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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 26D1077619 | (X3) Date Survey Completed 09/18/2024 |
| Name of Provider or Supplier Total Access Urgent Care | Street Address, City, State 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 |
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| D5413 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of the package insert for the Quidel Triage Total 5 Control, review of laboratory freezer temperature logs from January 1, 2024 to date September 11, 2024 and interview with the testing personnel (TP) #3, the laboratory failed to follow manufacturer's instructions for acceptable storage temperature for the Quidel Triage quality controls stored in freezer #1 for 254 of 254 testing days. Findings: 1. Review of the package insert for the Quidel Triage Total 5 Control states, "Store frozen at -20 degrees Celsius or colder in a non-defrosting freezer." 2. Review of laboratory freezer temperature logs from January 1, 2024 to date September 11, 2024 showed freezer #1 with an unacceptable temperature range for 254 of 254 testing days. 3. Interview with the testing personnel #3 on September 11, 2024 at 9:30 AM confirmed the laboratory failed to follow manufacturer's instructions for acceptable storage temperature for the Quidel Triage quality controls stored in freezer #1.</p> |
| D6029 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform</p> |

test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of testing personnel (TP) training documents and interview with the testing personnel #3, the laboratory director (LD) failed to ensure six of seventeen TP received the appropriate training prior to performing patient testing in 2023 and 2024. Findings: 1. Review of training documents showed TP #6 had no documented annual performance evaluation in 2023 and TP #11, TP #12, TP #13, TP #14 and TP #15 had no documented annual performance evaluation in 2024. 2. Interview with the TP #3 on September 11, 2024 at 9:30 AM confirmed the LD failed to ensure TP received the appropriate training prior to performing patient testing.