Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2201417	01/27/2022
Name of Provider or Supplier	**Street Address, City, State**	
Labelite	5824 N Northwest Hwy, Chicago, IL	

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
D0000	A complaint survey was performed on 1/26/2022 at approximately 10:30 am at 555 JFK Road, Dubuque, IA 52002. The sign at the entrance of the facility located at 555 JFK Road, Dubuque, IA 52002 stated "LabElite PCR & Rapid COVID Test". Management personnel #1 confirmed via phone interview at 10:38 am on 1/26/2022 and management personnel #2 confirmed via phone interview at 11:00 am on 1/26 /2022 that COVID-19 antigen testing had been performed at 555 JFK Road, Dubuque, IA 52002 under CLIA identification number 14D2201417 LabElite, 5824 N Northwest Hwy, Chicago, IL, 60631. It was determined that Immediate Jeopardy (IJ) existed for the following condition level deficiency: 42 C.F.R 493.1441 Condition: Laboratory Director
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 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. This STANDARD is not met as evidenced by: Based on observations made during the survey, review of Indicaid COVID-19 Rapid Antigen Test instructions for use, lack of training and reporting documents, lack of temperature records and interview with laboratory personnel #1 and management personnel #1 and #2, the laboratory failed to follow the manufacturer's instructions for performing the rapid antigen test. The findings include: 1. Interviews with laboratory personnel #1 at 10:38 am on 1/26/2022 and management personnel #2 at 11:00 am on 1/26/2022 confirmed the laboratory performed COVID-19 Rapid Antigen Testing using the Indicaid COVID-19 Rapid Antigen Test system from 12/26/2021 -1/26 /2022. 2. Review of the Indicaid COVID-19 Rapid Antigen Test instructions for use stated, "Store the test kit in a cool, dry place between 2-30 degrees C (36 - 86 degrees F)." 3. The laboratory failed to monitor and document daily room temperature of the

	testing facility. Management personnel #2 confirmed the laboratory did not document room temperature from 12/26/2021 - 1/26/2022. 4. Review of the Indicaid COVID-19 Rapid Antigen Test instructions for use stated, "Do not interpret the test result before 20 minutes or after 25 minutes, following application of the sample to the Test Device." 5. Observations of testing being performed on 1/26/2022 revealed the laboratory did not have timers in use when performing the COVID-19 rapid antigen test. Laboratory personnel #1 confirmed the laboratory did not use timers. Once the laboratory placed the reagent in the Indicaid test cartridge sample well the background of the test cartridge turned red. Laboratory personnel #1 reported out the COVID antigen result once the background of the test cartridge turned white. The laboratory could not verify the length of time it took for the test cartridge to turn from red to white. 6. Review of the Indicaid COVID-19 Rapid Antigen Test instructions for use stated, "The Indicaid COVID-19 Rapid Antigen Test is intended for use by trained clinical laboratory personnel and medical and healthcare personnel in Point of Care (POC) settings." 7. Email communication with Management Personnel #2 on 1/27 /2022 at 10:56 am revealed the laboratory staff did not have documented training for performing the Indicaid COVID-19 Rapid Antigen Test. 8. Review of the Indicaid COVID-19 Rapid Antigen Test instructions for use stated, "Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." 9. Interview with Management Personnel #2 on 1/26/2022 at 11:00 am revealed the laboratory performed 4,882 COVID-19 rapid antigen tests from 12/26/2021 - 1/25/22 and the results were not reported to the state agency.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 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. This CONDITION is not met as evidenced by: Based on observation of the laboratory located at 555 JFK Road, Dubuque, IA, 52002 lack of documentation and interviews, the laboratory failed to report SARS-CoV-2 Antigen test results as required for 4,882 patients. The findings include: 1. Interviews with laboratory personnel #1 at 10:38 am on 1/26/2022 and management personnel #2 at 11:00 am on 1/26/2022 confirmed the laboratory performed COVID-19 rapid antigen testing using the Indicaid COVID-19 Rapid Antigen Test system from 12/26 /2021 - 1/26/2022. 2. Review of the Indicaid COVID-19 Rapid Antigen Test instructions for use stated, "Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." 3. Interview with Management Personnel #2 on 1 /26/2022 at 11:00 am revealed the laboratory performed 4,882 COVID-19 rapid antigen tests from 12/26/2021 - 1/25/22 and the results were not reported to the state agency.

D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on observations made during the survey, review of Indicaid COVID-19 Rapid Antigen Test instructions for use, lack of training and reporting documents, lack of temperature records and interview with testing personnel #1 and management personnel #1 and #2, the laboratory director failed to ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing, refer to D6082.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on observations made during the survey, review of Indicaid COVID-19 Rapid Antigen Test instructions for use, lack of training and reporting documents, lack of temperature records and interview with laboratory personnel #1 and management personnel #1 and #2, the laboratory director failed to ensure the test systems used in the laboratory provide quality laboratory services for all aspects of test performance for COVID-19 antigen testing. The findings include: 1. Interviews with laboratory personnel #1 at 10:38 am on 1/26/2022 and management personnel #2 at 11:00 am on 1/26/2022 confirmed the laboratory performed COVID-19 Rapid Antigen Testing using the Indicaid COVID-19 Rapid Antigen Test system from 12/26/2021 - 1/26 /2022. 2. Review of the Indicaid COVID-19 Rapid Antigen Test instructions for use stated, "Store the test kit in a cool, dry place between 2-30 degrees C (36 - 86 degrees F)." 3. The laboratory failed to monitor and document daily room temperature of the testing facility. Management personnel #2 confirmed the laboratory did not document room temperature from 12/26/2021 - 1/26/2022. 4. Review of the Indicaid COVID-19 Rapid Antigen Test instructions for use stated, "Do not interpret the test result before 20 minutes or after 25 minutes, following application of the sample to the Test Device." 5. Observations of testing being performed on 1/26/2022 revealed the laboratory did not have timers in use when performing the COVID-19 rapid antigen test. Laboratory personnel #1 confirmed the laboratory did not use timers. Once the laboratory placed the reagent in the Indicaid test cartridge sample well the background of the test cartridge turned red. Laboratory personnel #1 reported out the COVID antigen result once the background of the test cartridge turned white. The laboratory could not verify the length of time it took for the test cartridge to turn from red to white. 6. Review of the Indicaid COVID-19 Rapid Antigen Test instructions for use stated, "The Indicaid COVID-19 Rapid Antigen Test is intended for use by trained clinical laboratory personnel and medical and healthcare personnel in Point of Care

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