Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1101671	04/20/2022
Name of Provider or Supplier	**Street Address, City, State**	
Physicians Now Llc	15215 Shady Grove Road Ste 100, Rockville, MD	

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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview with the laboratory director (LD) the laboratory failed to have written procedures for performing SARS-CoV-2 testing with the Quidel Solana SARS-CoV-2 assay (D5401, part I); failed to follow manufacturer's procedures for performing QC when performing SARS-CoV-2 testing with the Quidel Solana SARS-CoV-2 assay (D5401, part II); failed to provide the testing personnel with written preanalytical, analytical, and post analytical policies and procedures for testing with the Quidel Solana SARS-CoV-2 assay (D5403); failed to define, monitor, and document laboratory reagent freezer and heat block temperatures to ensure proper reagent storage and reliable test system operation (D5413); failed to ensure that the laboratory validated the Solana SARS-CoV-2 Assay to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer before being used for patient testing (D5421); failed to perform two levels of quality control (QC) each day of SARS-CoV-2 testing (D5445); and failed to ensure that both a positive and a negative control were run each day of testing with the Quidel Solana SARS-CoV-2 assay (D5449).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a)

	A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: I. Based on review of the test manufacturer's package insert and interview with the laboratory director (LD), the laboratory did not have written procedures for performing SARS-CoV-2 testing with the Quidel Solana SARS-CoV-2 assay. Findings: 1. The laboratory performs SARS-CoV-2 testing with the Quidel Solana SARS-CoV-2 assay. 2. During a tour of the laboratory at 10:30 AM on the day of the survey the LD explained the testing process, stating that after adding the patient specimen or control to the "Process Buffer Tube" the specimen is incubated in the heat block at 95 +/-2C and then placed in the refrigerator to cool for 15 minutes while the "Master Mix" thaws. 3. The laboratory did not have a written procedure for performing SARS-CoV-2 testing at the time of the survey. Upon request, the LD provided the manufacturer's package insert which was printed from the Quidel company website. 4. Review of the "Quidel Solana SARS-CoV-2 assay" package insert showed that after adding the patient specimen or control to the "Process Buffer Tube" and incubating the specimen in the heat block at 95 +/-2C there is a statement, "NOTE: Allow the heated Process Buffer Tubes to return to Room Temperature prior to addition to Master Mix." 5. The package insert did not instruct the testing person to put the specimen in the refrigerator. 6. During an interview on 03/30/2022 at 12:45 PM, the LD confirmed that the laboratory did not have a written procedure for performing SARS-CoV-2 testing. II: Based on review of the test manufacturer's package insert, quality control (QC) records, and interview with the laboratory director (LD), the laboratory did not follow manufacturer's procedures for performing QC when performing SARS-CoV-2 testing with the Quidel Solana SARS-CoV-2 assay. Findings: 1. During a tour of the laboratory at 10:30 AM on the day of the survey the LD explained the testing process, stating that the laboratory runs a positive and negative external control monthly, and that a positive control is run with the first batch/run of specimens each day. The LD stated that no other controls are run with each subsequent batch of patient specimens. 2. The laboratory did not have a written procedure for performing SARS-CoV-2 testing at the time of the survey. Upon request, the LD provided the manufacturer's package insert which was printed from the Quidel company website. 3. The "Quidel Solana SARS-CoV-2 assay" package insert was reviewed. The section, "Quality Control" states that "A positive control (such as a positive patient sample) should be processed and tested with each batch of specimens." 4. A review of QC records from 12/15/2021 to 3/30/2022 showed that positive and negative SARS-CoV-2 QC was run daily from 12/15/2021 through 12/21/2021, once weekly from 12/28/2021 through 2/1/2022, and then again on 3/1/2022. 5. During an interview on 03/30/2022 at 12:45 PM, the LD confirmed that the laboratory did not follow the manufacturer's instructions for performing QC with the Quidel Solana SARS-CoV-2 assay.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic

	examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on standard operating procedure manual (SOPM) review, surveyor observation, and interview with the laboratory director (LD), the laboratory did not provide the testing personnel with written preanalytical, analytical, and post analytical policies and procedures for testing with the Quidel Solana SARS-CoV-2 assay. Findings: 1. A review of the SOPM showed that there are no written procedures for patient preparation; specimen collection, labeling, storage, preservation, processing, and referral; criteria for specimen acceptability and rejection; step-by-step performance of the procedure; control procedures; and corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. 2. During a tour of the laboratory at 10:30 AM on the day of the survey, it was observed that the testing personnel use an abbreviated "Procedure Card" as a reference on how to perform the test procedure. The "Procedure Card" states, "For technical training use only" and "Study the Package Insert thoroughly before using this Procedure Card. This is not a complete Package Insert." 3. Document review showed that the laboratory did not have a copy of the manufacturer's package insert available at the time of the survey. 4. During an interview on 03/30/2022 at 12:45 PM, the LD confirmed that the SOPM did not contain written preanalytical, analytical, and post analytical policies and procedures for testing with the Quidel Solana SARS-CoV-2 assay.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on procedure manual and temperature log record review and interview with the laboratory director (LD), the laboratory failed to define, monitor, and document laboratory reagent freezer and heat block temperatures to ensure proper reagent storage and reliable test system operation. Findings: 1. The laboratory began

