| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br>23D2150140 | (X3) Date Survey Completed<br>03/01/2022 |
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| **Name of Provider or Supplier**<br>Troy Urgent Care Walk-In Clinic | **Street Address, City, State**<br>4060 Rochester Road, Troy, MI | |

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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| **D1001** | CERTIFICATE OF WAIVER TESTS<br>CFR(s): 493.15(e)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>. A. Based on record review and interview with the manager, the laboratory failed to follow manufacturers' instructions for internal quality control performance for the Clarity Diagnostics Pregnancy One Step Rapid Test Strips, Henry Schein OneStep + Ultra Mono Test Kit, and Henry Schein OneStep + Ultra Flu Test Kit test systems for 3 years and 8 months (June 2018 to February 2022) since the laboratory started testing. Findings include: 1. A review of the manufacturer's instructions for the Clarity Diagnostics Pregnancy One Step Rapid Test Strip revealed a section titled "Quality Control" stating, "Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique." 2. A review of the manufacturer's instructions for the Henry Schein OneStep + Ultra Mono Test Kit revealed a section titled "Internal Quality Control" stating, "The Henry Schein One Step+ Ultra Mono Test Kit provides two levels of internal procedural controls with each test procedure. The red Control Line is an internal positive control. The Test Stick must absorb the proper amount of sample and be working properly for the red Control Line to appear. A clear background is an internal negative control. If the test has been performed correctly and the Test Stick is working properly, the background will clear to give a discernible result. If the red Control Line does not appear, the test is invalid. If the background does not clear and interferes with the test result, the test may be invalid." 3. A review of the manufacturer's instructions for the Henry Schein OneStep + Ultra Flu Test Kit revealed a section titled "Internal Quality Control" stating, "Several controls are incorporated into each Test Stick as routine |

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| | quality checks for the test system and operator. The appearance of the control line in the results window is an internal procedural control. It also verifies proper assembly of the Test Stick. If the control line does not appear at the read time, the test is invalid. The clearing of the background in the results area is another internal procedural control. It also serves as an additional capillary flow control. At the read time, the background should appear white to light pink and not interfere with the reading of the test. If the background color does not clear and interferes with the test result, the test is invalid. 4. The surveyor requested documentation of the internal quality control results for the test systems listed above on 3/1/22 at 9:41 am and they were not made available. 5. An interview on 3/1/22 at 9:41 am with the manager revealed the laboratory did not have documentation of internal quality control available. B. Based on record review and interview with the manager, the laboratory failed to follow manufacturers' instructions for external quality control performance for the Clarity BG1000 Glucose Monitoring System test system for 3 years and 8 months (June 2018 to February 2022) since the laboratory started testing. Findings include: 1. A review of the manufacturer's instructions for the Clarity BG1000 Glucose Monitoring System revealed a section titled "Control Solution Test" stating, " Performing a control solution test lets you know that your meter and test strips are working properly. You should perform a control solution test when: You open a new box of test strips. You left the test strip container open. You want to check whether the meter and test strips are working correctly. Test strips were stored in extreme temperature or humidity. You dropped the meter. Test result does not agree with how patients feel. You want to check if you are testing correctly." 2. The surveyor requested documentation of the control solution quality control results for the test systems listed above on 3/1/22 at 9: 41 am and they were not made available. 3. An interview on 3/1/22 at 9:41 am with the manager revealed the laboratory did not have documentation of external quality control available. |
| **D1002** | REPORTING OF SARS-CoV-2 TEST RESULTS<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>. Based on record review and interview with the manager, the laboratory failed to report all SARS-CoV-2 test results as required for 17 (September 2020 to February 2022) of 17 months the laboratory has been testing patients for SARS-CoV-2. Findings include: 1. The surveyor requested documentation of the laboratory's attempts to report all SARS-CoV-2 testing results using its and BD Veritor SARS-CoV-2 testing system on 3/1/22 at 9:51 am and it was not made available. 2. An interview on 3/1/22 at 9:55 am with the manager revealed the laboratory started testing for SARS-CoV-2 on 9/22/20 and does not report all patient SARS-CoV-2 results obtained with the BD Veritor testing system as required. |