Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1101671	05/22/2019
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
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the written procedure manual, review of hematology quality control ((QC), and interview with the technical consultant (TC), the laboratory failed to ensure that hematology QC meet the laboratory's criteria of acceptability prior to performing patient testing(Refer to D5417); failed to ensure that hematology QC meet the laboratory's criteria of acceptability prior to releasing patient results (Refer to D5481); And failed to perform corrective action procedures when the hematology QC did not meet the laboratory's criteria of acceptability (Refer to D5783)
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of hematology quality control (QC) records and interview with the technical consultant (TC), the laboratory did not ensure that hematology QC meet the laboratory's criteria of acceptability prior to performing patient testing. Findings: 1. Between March 24-25 2018 the hematology QC showed a error code of "EC". 2. On 3 /24/18 the low and high QC had the error code of "EC". 3. On 3/25/18 the low and

	high QC had the error code of "EC". 4. The TC stated that was unsure the definition of the code but later learned that the code stood for "expired control". 5. The laboratory did not have the hematology QC package inserts available for review to ensure the lot number and expiration dates of the QC. 6. No patients were tested on 3 /24/18 and one patient was tested on 3/25/18 and the laboratory director approved the results.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the written procedure manual, hematology quality control (QC) records, and interview with the technical consultant (TC), the laboratory did not ensure that hematology QC meet the laboratory's criteria of acceptability prior to releasing patient results. Findings: 1. The TC documented in the quality assurance report that on 10/25/18 the normal and high hematology QC was out of range. Review of the QC summary report showed that the two out of the three levels of QC was not in range with the normal and high QC out. 2. The laboratory written procedure states that two out of three levels of QC must be in range prior to patient results being released. 3 Three patients were tested on 10/25/18 and results were released. 4. The TC stated that she does not know why she did not have testing personnel run the QC again and start troubleshooting procedures.
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 written procedure manual, hematology quality control (QC) records, and interview with the technical consultant (TC), the laboratory did perform corrective action procedures when the hematology QC did not meet the laboratory's criteria of acceptability. Findings: 1. The TC documented in the quality assurance report that on 10/25/18 the normal and high hematology QC was out of range. Review of the QC summary report showed that the two out of the three levels of QC was not in range with the normal and high QC out. 2. The laboratory written procedure states that's two out of three levels of QC levels must be in range prior to patient results being released and troubleshooting procedures should be performed when two out of the three levels of QC are not within range. 3. Troubleshooting procedures were not

	performed on the hematology analyzer on 10/25/18 4. The TC stated that she does not know why she did not have testing personnel run the QC again and start troubleshooting procedures.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of temperature records and interview with the technical consultant (TC), the laboratory did not perform corrective action procedures when the laboratory freezer was outside of the established temperature range. Findings: 1. The laboratory freezer temperature was outside of the 0-20 Degrees Celsius range during the year 2018 on March 13th, 17th, 18th, 19th, 20th, 21st, 22nd, 23rd, 224th, 25th 26th, 27th, 28th, 29th, 30th, and the 31st. 2. The TC documented in the quality assurance note that all temperatures were within range for the month of March 2018. 3. Corrective action and troubleshooting procedures were not performed and freezer temperatures were not retaken to ensure the quality of laboratory services provided.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of the written procedure manual, hematology quality control (QC) records, and interview with the technical consultant(TC), the TC failed ensure that hematology QC meet the laboratory's criteria of acceptability prior to releasing patient results. Findings: Refer to D5481 and D5417
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on review of temperature records and interview with the technical consultant (TC), the TC failed to ensure that corrective action procedures were performed when the laboratory freezer was outside of the established temperature range. Findings: Refer to D5785

D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on review of the written procedure manual, hematology quality control (QC) records, and interview with the technical consultant (TC), the TC failed ensure that corrective action procedures were perfromed when the hematology QC did not meet the laboratory's criteria of acceptability. Findings: Refer to D5783