to perform the semiannual performance evaluation for TP #9. 2 .Interview with TC on January 18, 2023 at 10:00 AM confirmed that the TC failed to perform the semiannual performance evaluation for TP #9.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least

	annually, after the first year. This STANDARD is not met as evidenced by: Based on review of employee competencies and interview with the technical consultant (TC), the TC failed to perform annual performance evaluations for 2 of 9 testing personnel (TP) in 2022. Findings: 1. Review of employee performance evaluations showed the TC failed to perform the annual performance evaluations for TP #1 and TP #8 in 2022. 2. Interview with TC on January 18, 2023 at 10:00 AM confirmed that the TC failed to perform the annual performance evaluation for TP #1 and TP #8.