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| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>14D0646585 | <b>(X3) Date Survey Completed</b><br><br>02/25/2021 |
| <b>Name of Provider or Supplier</b><br><br>Unilab, Inc                                                                     | <b>Street Address, City, State</b><br><br>418 N Austin Blvd, Oak Park, IL  |                                                     |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |                                                                            |                                                     |

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| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>D1002</b>              | <p>REPORTING OF SARS-CoV-2 TEST RESULTS</p> <p>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 the laboratory's testing menu; testing kits; test reports; patients' test reports; and interview with Oak Park Department of Public Health and the technical supervisor, the laboratory failed to report SARS-CoV-2 test results to the Secretary during the Public Health Emergency. Findings: 1. Review of the laboratory's testing menu revealed, the laboratory performed waived SARS-CoV-2 and moderate complexity serologic testing for the presence of SARS-CoV-2 IgG/IgM antibodies. 2. Review of the waived test kit revealed the name of the test kit as CareStart COVID-19 Rapid Antigen Test for Detection of SARs- CoV-2 Antigen. 3. On survey date February 25, 2021 at 11:00 AM, the surveyor selected a total of 5 patients test reports for review (2 Antigen and 3 IgG/IgM. Two of 2 Antigen test reports for were negative for SARs-CoV-2 Antigen and 3 of 3 IgG/IgM were negative for both IgG and IgM antibodies 4. On survey date February 25, 2021 at 11:15 AM, the surveyor asked the technical supervisor if Rapid Antigen SARs- CoV-2 test were reported to the Illinois Department of Public Health. The technical supervisor told the surveyor that he reports his results to Oak Park Department of Public Health. 5. On survey date February 25, 2021 at 11:30 AM in a phone interview with a representative from Oak Park Department of Public Health, it was revealed that the laboratory was instructed to report waived Rapid SARs CoV-2 Antigen tests to Oak Park Department of Public Health and SARs CoV-2 IgG/IgM results to the Illinois Department of Public Health. The representative stated that the laboratory did not report SARs CoV-2 Antigen tests even after instructed to do so.</p> |

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| <p><b>D2000</b></p> | <p><b>ENROLLMENT AND TESTING OF SAMPLES</b><br/>CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by:<br/>Based on review of the laboratory's application for CLIA Certification (CMS 116); procedures manual; proficiency testing (PT) records; and interview with the technical supervisor reveal that the laboratory failed to be enrolled in an approved proficiency testing program for COVID -19 testing. Findings: 1. Review of Form CMS 116 revealed that the laboratory listed waived and non-waived COVID tests it performs. 2. Review the laboratory procedures manuals revealed that the laboratory performed waived COVID - 19 Antigen (Ag) testing using Care Start COVID -19 Antigen Test kits and Serologic COVID-19 IgG/IgM testing using Healgen Covid-19 IgG/IgM Rapid Test Cassette kits. 3. Review of PT records revealed that the laboratory failed to enroll in PT for either of its COVID-19 testing. 4. On February 25, 2021 at 12:30 PM, the technical supervisor confirmed the surveyor's findings.</p>                                                                                                                                                            |
| <p><b>D3000</b></p> | <p><b>FACILITY ADMINISTRATION</b><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 the laboratory's testing menu; testing kits; test reports; patients' test reports; and interview with Oak Park Department of Public Health and the technical supervisor, the laboratory failed to report SARS-CoV-2 test results to the Secretary during the Public Health Emergency. Findings: 1. Review of the laboratory's testing menu revealed, the laboratory performed waived SARS-CoV-2 Antigen and moderate complexity serologic testing for the presence of SARS-CoV-2 IgG/IgM antibodies. 2. Review of the of the moderate complexity test kit revealed Healgen COVID-19 IgG/IgM Rapid Test Cassette, 3. On survey date February 25, 2021 at 11:00 AM, the surveyor selected a total of 5 patients test reports for review (2 Antigen and 3 IgG/IgM. Two of 2 Antigen test reports were negative for SARs-CoV-2 and 3 of 3IgG/IgM were negative for both IgG and IgM Antibodies. 4. On survey date February 25, 2021 at 11:15 AM, the surveyor asked the technical supervisor if SARs-</p> |

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|              | <p>CoV-2 test were reported to the Illinois Department of Public Health. The technical supervisor told the surveyor that he reports his results to Oak Park Department of Public Health. 5. On survey date February 25, 2021 at 11:30 AM in a phone interview with a representative from Oak Park Department of Public Health, it was revealed that the laboratory was instructed to report waived Rapid SARs CoV-2 Antigen tests to Oak Park Department of Public Health and SARs CoV-2 IgG/IgM results to the Illinois Department of Public Health. 6. On survey date February 25, 2021 at 1:00 PM, the technical supervisor stated that he did not report SARs CoV-2 IgG/IgM patient test results to the Illinois Department of Public Health.</p>                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>D6015</b> | <p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b><br/>CFR(s): 493.1407(e)(4)</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 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of laboratory's testing menu; proficiency testing (PT) records; and interview with the technical supervisor, the laboratory director failed to ensure that the laboratory is enrolled in an HHS approved proficiency testing programs for its COVID-19 testing. Findings: 1. The laboratory was not enrolled in PT for COVID-19 Testing. See D2000 2. On February 25, 2021 at 12:30 PM, the technical supervisor confirmed that the laboratory was not enrolled in PT for its COVID-19 testing.</p> |