

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 33D0863268	<b>(X3) Date Survey Completed</b> 12/02/2021
<b>Name of Provider or Supplier</b> Paul K Wein Md Pc Associates	<b>Street Address, City, State</b> 2985 Quentin Rd, Brooklyn, 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><b>RETENTION REQUIREMENTS</b> 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 surveyor's review of the laboratory's procedure for the Laboratory Information System (LIS) software LABDAQ and an interview with the testing person, the laboratory failed to establish a complete LIS policy that specifies the frequency for which a laboratory should evaluate its record storage and retrieval system. <b>FINDINGS</b> The testing person confirmed on December 2, 2021 at approximately 10:15 AM, that the laboratory failed to establish a complete LIS policy that specifies the frequency for which a laboratory should evaluate its record storage and retrieval system. a. The LIS system was not backed up to include instrument charts, graphs, printouts, transcribed data, and manufacturers' assay information sheets for control and calibration materials. b. The laboratory failed to identify and take corrective action for the following issues: c. The letter written by the physician regarding the flood failure to state the paperwork that was destroyed in the flood on 8/22/21, the following records were not available for review for QC/calibration records for Beckman Access 2 endocrinology analyzer &amp; Alfa Wasserman Ace chemistry analyzer and the Beckman Coulter AcT Diff hematology analyzer, maintenance &amp; preventative maintenance &amp; service records for the analyzers, training for the current testing person, instrument printouts, assay sheets for calibration &amp; QC material, linearity for chemistry analyzer and corrective action for the calendar years 2019, 2020 and 2021.</p>
<b>D3037</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(4)</p>

Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of Medical Laboratory Evaluation (MLE) Proficiency Testing (PT) records for 1st event of 2019, 2nd & 3rd event of 2020 and an interview with the testing person, the laboratory failed to retain documentation to include signed attestation forms, instrument printouts, MLE test result forms and a signed PT summary reports, corrective action documentation for the all three events for 2019, 2020 and 1st & 2nd event of 2021 1st and 2nd events for hematology, endocrinology and chemistry challenges. Refer to D6021

**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 the surveyor's review of the laboratory's competency evaluation policy and lack of training documentation for the testing person hired October 30, 2021 and an interview with the testing person, the laboratory director failed to follow their establish competency assessment policy and perform the initial training for the testing person prior to performing endocrinology, chemistry and hematology testing. Refer to D6029 FINDINGS: The testing person confirmed on December 2, 2021 at approximately 10:00 AM, the surveyor's findings that the laboratory failed to follow their written competency assessment policy. a. the laboratory's competency policy requires training of personnel who perform endocrinology, chemistry and hematology testing, prior to 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 surveyor's review of the laboratory's Quality Assessment (QA) policy, lack of QA records and an interview with the testing person, the laboratory failed to follow their established QA policy for an ongoing mechanism to monitor, assess and correct problems identified in the general laboratory systems. Refer to D3030, D3037 and D5209 FINDINGS: 1. The testing person confirmed on December 2, 2021 at approximately 10:15 AM, that the laboratory failed to follow their established QA policy for an ongoing mechanism to monitor, assess and correct problems identified in the general laboratory systems. 2. The laboratory's QA policy requires a annual review of all phases of the laboratory's testing. 3. The laboratory failed to identify and take corrective action for the following issues: a. failure to state the paperwork that

	<p>was destroyed in the flood on 8/22/21 b. no records or documentation for the following QC, calibration, maintenance records, service records, preventative maintenance records, training &amp; competency for the previous testing personnel, instrument printouts, assay sheets for calibration &amp; QC material, linearity for chemistry analyzer and corrective action for the calendar years 2019, 2020 and 2021.</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor's findings and confirmed in an interview with the testing person at this survey, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the: 1. laboratory's QA program was maintained, refer to D6021; 2. laboratory maintained the competency assessment policy, refer to D6029.</p>
<p><b>D6021</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor's review of the laboratory QA policy, lack of the QA documentation and confirmed in an interview with the testing person 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: D3031, D3037, D5209 and D5291</p>
<p><b>D6029</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(11)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on the lack of training records for the current testing person and an interview with the testing person, and confirmed at the time of this survey, the laboratory director failed to ensure that appropriate training was documented for the current testing person who performs moderate complexity testing. Refer to D5209