Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0419924	01/24/2022
Name of Provider or Supplier	**Street Address, City, State**	
Doctors General Laboratory	59 Ogden Ave, Clarendon Hills, 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 1/18/2022 at approximately 12:00 pm at 1100 Blairs Ferry Rd NE Suite 113, Cedar Rapids, IA 52402. The sign at the entrance of the facility located at 1100 Blairs Ferry Rd NE Suite 113, Cedar Rapids, IA 52402 stated "Quick N Free COVID testing conducting PCR and Rapid Tests". Management personnel #1 confirmed via email on 1/18/2022 at 4:13 pm that COVID-19 antigen testing had been performed at Quick N Free COVID located at 1100 Blairs Ferry Rd NE, Suite 113 Cedar Rapids, IA 52402 under CLIA identification number 14D0419924, Doctors General Laboratory, 59 Ogden Avenue, Clarendon Hills, IL 60514.
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 Celltrion DiaTrust COVID-19 Antigen Rapid Test and Sienna-Clarity COVID-19 Antigen Rapid Test instructions for use, lack of training and reporting documents, lack of temperature records and interview with testing personnel #1, management personnel #1, and Iowa Department of Public Health personnel #1, the laboratory failed to follow the manufacturer's instructions for performing the rapid antigen test. The findings include: 1. On 1/18 /2022 at approximately 12:00 pm, observations of the testing facility included a laboratory area consisting of a reception desk, two tables and a electronic tablet. One of the tables had biohazard bags that contained labeled swabs with patient information. 2. Interview with testing personnel #1 on 1/18/2022 at approximately 12: 00 pm, confirmed samples were being collected for PCR testing. 3. Testing personnel #1 also stated COVID rapid antigen testing had been performed, but the laboratory ran

	out of test kits. Testing personnel #1 stated that they had performed COVID rapid antigen testing on 1/15/2022 - 1/17/2022. Testing personnel #1 did not know that name or the manufacturer of the rapid antigen test kits. 4. Management personnel #1 confirmed via email on 1/18/2022 at 4:13 pm that the facility used either the Celltrion DiaTrust COVID-19 Rapid Antigen Test or the Sienna-Clarity COVID-19 Rapid Antigen Test on 1/15/2022 - 1/17/2022. 5. Review of the Celltrion DiaTrust COVID-19 Rapid Antigen Test and Sienna-Clarity COVID-19 Rapid Antigen Test instructions for use indicated storage of both test kits between 2 - 30 degrees C (36 - 86 degrees F). 6. The laboratory failed to monitor and document daily room temperature of the testing facility. Testing personnel #1 confirmed she did not document the room temperature on 1/15/2022 - 1/17/2022. 7. Review of the Celltrion DiaTrust COVID-19 Rapid Antigen Test and Sienna-Clarity COVID-19 Rapid Antigen Test instructions for use indicated that both kits were, "intended for use by medical professionals or trained operators who are proficient in performing tests, trained clinical laboratory personnel, or individuals trained in Point of Care (POC) settings." 8. Testing personnel #1 confirmed that they did not have documented training prior to performing patient testing. 9. Review of the Celltrion DiaTrust COVID-19 Rapid Antigen Test and Sienna-Clarity COVID-19 Rapid Antigen Test instructions for use indicated for both kits,"Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories." 10. Management personnel #1 confirmed via email on 1/18/2022 at 4:13 pm that the facility performed rapid COVID testing at Quick N Free COVID located at 1100 Blairs Ferry Rd, NE, Suite 113 Cedar Rapids, IA, 52402 from 1/15/2022 - 1/17/2022. When asked for the exact volume of rapid antigen testing, Management personnel #1 confirmed via email on 1/24/2022 at 10:42 am, the facility performed 47 rapid tests on 1/15/2022 and 37 rapid tests on 1/16/2022. 11. Management personnel #1 confirmed via email on 1/18/2022 at 4:13 pm that COVID antigen testing had been performed at Quick N Free COVID located at 1100 Blairs Ferry Rd NE, Suite 113 Cedar Rapids, IA 52402 under the CLIA identification number 14D0419924, Doctors General Laboratory, 59 Ogden Avenue, Clarendon Hills, IL 60514. 12. Iowa Department of Public Health (IDPH) personnel #1 confirmed via email on 1/21/22 , IDPH had not receive any rapid antigen testing results from either Quick N Free COVID located at 1100 Blairs Ferry Rd, NE, Suite 113 Cedar Rapids, IA, 52402 or Doctors General Laboratory, 14D0419924, 59 Ogden Ave, Clarendon Hills, IL, 60514.
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 1100 Blairs Ferry Rd NE Suite 113, Cedar Rapids, IA 52402, lack of documentation, email correspondence, and interview, the laboratory failed to report SARS-CoV-2 Antigen test results as required for 84

