Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1101671	01/19/2024
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
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 instructions for use (IFU) and quality control (QC) records and interview with the laboratory director (LD), the laboratory failed to consistently run a positive control with each batch of specimens as specified in the manufacturer's IFU for the Quidel Solana severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) assay. Findings: 1. The manufacturer's IFU stated "A positive control (such as a positive patient sample) should be processed and tested with each batch of specimens." 2. Instrument data for "8-7-22 batch 2" showed that no QC was run with the 2 patient specimens tested in the batch. 3. During the survey on 01/19/2024 at 1:15 PM, the LD confirmed that a single set of external positive and negative QC are run each day of testing and confirmed that the manufacturer's IFU stated that a positive control should be processed with each batch of specimens tested.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or

	both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for use (IFU), review of quality control (QC) records, and interview with the laboratory director (LD), the laboratory failed to document corrective actions taken when QC results were unacceptable for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) testing. Findings: 1. The laboratory performed the Quidel Solana SARS-CoV-2 Assay. 2. The manufacturer's IFU stated that "The external positive control is intended to monitor substantial reagent and instrument failure," "The external negative control is used to detected reagent or environmental contamination (or carry-over) by SARS-CoV-2 RNA or amplicon," and "The Solana SARS-CoV-2 Assay should not be used in patient testing if the controls do not produce the correct results." 3. The laboratory documented the QC results in the "Solana SARS Cov-2 Daily Quality Control Log" (QC log). 4. The QC log showed that on 08/06/2022, the negative QC had a positive result and on 08/07/2022, the positive QC had a negative result. The comment section for both dates stated "ON SOLANA 21022223" with no documentation of what corrective actions were taken for the failed QC results. 5. Backed up instrument files showed that at 11:32 AM "8-6-22 Batch 4" included a positive QC with a negative result and 10 patients tested. No other instrument files reviewed for 08/06/2022 or 08 /07/2022 showed that those 10 patients tests were repeated. 6. Backed up instrument files showed that at 1:18 PM "8-6-22 Batch 3" included a negative QC with a positive result and a single patient tested. No other instrument files showed that the patient test was repeated. 7. There was only a single instrument file for 08/07/2022 named "8-7-22 batch 2" that included 2 patient results and no QC results. 8. During the survey on 01/19/2024 at 2:15 PM, the LD confirmed that QC for the Solana SARS-CoV-2 Assay failed on batches from 08/06/2022 and 08/07/2022, no corrective actions were documented, and there was no documentation that patient results were repeated with passing QC results.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, review of patient testing logs, and interview with the laboratory director (LD), the LD failed to ensure that corrective actions were taken for unacceptable PT results and patient results that were potentially affected. Findings: 1. The laboratory received PT scores of 50% for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and 60% for group A Streptococcus (GAS) in the 2023 3rd PT event. 2. The performance evaluation form

	had a written note stating "Both strep A and SARS-CoV-2 results contained unacceptable results. So we ordered remediation tests for both." Records showed that the laboratory received 100% on the remediation PT samples. 3. The laboratory didn't use the PT investigation form to investigate the root cause of the 2023 3rd PT event failures and there was no documentation that patient results were evaluated to ensure they were not affected by the same issues affecting the PT samples. 4. Attestation statements indicated that unacceptable PT samples were run on 09/20/2023. Patient testing logs showed that 4 patients (1 positive, 3 negative) were tested for GAS and 5 patients (all negative) were tested for SARS-CoV-2 on 09/20/2023. 5. During the survey on 01/19/2023 at 2:15 PM, the LD confirmed that an investigation into the failed PT results was not performed, and corrective actions were not taken for failed PT results and for patients that were potentially affected.
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: Based on review of quality control (QC) records, the testing procedure, instrument data, patient logs, and the manufacturer's instructions for use (IFU), and interview with the laboratory director (LD), the LD failed to ensure that the QC program was maintained to assure the quality of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) results. Findings: 1. The laboratory tested patient specimens for SARS-CoV-2 using the Quidel Solana instrument. 2. The laboratory documented the QC results in the "Solana SARS Cov-2 Daily Quality Control Log" (QC log). 3. The "Solana SARS-Cov-2 Assay Testing procedure manual" stated that once patient testing was complete to "Upload the run files results from the Solana instrument onto a USB drive and then download it into the 'Patient PCR folder' in the save drive." a. The laboratory had two Solana instruments. The uploaded instrument data did not differentiate between the two instruments. b. The QC log showed QC results for a single batch of testing on 08/06/2022, but the uploaded instrument data showed results for three separate batches tested at 11:13 AM, 11:32 AM, and 1:18 PM. c. The QC log showed QC results for three separate batches of testing on 08/07/2022, but the uploaded instrument data showed results for a single batch tested with two patients and no QC. d. The QC log showed QC results for a single batch of testing on 08/08 /2022 and patient logs showed that patients were tested, but there was no uploaded instrument data for that day. 4. The LD did not ensure that a positive control was run with each batch of specimens as specified in the manufacturer's instructions for use (IFU) (cross-refer to tag D5445 for details). 5. Corrective actions for failed QC results were not documented and there was no documentation that patient results were reviewed or repeated prior to acceptable QC results (cross-refer to tag D5783 for details). 6. During the survey on 01/19/2024 at 2:15 PM, the LD confirmed that the uploaded instrument data did not differentiate between the 2 instruments, that the QC log did not consistently record the QC results for each batch tested in a day, that the instrument data was not consistently uploaded for each batch tested, that a positive control was not run with each batch of specimens as stated in the manufacturer's IFU,

	and that corrective actions for failed QC were not documented prior to releasing patient results.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the laboratory director (LD), the LD acting as the technical consultant had not performed the semi-annual competency assessment for testing person number 5 (TP5). Findings: 1. The laboratory had six testing personnel listed on the Laboratory Personnel Report form (CMS-209). 2. TP5 had training records dated 06/10/2023. 3. There was no documentation of a 6-month competency assessment. 4. During the survey on 01/19 /2024 at 11:40 AM, the LD confirmed that the 6-month competency assessment for TP5 was overdue to be performed.