

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D0130044	<b>(X3) Date Survey Completed</b>  05/12/2021
<b>Name of Provider or Supplier</b>  Yashar Hirshaut Md Pc	<b>Street Address, City, State</b>  6323 7th Ave, 1st Floor, 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 Horiba AbX Micros 60 hematology QC records, 2021 Micros 60 maintenance logs and an interview with the laboratory testing person, the laboratory failed to retain copies of the Micros 60 2019, 2020 instrument maintenance records and the laboratory refrigerator temperature logs. FINDINGS: 1. The laboratory testing person confirmed on May 12, 2021 at approximately 10:30 AM, the surveyors findings that the laboratory failed to retain copies of the Horiba ABX Micros 60 instrument maintenance records and the laboratory refrigerator temperature logs for the calendar years 2019 and 2020. 2. The testing person could not locate these logs when preparing for the inspection 3. Horiba AbX Micros 60 manufacturer requires the controls to be stored between 2-8C and/or 36-46F a. Due to the lack of records, the surveyor could not determine if the laboratory refrigerator temperature was in the acceptable range of 2-8C and/or 36-46F from 1/1/2019 through 1/31/2020. b. The surveyor's review of the QC records revealed the following Mintrol controls were stored during this time period: Lot# MX426 expiration 3-5-20; MX427 expiration 5-5-20; MX428 expiration 5-5-21 and current lot in use MX429 expiration 7-5-21 4. The surveyor could not verify if the required maintenance for the analyzer was performed, due to the lack of records.</p>