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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>38D2047226 | <b>(X3) Date Survey Completed</b><br>10/26/2020 |
| <b>Name of Provider or Supplier</b><br>Urgent Care Express DbA Portland Urgent Care  | <b>Street Address, City, State</b><br>4160 Ne Sandy Blvd, Portland, OR |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>   |
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| <b>D3000</b>              | <p>FACILITY ADMINISTRATION<br/>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 timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by:<br/>Based on review of patient records and discussion with laboratory staff the laboratory failed to report the Healgen COVID 19 IgG/IgM Rapid Test Cassette test results to appropriate County Health Department or State Agency since mandatory reporting was enacted by Center of Medicare &amp; Medicaid Services (CMS) on September 23,2020. Findings include. 1. Review of patients records and test reports revealed the laboratory was not reporting any positive or negative test results of the Healgen COVID 19 IgG/IgM Rapid Test Cassette to their local county health department or State Agency. 2. The Clinic Director and the testing personnel concurred with these findings on 10/26/2020 at 11:30AM.</p> |
| <b>D5217</b>              | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br/>CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p>   |

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|                     | <p>This STANDARD is not met as evidenced by:<br/> Based on review of Proficiency Testing (PT) records and discussion with the staff the laboratory failed to verify the accuracy of the test or procedure twice annually for the Healgen Scientific COVID 19 IgG/IgM Rapid Test Cassette test system. Findings include: 1. Review of Proficiency Testing (PT) records revealed the laboratory was not enroll in PT and failed to verify the accuracy of the Healgen Scientific COVID 19 IgG/IgM Rapid Test Cassette test system twice annually at the time of survey. 2. The Clinic Director and the testing personnel concurred with the findings on 10/26/2020 at 11:30 AM.</p>  |
| <p><b>D5445</b></p> | <p><b>CONTROL PROCEDURES</b><br/> CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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--<br/> (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by:<br/> Based on review of Quality Control Records revealed that the laboratory failed to perform external quality controls each day of patient testing for the Healgen Scientific COVID19 IgG/IgM Rapid Test Cassette Test System. Findings include: 1. Quality Control records revealed that external quality controls using a positive and a negative control were not being performed since the test system was implemented on 06/29 /2020. 2. Quality Control records also revealed that the internal procedural control for the test system were not being documented at the time of survey. 3. The Clinic Director and the testing personnel concurred with these findings 10/26/2020 at 11: 30AM.</p> |
| <p><b>D6063</b></p> | <p><b>LABORATORY TESTING PERSONNEL</b><br/> CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by:<br/> Review of Personnel Records and discussion with the laboratory staff revealed five (5) out of six (6) testing personnel performing moderate complexity testing do not have their diplomas or transcripts of records on file. Refer to D6065.</p>   |
| <p><b>D6065</b></p> | <p><b>TESTING PERSONNEL QUALIFICATIONS</b><br/> CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the</p>   |

laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Review of Personnel records revealed five (5) testing personnel performing moderate complexity testing do not have copies of their diplomas or transcripts of records on file. Findings include: 1. Five (5) out of Six (6) testing personnel performing the Healgen Scientific COVID 19 IgG/IgM Rapid Test Cassette test system do not have copies of their diploma or transcript of records at the time of survey. 2. The Clinic Director and the testing personnel concurred with these finding on 10/26/2020 at 11:30 AM.