	patients. The findings include: 1. Management personnel #1 confirmed via email on 1 /18/2022 at 4:13 pm that the facility used either the Celltrion DiaTrust COVID-19 Rapid Antigen Test or the Sienna-Clarity COVID-19 Rapid Antigen Test on 1/15 /2022 - 1/17/2022. 2. Review of the Celltrion DiaTrust COVID-19 Rapid Antigen Test and Sienna-Clarity COVID-19 Rapid Antigen Test instructions for use indicated for both kits,"Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories." 3. Management personnel #1 confirmed via email on 1/18/2022 at 4:13 pm that the facility performed rapid COVID testing at Quick N Free COVID located at 1100 Blairs Ferry Rd, NE, Suite 113 Cedar Rapids, IA, 52402 from 1/15/2022 - 1/17/2022. When asked for the exact volume of rapid antigen testing, Management personnel #1 confirmed via email on 1/24/2022 at 10:42 am, the facility performed 47 rapid tests on 1/15/2022 and 37 rapid tests on 1/16/2022. 4. Management personnel #1 confirmed via email on 1/18 /2022 at 4:13 pm that COVID antigen testing had been performed at Quick N Free COVID located at 1100 Blairs Ferry Rd NE, Suite 113 Cedar Rapids, IA 52402 under the CLIA identification number 14D0419924, Doctors General Laboratory, 59 Ogden Avenue, Clarendon Hills, IL 60514. 5. Iowa Department of Public Health (IDPH) personnel #1 confirmed via email on 1/21/22 , IDPH had not receive any rapid antigen testing results from either Quick N Free COVID located at 1100 Blairs Ferry Rd, NE, Suite 113 Cedar Rapids, IA, 52402 or Doctors General Laboratory, 14D0419924, 59 Ogden Ave, Clarendon Hills, IL, 60514.
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 Celltrion DiaTrust COVID-19 Antigen Rapid Test and Sienna-Clarity COVID-19 Antigen Rapid Test instructions for use, lack of training and reporting documents, lack of temperature records and interview with testing personnel #1, management personnel #1, and Iowa Department of Public Health personnel #1, 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 Celltrion DiaTrust COVID-19 Antigen Rapid Test and Sienna-Clarity COVID-19 Antigen Rapid Test instructions for use, lack of training and reporting documents, lack of temperature records and

	interview with testing personnel #1, management personnel #1, and Iowa Department of Public Health personnel #1, 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. On 1/18/2022 at approximately 12:00 pm, observations of the testing facility included a laboratory area consisting of a reception desk, two tables and a electronic tablet. One of the tables had biohazard bags that contained labeled swabs with patient information. 2. Interview with testing personnel #1 on 1/18/2022 at approximately 12:00 pm, confirmed samples were being collected for PCR testing. 3. Testing personnel #1 also stated COVID rapid antigen testing had been performed, but the laboratory ran out of test kits. Testing personnel #1 stated that they had performed COVID rapid antigen testing on 1/15/2022 - 1/17/2022. Testing personnel #1 did not know that name or the manufacturer of the rapid antigen test kits. 4. Management personnel #1 confirmed via email on 1/18/2022 at 4:13 pm that the facility used either the Celltrion DiaTrust COVID-19 Rapid Antigen Test or the Sienna-Clarity COVID-19 Rapid Antigen Test on 1/15/2022 - 1/17/2022. 5. Review of the Celltrion DiaTrust COVID-19 Rapid Antigen Test and Sienna-Clarity COVID-19 Rapid Antigen Test instructions for use indicated storage of both test kits between 2 - 30 degrees C (36 - 86 degrees F). 6. The laboratory failed to monitor and document daily room temperature of the testing facility. Testing personnel #1 confirmed she did not document the room temperature on 1/15/2022 - 1/17/2022. 7. Review of the Celltrion DiaTrust COVID-19 Rapid Antigen Test and Sienna-Clarity COVID-19 Rapid Antigen Test instructions for use indicated that both kits were, "intended for use by medical professionals or trained operators who are proficient in performing tests, trained clinical laboratory personnel, or individuals trained in Point of Care (POC) settings." 8. Testing personnel #1 confirmed that they did not have documented training prior to performing patient testing. 9. Review of the Celltrion DiaTrust COVID-19 Rapid Antigen Test and Sienna-Clarity COVID-19 Rapid Antigen Test instructions for use indicated for both kits,"Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories." 10. Management personnel #1 confirmed via email on 1/18/2022 at 4:13 pm that the facility performed rapid COVID testing at Quick N Free COVID located at 1100 Blairs Ferry Rd, NE, Suite 113 Cedar Rapids, IA, 52402 from 1/15/2022 - 1/17/2022. When asked for the exact volume of rapid antigen testing, Management personnel #1 confirmed via email on 1/24/2022 at 10:42 am, the facility performed 47 rapid tests on 1/15/2022 and 37 rapid tests on 1/16 /2022. 11. Management personnel #1 confirmed via email on 1/18/2022 at 4:13 pm that COVID antigen testing had been performed at Quick N Free COVID located at 1100 Blairs Ferry Rd NE, Suite 113 Cedar Rapids, IA 52402 under the CLIA identification number 14D0419924, Doctors General Laboratory, 59 Ogden Avenue, Clarendon Hills, IL 60514. 12. Iowa Department of Public Health (IDPH) personnel #1 confirmed via email on 1/21/22 , IDPH had not receive any rapid antigen testing results from either Quick N Free COVID located at 1100 Blairs Ferry Rd, NE, Suite 113 Cedar Rapids, IA, 52402 or Doctors General Laboratory, 14D0419924, 59 Ogden Ave, Clarendon Hills, IL, 60514.