

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D0923416	<b>(X3) Date Survey Completed</b>  10/27/2021
<b>Name of Provider or Supplier</b>  Star Medical Offices Pc	<b>Street Address, City, State</b>  415 Oceanview Avenue, Ground 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 Mintrol-16 Peer Review Quality Control (QC) records, ABX Horiba Micros 60 instrument current electronic QC records and an interview with the general supervisor/testing person, the laboratory failed to retain the monthly QC printouts Levy Jennings graphs and the daily start-up printouts for the Micros 60 instrument from January 1, 2019 through September 30, 2021. FINDINGS: The general supervisor/testing person confirmed on October 27, 2021 at approximately 2:45 PM, the surveyor's findings that the laboratory failed to retain the monthly QC printouts/Levy Jennings graphs and daily start-up printouts for the ABX Horiba Micros 60 instrument from January 1, 2019 through September 30, 2021. a. The general supervisor/testing person stated, "that he prints the 3 levels of Mintrol-16 QC monthly printouts submitted to the ABX Diagnostic Peer Review Evaluation program. He then scans the Peer Review Result sheets into the Laboratory's Information System (LIS) LABDAQ and then discards the original printouts." b. The general supervisor/testing person stated, "that he does not retain copies of the start-ups for the ABX Horiba Micros 60 instrument." c. Approximately 2,000 patient samples were tested and reported for automated CBC performed on the ABX Horiba Micros 60 from January 1, 2019 through September 30, 2021.</p>