Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0129928	02/08/2022
Name of Provider or Supplier	**Street Address, City, State**	
Barry J Klyde Md Pc	520 East 72nd Street, L-0, New York, 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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation of beverage and food in the laboratory refrigerator which contained Horiba control & calibration materials, Quantimetrix Dipper urine control the laboratory failed to follow the laboratory's Safety and Universal procedures. FINDINGS: 1. The laboratory's Safety & Universal procedures states, "that no food, beverages, smoking is permitted in the laboratory." 2. The surveyor observed a beverage an salad at 9:30 AM in the laboratory refrigerator which contained Horiba control & calibration materials, and Quantimetrix Dipper urine controls.
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 review of the Quality Assessment (QA) policy, lack of the 2020 & 2021 QA documentation and an interview with the laboratory testing personnel, the laboratory failed to follow the establish QA policy and perform an annual review, as required. FINDINGS: 1. The laboratory's QA policy requires an annual review to identify

	problems, perform a corrective/remedial action and monitor the remedial action to ensure the problem was corrected. 2. The laboratory failed to perform and document an annual QA review in the calendar year 2020 and 2021.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview with the testing personnel, the laboratory failed to establish written policies and procedures for specimen collection, labeling, storage, transportation, acceptability and rejection. FINDINGS: 1. The laboratory failed to provide written policies and procedures for specimen collection. 2. The laboratory failed to provide written policies and procedures for specimen labeling. 3. The laboratory failed to provide written policies and procedures for specimen storage. 4. The laboratory failed to provide written policies and procedures for specimen transportation. 5. The laboratory failed to provide written policies and procedures for specimen acceptability and rejection. 6. The testing personnel confirmed on February 8, 2022 at approximately 10: 00 AM, the laboratory failed to establish written procedures and policies for urine and blood specimens.
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 observation of the Horiba calibration material stored in the laboratory's refrigerator Siemens Multistix 10SG urine test strips interview with the laboratory testing personnel, the laboratory failed to review calibration materials and reagent test strips for expired dates. FINDINGS: 1. The surveyor observed 3 boxes of Horiba Minocal calibration material at 9:45AM in the laboratory refrigerator and urine test strips on the counter. Minocal Lot # CX450 expiration date 6-5-21 (1 box) Minocal Lot# CX460 expiration date 2-5-22 (2 boxes) Siemens Multistix 10SG urine test strips Lot# 802037 expiration 8/31/19 (100 strips in the vial- not used for patient testing) 2. The laboratory testing personnel confirmed on February 8, 2022 at approximately 9: 45AM, the surveyor's findings of the expired calibration material was not used for calibration of the Horiba Micros 60 hematology analyzer and the urine test strips were not used for patient testing.
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 review of the laboratory standard operating procedure (SOP), lack of QA records and an interview with the laboratory testing personnel, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to implement and maintain the: 1. laboratory's Quality Assessment program was maintained, Refer to D6021; 2. laboratory's corrective/remedial action, Refer to D6024
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 of review of the laboratory's QA procedures, lack of the corrective action documentation and an interview with the laboratory testing personnel, the laboratory director failed to maintain and perform a QA review in 2020, 2021, as required by the QA policy, to identify and take remedial action when problems occur in all aspects of laboratory testing. Refer to: D3011, D5291, D5311, and D5417
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on review laboratory's SOP, observation of calibration material & reagent expiration dates and an interview with the laboratory testing personnel, the laboratory director failed to ensure that remedial action was taken and documented when problems were identified. Refer to D3011, D5291, D5311, and D5417