Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0146599	04/29/2021
Name of Provider or Supplier	**Street Address, City, State**	
Niranjan K Mittal Physician Pllc	7404 5th Avenue, Brooklyn, NY	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on surveyor's review of the 2019 and 2020 American Proficiency Institute (API) proficiency testing (PT) records and an interview with the laboratory director and testing person, the laboratory failed to enroll in an approved PT program for the specialties Hematology for Hemochron/Activated Clotting Time (ACT) and Routine Chemistry/Comprehensive Metabolic panel(CMP) in the calendar years 2019 and 2020.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on surveyor's review of API Hematology PT records for 2019, 2020 and 1st

	event of 2021 and an interview with the laboratory director and testing person, the laboratory director failed to sign the attestation forms attesting that the PT samples were tested in the same manner as patient specimens.
D2011	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program. This STANDARD is not met as evidenced by: Based on surveyor's review of API PT attestation statement, PT test result forms and an interview with the laboratory director and testing person, the laboratory failed not to engage in inter-laboratory communications between the four routine testing personnel for all 3 test events for 2019 and 2020 and 1st event of 2021. FINDINGS. The laboratory director and testing person confirmed on April 29, 2021 at approximately 2:00 PM, the surveyor's findings that all four testing personnel performed all three test events for 2019, 2020 and 1st event of 2021. The laboratory testing personnel ran the specimens as follows: a. All 3 2019 and 2020 hematology PT test events was tested by the same four testing personnel and then one set of test results was selected to submit to API PT program b. 2021 1st event was tested by the same four testing personnel and then one set of test results was selected to submit to API PT program. c. The testing person stated," that she was using these events as a training for the three other testing personnel".
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on surveyor's review of laboratory records and an interview with the laboratory director and testing person, the laboratory failed to: 1. Maintained the PT program, Refer to D2000, D2009 and D2011; 2. Maintain and follow the competency assessment policy, Refer to D5209; 3. Maintain the Quality Assessment program, Refer to D5291.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235

	As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on lack of competency assessment records for the four of four testing personnel , the laboratory's competency assessment policy and an interview with the laboratory director and testing person, the laboratory failed to follow their written policies for competency assessment for four of four testing personnel . FINDINGS: The laboratory director and testing person confirmed on April 29, 2021 at approximately 2: 30 PM, the surveyor's findings that the laboratory failed to follow their written competency assessment polices for the following: a. four of four who routinely perform hematology and chemistry testing failed to be trained on the Sysmex pocH-100i hematology analyzer, Hemochron/Activated Clotting Time (ACT), Coagu-Sense Monitoring system for Prothrombin Time (PT)/International Normalized Ratio (INR) and i-Stat chemistry analyzer, prior to performing patient testing.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a surveyor's review of laboratory records and an interview with the laboratory director and testing person, the laboratory failed to follow their written Quality Assessment (QA) policy and procedure for an ongoing mechanism to monitor, assess, and when indicated correct problems that may occur in the laboratory testing. Refer to D5209 and D5437.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on surveyor's review of hematology analyzer Sysmex pocH-100i records and an interview with the laboratory director and testing person,the laboratory failed to perform the required six month calibration in the calendar years 2019 and 2020.

	FINDINGS: The laboratory director and testing person on April 29, 2021 at approximately 3:00 PM, that the laboratory did not perform the required six month calibration for the hematology analyzer in the calendar years 2019 and 2020. a. The laboratory's calibration policy and the manufacturer policy for the Sysmex pocH-100i hematology analyzer requires the analyzer to be calibrated every six months and/or as needed after preventative maintenance. b. The surveyor could not determine when the last calibration was performed, therefore, the analyzer remains out of calibration from 2018 through survey date. b. Approximately 2000 patient specimens were tested and reported for hematology during the time period when analyzer was out of calibration.
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 surveyor's findings and an interview with the laboratory director and testing person, the laboratory director failed to provide overall management of the laboratory. FINDINGS: The laboratory director failed to ensure that the laboratory: 1. Enrolled in proficiency testing program for testing performed in the laboratory, Refer to D6015; 2. Maintained the quality control program for hematology, Refer to D6020; 3. Maintained their written QA policy for all phases of laboratory testing, Refer to D6021; 4. Personnel had appropriate training, prior to patient testing, Refer to D6029.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on surveyor's review of the 2019 and 2020 American Proficiency Institute (API) proficiency testing (PT) records and an interview with the laboratory director and testing person, the laboratory director failed to enroll in an approved PT program for the specialties Hematology for Hemochron/Activated Clotting Time (ACT) and Routine Chemistry/Comprehensive Metabolic panel(CMP) in the calendar years 2019 and 2020. Refer to D2000.
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 a surveyor's review of hematology QC records and confirmed in an interview with the laboratory director and testing person at the time of this survey, the laboratory director failed to ensure that the QC program for hematology was maintained to assure the quality of laboratory services. Refer to: D5437.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a surveyor review of the laboratory Quality Assessment (QA) policy, lack of QA documentation and interview with the laboratory director and testing person confirmed at the time of this survey, the laboratory director failed to ensure that the laboratory's QA program was maintained for all phases of laboratory testing. Refer to: D5437.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a surveyor's review of the four personnel records and in an interview with the laboratory director and testing person, and confirmed at the time of this survey, the laboratory director failed to ensure that appropriate training was documented for the four current testing personnel performing moderate complexity.