Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2233521	01/05/2022
Name of Provider or Supplier	**Street Address, City, State**	
Being Human Medical, Llc, Am Laboratory	6027 N Cicero Ave, 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	Based on interviews with laboratory personnel identifier #1 (refer to appendix 1) at approximately 1:50 pm on 1/05/2022, laboratory personnel identifier #1 confirmed the COVID antigen testing being performed at Amita Laboratory 320 W Kimberly Rd, Davenport Iowa fell under the CLIA number 14D2233521 - Being Human Medical, LLC. Identifier #1 again confirmed via interview at approximately 2:15 pm the COVID antigen testing being performed at Amita Laboratory 320 W Kimberly Rd, Davenport Iowa fell under the CLIA number 14D2233521 - Being Human Medical, LLC. A complaint survey was completed on January 5, 2022. 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 at the time of the survey, lack of temperature records, review of the Sienna COVID-19 Antigen Rapid Test Cassette Instruction for use, and interview with laboratory personnel identifier #2 (refer to Appendix 1), the laboratory failed to follow manufacturer's instructions for storage of COVID-19 antigen test kits. The findings include: 1. The Sienna COVID-19 Antigen Rapid Test Cassette Instruction for use states under the Precautions section: *"Allow the test cassette, specimen, supporting buffer to equilibrate to room temperature 15 degrees Celsius (C) - 30 degrees C [59 degrees Fahrenheit (F) - 86 degrees F] prior to testing." *"Do not store this kit in frozen conditions." 2. On 1/5/22, the temperature around the time of the survey was approximately 11 degrees F with a windchill of -10 degrees F. The testing personnel performed the testing in a mobile storage unit that had two small

	heaters. Testing personnel constantly went in and out of the door (which is located directly across from the testing area) to collect COVID samples from patients waiting in their vehicles. The surveyor wore a long winter coat, stocking cap, wool socks and boots during the survey and still felt cold, indicating a temperature below 59 degree F. 3. At the time of the survey, the laboratory did not have a thermometer available to document the temperature inside the facility. Additionally, the laboratory did not have temperature records documenting the daily room temperature of inside the facility for any previous dates of testing. 4. Interview at 2:30 pm on 1/5/2022 with laboratory personnel identifier #2 revealed that the generator used to heat the storage facility did not run 24 hours a day. The laboratory used the generator to heat the storage facility during the 8 hours of operation. The Sienna COVID-19 Antigen Rapid Test Cassettes remained in the facility 24 hours a day. Based on observations at the time of the survey, review of the Sienna COVID-19 Antigen Rapid Test Cassette Instruction for use and confirmed by testing personnel identifiers #2 and #3 (refer to Appendix 1) at approximately 2:30 pm on 1/5/2022, the laboratory failed to follow manufacturer's instructions for performing COVID-19 antigen testing. The findings include: 1. The Sienna COVID-19 Antigen Rapid Test Cassette Instruction for use states under the Directions for Use section: *"Place the extraction buffer in the workstation. Open the cap 1 and place the swab specimen in the extraction buffer. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab. Leave the swab in the extraction buffer for 1 minute." *Add 3 drops of the solution to the sample well and then start the timer. Read the result at 10 minutes. Do not interpret the result after 20 minutes. Note: Erroneous results can occur if the test results are read before or after 10-20 minutes." 2. At the time of the survey, the laboratory did not have timers available in the storage facility and testing personnel identifiers #2 and #3 confirmed the laboratory did not use timers when performing COVID antigen testing. 4. Observations of testing being performed at the time of the survey revealed that testing personnel would put the patient sample in the extraction buffer for approximately 10 - 20 seconds instead of 1 minute. 5. Testing personnel identifier #2 revealed that once the swab has been taken out of the extraction buffer and 3 drops of the solution are placed in the sample well of the cassette, the cassette has a red color in the region where the test results are interpreted. The testing personnel confirmed they interpreted the results when the testing region of cassette has turned white in color. Observation of this process revealed that testing personnel read the COVID antigen test results at approximately 5 minutes instead of 10 -20 minutes. Interview at 2:30 pm on 1/5/2022 with personnel identifier #2 confirmed the laboratory failed to follow manufacturer's instructions for performing COVID-19 antigen testing.
