STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	14D2201417	A. BUILDING _____ B. WING _____	C 01/27/2022

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
LABELITE	5824 N NORTHWEST HWY CHICAGO, IL 60631

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D 000	INITIAL COMMENTS 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:	D 000		
D1001	42 C.F.R 493.1441 Condition: Laboratory Director 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:	D1001		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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D1001	Continued From page 1 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.	D1001		

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D1001	Continued From page 2 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.	D1001		
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	D6076		

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D6076	Continued From page 3 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.	D6076		
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 -	D6082		

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D6082	Continued From page 4 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."	D6082		

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D6082	Continued From page 5 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.	D6082		