	performing SARS-CoV-2 testing in December, 2021 with the Quidel Solana SARS-CoV-2 assay. The package insert states that one of the kit components, the "Master Mix" must be stored at "-70C or below." The test procedure also requires that specimens be incubated in a heat block "at 95 +/-2C." 2. A review of laboratory temperature logs from December 2021 to March 2022 showed that the laboratory was not documenting the temperature of the reagent freezer or the heat block. 3. A review of the procedure manual showed that there was no written procedure for taking temperatures in the laboratory. 4. During an interview during the survey on 03/30 /2022 at 11:37 AM, the LD confirmed that the laboratory failed to monitor and document temperatures in the laboratory to ensure proper reagent storage and reliable test system operation.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director (LD), the laboratory failed to ensure that the laboratory validated the Solana SARS-CoV-2 Assay to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer before being used for patient testing. Findings: 1. The laboratory performs SARS-CoV-2 testing using the Solana SARS-CoV-2 Assay. Document review showed that the laboratory performed a "SARS-CoV-2 Molecular Testing Panel" on 12/15/2021 in order to validate the new analyzer. The panel contained 24 "Panel Members" (specimens) with the "Expected Results" ("SARS Negative" or "SARS Positive") listed on a "Testing Panel Answer Key." 2. Review of the "Testing Panel Answer Key" showed that the person performing the validation testing wrote a check mark next to the "Expected Results" on each "Panel Member" but there was no evidence that the laboratory had reviewed and evaluated the verification data or that the LD had approved the validated instrument for use before beginning patient testing. 3. During an interview on 03/30/2022 at 12:45 PM the LD confirmed that there was no documentation that the validation of the Solana SARS-CoV-2 Assay was acceptable before performing patient testing.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of the manufacturer's package insert for performing SARS-CoV-2 testing and interview with the laboratory director (LD), the laboratory did not perform two levels of quality control (QC) each day of testing as required in paragraph (d)(3) of this section for SARS-CoV-2 testing. Findings: 1. The laboratory performs SARS-CoV-2 testing with the Quidel Solana SARS-CoV-2 assay. 2. During a tour of the laboratory at 10:30 AM on the day of the survey the LD explained the testing process, stating that the laboratory runs a positive and negative external control monthly, and that a positive control is run with the first batch/run of specimens each day. The LD stated that no other controls are run with each subsequent batch of patient specimens. Cross-refer to D5401, part II. 3. The laboratory is required to test two levels of QC materials each day of testing unless they have a written Individualized Quality Control Plan (IQCP). An IQCP requires the laboratory to perform a risk assessment that included an evaluation of the specimen used; environment for testing; integrity of the reagent; components of the test system; and competency of the testing personnel. The quality assessment portion of the IQCP should include a review of the QC, proficiency testing records, patient results and all other records pertaining to the SARS-CoV-2 test. 4. During the survey on 03/30/2022 at 12:45 PM the LD confirmed that the laboratory did not have an established IQCP for performing SARS-CoV-2 testing to reduce the frequency of QC testing.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: The laboratory did not ensure that both a positive and a negative control were run each day of testing with the Quidel Solana SARS-CoV-2 assay. Cross-refer to D5445.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with the laboratory director (LD), the LD failed to ensure that verification procedures used for the Solana SARS-CoV-2 Assay are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method (D6013); failed to ensure that laboratory personnel are performing the test methods as required for accurate and reliable results (D6014); failed to ensure that the quality control program is established and maintained to assure the quality of laboratory services provided (D6020); and failed to ensure that

	an approved procedure manual is available to all personnel responsible for any aspect of the testing process (D6031).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: The laboratory director failed to ensure that verification procedures used for the Solana SARS-CoV-2 Assay are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. Cross-refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: The laboratory director failed to ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. Cross-refer to D5401, part I.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: The laboratory director failed to ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. Cross-refer to D5445 and D5449.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)

	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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: The laboratory director failed to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. Cross-refer to D5403.