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 observations at the time of the survey, lack of COVID reporting documentation and interview with laboratory personnel identifiers #1 and #2 (refer to Appendix 1) at approximately 2:30 pm on 1/5/2022, the laboratory failed to report SARS-CoV-2 test results to the proper State Health Department for 73 out of 73 patients on 1/5/2022. The findings include: 1. Observation showed the laboratory documented on a patient log the patient's name, date of birth, and phone number of each patient having COVID antigen testing performed. As of approximately 2:30 pm on 1/5/22 , the patient log for the day of testing had 73 patients list as having COVID antigen testing performed. 2. Laboratory personnel #1 stated the laboratory reported SARS-CoV-2 results to the appropriate State Health Department but did not know how or when the laboratory transmitted the results. 3. Laboratory personnel #2 did not know if the laboratory reported SARS-CoV-2 results to the appropriate State Health Department. 4. At the time of the survey, the laboratory did not have documentation of SARS-CoV-2 results being reported to the appropriate State Health Department.
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 at the time of the survey, lack of temperature records, review of the Sienna COVID-19 Antigen Rapid Test Cassette Instruction for use and interviews with testing personnel, the laboratory directior 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 at the time of the survey, lack of temperature records, review of the Sienna COVID-19 Antigen Rapid Test Cassette Instruction for use and interviews, the laboratory director failed to ensure the tests systems used in the laboratory provide quality laboratory services for all aspects of test performance for COVID-19 antigen testing. The findings include: 1. The Sienna COVID-19 Antigen Rapid Test Cassette Instruction for use states under the precautions section: *"Allow the test cassette, specimen, supporting buffer to equilibrate to room temperature 15 degrees Celsius (C) - 30 degrees C [59 degrees Fahrenheit (F) - 86 degrees F] prior to testing." *"Do not store this kit in frozen conditions." 2. On 1/5/22, the temperature around the time of the survey was approximately 11 degrees F with a windchill of -10 degrees F. The testing personnel performed the testing in a mobile storage unit that

had two small heaters. Testing personnel constantly went in and out of the door (which is located directly across from the testing area) to collect COVID-19 samples from patients waiting in their vehicles. The surveyor wore a long winter coat, stocking cap, wool socks and boots during the survey and still felt cold, indicating a temperature below 59 degree F. 3. At the time of the survey, the laboratory did not have a thermometer available to document the temperature inside the facility. Additionally, the laboratory did not have temperature records documenting the daily room temperature of inside the facility for any previous dates of testing. 4. Laboratory personnel identifier #2 revealed that the generator used to heat the storage facility did not run 24 hours a day. The laboratory used the generator to heat the storage facility during the 8 hours of operation. The Sienna COVID-19 Antigen Rapid Test Cassettes remained in the facility 24 hours a day. Based on observations at the time of the survey and interview, the laboratory director failed to ensure the tests systems used in the laboratory provide quality laboratory services for all aspects of test performance for COVID-19 antigen testing by failing to ensure confidentiality of patient information. The findings include: 1. Observation showed patients waited in their cars for a COVID-19 antigen test. 2. Testing personnel would go to the patients vehicle and hand them a clipboard with a paper log. The patient would write down their name, date of birth and phone number on the clipboard. Multiple patients recorded their personal health information on the same log. Therefore, patients could see the personal health information of other individuals who had COVID-19 antigen testing performed. 3. Testing personnel would then collect the COVID-19 specimens and rapid antigen testing would be performed by the laboratory. 4. Testing personnel would then text the patient results through "What's App" on their personal cellular phones to the main laboratory, where the results would be entered into an electronic health record. The text included the patient's name, date of birth and test result. For positive test results, testing personnel would also send a picture of the test cassette. 5. Interview with laboratory personnel identifier #2 (refer to Appendix 1) at approximately 2:30 pm on 1/5/2022 confirmed the laboratory director failed to ensure the tests systems used in the laboratory provide quality laboratory services for all aspects of test performance for COVID-19 antigen testing by failing to ensure confidentiality of patient information. Based on observations at the time of the survey, review of the Sienna COVID-19 Antigen Rapid Test Cassette Instruction for use, and interviews with the laboratory personnel identifiers #2 and #3 (refer to Appendix 1) at , the laboratory director failed to ensure the tests systems used in the laboratory provide quality laboratory services for all aspects of test performance for COVID antigen testing by failing to safety procedures to ensure the protection of individuals from biohazard materials. The findings include: 1. The Sienna COVID-19 Antigen Rapid Test Cassette Instruction for use states under the Precautions section: *"All samples, even after the extraction procedure, and reagents containing biological materials used for the assay must be considered as potentially able to transmit infections agents; accordingly samples, reagents and the waste must be handled with the utmost care and disposed of in compliance with the laboratory guidelines and the statutory provisions in force in each country." 2. Interviews with laboratory personnel identifiers #2 and #3 at 2:30 pm on 1/5/2022, confirmed the laboratory placed all samples, reagents, gloves and COVID antigen cassettes in the regular trash. Testing personnel identifiers #2 and #3 confirmed that they did not take biohazard precautions.