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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 01D2185967 | (X3) Date Survey Completed 08/12/2021 |
| Name of Provider or Supplier Allegra Family Clinic | Street Address, City, State 1116 Mitt Lary Road, Northport, AL | |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. | | |

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| D5429 | <p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Hematology Sysmex XP-300 maintenance records, a review of the Sysmex XP-300 Instructions For Use, and an interview with Testing Personnel #1, the laboratory failed to document quarterly maintenance. This was noted from August 2020 (when patient testing started) to July 2021. The findings include: 1. A review of the Hematology maintenance records revealed a place to document quarterly maintenance on the Sysmex XP-300 Maintenance Log and this was left blank from August 2020 to July 2021. During this time period quarterly maintenance should have been documented at least three times. 2. A review of the Sysmex XP-300 Instructions For Use revealed in section 12, page 12-12 under Clean SRV, "When the main power switch is turned ON, and if either the counter value exceeds 4,500, or if 3 months have passed since the last maintenance, a message will appear prompting the operator to perform periodic maintenance (SRV cleaning)...". 3. During an interview on 08/12/2021 at 1:21 PM, Testing Personnel #1 confirmed the above findings, and was not aware of performing this maintenance since she started in April 2021.</p> |