

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2184806	(X3) Date Survey Completed 09/29/2021
Name of Provider or Supplier Quickmed Urgent Care Medina	Street Address, City, State 955 N Court St, Medina, OH	
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	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the laboratory failed to follow their policy and procedure regarding COVID-19 result reporting of 1,877 out of 2,187 COVID-19 tests conducted from 09/01/2021 through 09/19/2021. Findings Include: 1. Review of the laboratory's "CLIA Waved CareStart Covid-19 Antigen Rapid" and "CLIA Waved CareStart Covid-19 Antigen Reporting" policies and procedures, provided for inspection of the SARS-CoV-2 testing and reporting found the following statements: "REPORTING OF TEST RESULTS: NOTE: All "Reportable" tests must be reported to the state authorities within the allotted time. frame. Per ODH, Covid-19 results must be reported with 24 hours." 2. The laboratory's SARS-CoV-2 patient result reporting documentation was reviewed from 09/01/2021 through 09/19/2021 and found 1,877 COVID-19 individuals tested that were not reported to the Ohio Department of Health within 24 hours of testing, as required. See below. Date Tested Number Tested Date Reported 09/01/2021 139 09/09/2021 09/02/2021 120 09/06/2021 09/03/2021 100 09/06/2021 09/04/2021 92 09/06/2021 09/05/2021 57 not reported 09/06/2021 135 09/11/2021 09/07/2021 99 09/11/2021 09/08/2021 147 not reported 09/09/2021 146 not reported 09/10/2021 125 09/12/2021 09/11/2021 95 09/13/2021 09/12/2021 87 09/15/2021 09/14/2021 150 09/16/2021 09/15/2021 119 not reported 09/16/2021 124 not reported 09/17/2021 142 not reported ===== 1,877 3. The Inspector requested the laboratory's evidence that the above mentioned 1,877 COVID-19 test results were reported to the Ohio Department of Health within 24 hours of testing from the Laboratory Director. The Laboratory Director confirmed via telephone on 09/29/2021 at 11:14 AM that the laboratory did</p>

not report all COVID test results to the Ohio Department of Health within 24 hours of testing, as required and per their policies and procedures and the Laboratory Director was unable to provide the requested documentation.

D1002

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 record review and an interview with the Laboratory Director, the laboratory failed to report all SARS-Co-V-2 test results within 24 hours of testing as required for 1,877 out of 2,187 patients tested from 09/01/2021 through 09/19/2021. Findings Include: 1. Review of the laboratory's "CLIA Waved CareStart Covid-19 Antigen Rapid" and "CLIA Waved CareStart Covid-19 Antigen Reporting" policies and procedures provided for inspection of the SARS-CoV-2 testing and reporting found the following statements: "NOTE: All "Reportable" tests must be reported to the state authorities within the allotted time.frame. Per ODH, Covid-19 results must be reported with 24 hours." 2. The laboratory's SARS-CoV-2 patient result reporting documentation was reviewed from 09/01/2021 through 09/19/2021 and found 1,877 COVID-19 individuals tested that were not reported to the Ohio Department of Health within 24 hours of testing, as required. See below. Date Tested Number Tested Date Reported 09/01/2021 139 09/09/2021 09/02/2021 120 09/06/2021 09/03/2021 100 09/06/2021 09/04/2021 92 09/06/2021 09/05/2021 57 not reported 09/06/2021 135 09/11/2021 09/07/2021 99 09/11/2021 09/08/2021 147 not reported 09/09/2021 146 not reported 09/10/2021 125 09/12/2021 09/11/2021 95 09/13/2021 09/12/2021 87 09/15/2021 09/14/2021 150 09/16/2021 09/15/2021 119 not reported 09/16/2021 124 not reported 09/17/2021 142 not reported ===== 1,877 3. The Inspector requested the laboratory's evidence that the above mentioned 1,877 COVID-19 test results were reported to the Ohio Department of Health within 24 hours of testing from the Laboratory Director. The Laboratory Director confirmed via electronic mail on 09/29/2021 at 9:28 AM and verbally via telephone on 09/29/2021 at 11:14 AM that the laboratory reported all COVID test results to the Ohio Department of Health with some result submissions delayed an additional day or more due to weekend testing and the lack of a COVID result reporter scheduled to work. The evidence provided failed to show COVID result reporting to the Ohio Department of Health within 24 hours of testing and the Laboratory Director was unable to provide the requested documentation.