

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D1042724	<b>(X3) Date Survey Completed</b> 03/30/2023
<b>Name of Provider or Supplier</b> Clinica Familiar San Jose Pa	<b>Street Address, City, State</b> 8030 N Fm 1015 Ste B, Mercedes, TX	
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>D3037</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based upon review of 2022 and 2023 proficiency testing records and interview of facility personnel the laboratory failed to retain original submission forms for three of four proficiency testing events for a minimum of two years. The findings included: 1. Review of the American Proficiency Institute (API) Hematology proficiency testing records found the laboratory failed to retain the original submission forms for the following proficiency testing events: 2022 Testing event 2 2022 Testing event 3 2023 Testing event 1 2. During interview of testing person one as listed on the CMS-209 conducted March 30, 2023 at 9:35 AM, she confirmed she discarded proficiency testing original submission forms after submission of result to the proficiency testing agency.</p>
<b>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> 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 upon review of Sysmex XP-300 maintenance instructions, maintenance records and interview of facility personnel, the laboratory failed to perform quarterly maintenance procedures at least once every three months on the Sysmex XP 300 Hematology analyzer between April 2022 and March 30, 2023. The findings included:</p>

1. Review of the Sysmex XN-300 Operator's manual maintenance instructions found on page 12-1 under maintenance schedule: "Every 3 months (or every 4500 samples) Clean the 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). Press the [Cancel] button to continue start up without executing SRV cleaning operation. Until the SRV is cleaned, the above message is displayed at start up. When the message is displayed, perform SRV cleaning according to the following procedures..." 2. Review of 12 months maintenance logs between April 2022 and March 30, 2023 found no documentation of quarterly maintenance being performed on the Sysmex XN-300. 3. During interview of the Technical consultant conducted March 30, 2023 at 10:32 AM, she confirmed quarterly maintenance procedures were not being performed and documented.

**D6049**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:  
Based upon review of manufacturer's instructions, maintenance records and interview of facility personnel, the Technical consultant failed to ensure quarterly maintenance procedures were performed on the Sysmex XN 300 at least once every 3 months between April 2022 and March 2023. (see D 5429)