

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D0932353	<b>(X3) Date Survey Completed</b>  01/31/2024
<b>Name of Provider or Supplier</b>  Amit H Sheth Md Pc	<b>Street Address, City, State</b>  22878 Three Notch Road, California, MD	
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>D6070</b>	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1)</p> <p>Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Coulter Act2 Diff (hematology analyzer) patient log, patient reports, and interview with the technical consultant (TC), the testing personnel (TP) failed to assign the correct analyzer sequence ID number to two of five patients that were reviewed during the survey. Findings: 1. The Coulter Act2 Diff patient log was reviewed and five patient reports were pulled for verification. Two of the five that were reviewed failed to have the correct analyzer sequence identification (ID) number (#) listed on the final report. 2. The Coulter Act2 Diff patient log for 02/28/22 showed that patient "NV" had a sequence ID# of 88. When the patient chart was pulled the sequence ID# was listed on the analyzer printout as 89. 3. The Coulter Act2 Diff patient log for 03/07/23 showed that patient "VS" had a sequence ID# of 8. When the patient chart was pulled the sequence ID# was listed on the analyzer printout as 10. 4. During the survey on 01/31/2024 at 12:30 pm, the TC confirmed that the TP were not documenting the correct analyzer sequence ID# on the Coulter Act2 Diff patient log and entering the correct analyzer sequence ID# into the analyzer when the patient sample was being testing. The ID# listed on the patient log did not match the ID# of the printout in the patient's chart. The cumulative effect of these ID# errors can result in the laboratory's ability to ensure accurate and reliable patient test results.</p>