

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D0129928	<b>(X3) Date Survey Completed</b>  10/31/2024
<b>Name of Provider or Supplier</b>  Barry J Klyde Md Pc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3031</b>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, lack of standard operating procedures (SOPs), quality control (QC), calibration, and preventative maintenance (PM) records, as well as interview with the medical assistant (MA), the laboratory failed to maintain and retain Horiba Micros 60 analyzer documentation. FINDINGS: 1. There was no documentation of Horiba Micros 60 analyzer quality control and calibration, daily functions checks, and preventative maintenance. 2. The current, approved SOPs did not include instructions for performing such activity. 3. Findings were confirmed by interview with the MA on October 31, 2024, at approximately 4:00 P.M.</p>
<b>D3039</b>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5)</p> <p>Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, lack of SOPs and Quality Assurance (QA) records, as well as interview with the MA, the laboratory failed to maintain and retain quality system assessment records. FINDINGS: 1. There was no documentation of current, approved procedure manual, QC and calibration records, personnel training and competency assessments, as well as quality assessment review for 2022, 2023, and</p>

2024. 2. Findings were confirmed by interview with the MA on October 31, 2024, at approximately 4:00 P.M.

**D5221**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on review of Centers for Medicare & Medicaid Services (CMS) Proficiency Testing (PT) Certification and Survey Provider Enhanced Reporting system (CASPER 0155D) and College of American Pathologists (CAP) Proficiency Testing (PT) records, as well as interview with the testing personnel (TP), the laboratory failed perform and document remedial action for PT scores less than 100%.

FINDINGS: 1. A review of the CASPER 155 report revealed the following unsatisfactory scores: Hematology Specialty: 2022 First Event = 0% 2022 Second Event = 73% 2023 First Event = 23% Cell ID or WBC (White Blood Cell) Diff Test Analyte: 2022 First Event = 0% 2022 Second Event = 40% 2022 Third Event = 73% 2023 First Event = 60% RBC (Red Blood Cell) Test Analyte: 2022 First Event = 0% 2022 Second Event = 60% 2023 First Event = 0% HCT (Hematocrit) (Non-Waived) Test Analyte: 2022 First Event = 0% 2022 Second Event = 60% 2023 First Event = 0% HGB (Hemoglobin) (Non-Waived) Test Analyte: 2022 First Event = 0% 2023 First Event = 40% WBC Count Test Analyte: 2022 First Event = 0% 2023 First Event = 20% Platelets Test Analyte: 2022 First Event = 0% 2023 First Event = 20% 2. A review of the proficiency testing scores from CAP (2022 and 2023) confirmed the above findings. 3. There was no documentation of remedial action or corrective action performance for PT scores less than 100%. 4. Findings were confirmed by interview with the TP on October 31, 2024, at approximately 4:00 P.M.

**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 direct observation, lack of QA SOPs, as well as interview with the TP, the laboratory failed to draft, approve, and maintain QA procedures. FINDINGS: 1. The current, approved SOPs did not include instructions for monitoring and evaluating all phases of the laboratory's pre-analytic, analytic, and post-analytic systems. 2. Findings were confirmed by interview with the TP on October 31, 2024, at approximately 4:30 P.M.

**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

	<p>appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on lack of SOPs, review of patient specimen test requisitions, as well as interview with the TP, the laboratory failed to draft, approve, and maintain policies and procedures for specimen collection, labeling, storage, transportation, acceptability, and rejection. FINDINGS: 1. The current, approved SOPs did not include instructions for patient specimen collection, labeling, storage, transportation, as well as acceptability and rejection. 2. Findings were confirmed by interview with the TP on October 31, 2024, at approximately 4:00 P.M.</p>
<p><b>D5401</b></p>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, lack of SOPs, and an interview with the TP, the laboratory failed to draft, approve, and maintain procedures for all phases of laboratory specimen testing and QA. Refer to D3031, D3039, D5291, and D5311.</p>
<p><b>D5417</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, lack of SOPs, as well as interview with TP, the laboratory failed to remove from inventory expired calibration materials and reagents located in the laboratory refrigerator. FINDINGS: 1. The surveyor's observations confirmed on October 31, 2024, at approximately 4:00 P.M. the following reagents and calibration materials were not removed from inventory: a. Quantimetrix Dipper QC; expiration: January 31, 2024; and expiration: August 31, 2023, were stored in the laboratory refrigerator. b. Siemens Multistix 10 SG lot: 211039, expiration: May 31, 2024, was stored in the laboratory refrigerator. 2. The current, approved SOPs did not include instructions for removing expired calibration materials and reagents from inventory. 3. Due to lack of documentation, the surveyor was unable to determine if the respective expired calibration materials were utilized for patient specimen processing. 4. Findings were confirmed by interview with the TP on October 31, 2024, at approximately 4:00 P.M.</p>
<p><b>D5437</b></p>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(a)</p>

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 direct observation, lack of SOPs, QC, and calibration records, as well as interview with the TP, the laboratory failed to perform and document Horiba Micros 60 analyzer calibration. FINDINGS: 1. There was no documentation of Horiba Micros 60 analyzer quality control and calibration performance every six months for 2022, 2023, and 2024. The most recent analyzer calibration was performed in 2021. 2. The current, approved SOPs did not include instructions for performing such activity. 3. Approximately 960 patient specimens were tested during 2024. 4. Findings were confirmed by interview with the TP on October 31, 2024, at approximately 4:00 P.M.

**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 direct observation, review of PT records, lack of QC, QA, and analyzer PM documentation, lack SOPs, as well as interview with the TP, the laboratory director (LD) failed to provide overall management of the laboratory. FINDINGS: 1. The LD failed to ensure that the laboratory: a. Retained and maintained compliance with the plan of correction for deficiencies cited during the on-site survey conducted February 8, 2022; b. Successfully participated in PT for the hematology specialty; Refer to D5221. c. Maintained the QC program; Refer to D3039 and D5291. d. Maintained the QA program for all phases of laboratory testing; Refer to D6021. e. Performed and documented annual competency assessments and training for personnel performing moderate complexity testing; Refer to D6064. f. Findings were confirmed by interview with the TP on October 31, 2024, at 4:00 P.M.

**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 direct observation, lack of SOPs and QA records, as well as interview with the General Supervisor (GS), the LD failed to maintain and comply with the laboratory's quality assessment program. FINDINGS: 1. There was no documentation of periodic quality assessment performance. 2. The current, approved SOPs did not include instructions for performing such activity. 3. Findings were confirmed by interview with the TP on October 31, 2024, at 4:00 P.M.

**D6064**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1423(a)

Each individual performing moderate complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

This STANDARD is not met as evidenced by:  
Based on lack of TP records, SOPs as well as interview with the TP, the LD failed to perform and document TP training and competency evaluation. FINDINGS: 1. There was no documentation of education, training, and competency evaluation for TP who perform on-site patient specimen processing and result reporting. 2. The current, approved SOPs did not include instructions for performing such activity. 3. Findings were confirmed by interview with the TP on October 31, 2024, at 4:00 P.M.