

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D0971816	<b>(X3) Date Survey Completed</b>  11/29/2023
<b>Name of Provider or Supplier</b>  Sfmg Pediatrics	<b>Street Address, City, State</b>  104 Contempo Avenue, West Monroe, LA	
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>D0000</b>	<p>An Offsite revisit survey was conducted at Rosales Children's Clinic - CLIA ID #19D0971816 on Feb 14, 2023. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories. No deficiencies were cited.</p> <p>A Certification survey was performed on November 29, 2023 at Rosales Children's Clinic, CLIA ID #19D0971816. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standards 493.1254(a)(1) and 493.1254(b)(1) were cited.</p>
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing records with personnel, the laboratory failed to ensure testing personnel and laboratory director signed the attestations for one (1) of six (6) proficiency testing (PT) events reviewed in 2022 and 2023. Findings: 1. Review of 1 American Association of Bioanalysts (AAB) proficiency testing (PT) records from 2022 and 2023 revealed that statements were not signed by the laboratory director and/or testing personnel for the following one (1) event reviewed: a) AAB NonChemistry M2 2023: Laboratory Director and Testing Personnel did not sign attestations. During an interview on November 29, 2023 at 10:04 am, the laboratory supervisor confirmed the attestations were signed by appropriate personnel as required.</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 preventive maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p>

This STANDARD is not met as evidenced by:

Based on observation by surveyor, review of maintenance records, and interview with personnel, the ensure the weekly maintenance on the Sysmex XP-300 was performed as required by the manufacturer. Observation by surveyor during the laboratory tour on November 29, 2023 at 09:15 am revealed the 1 Sysmex XP-300 analyzer for Complete Blood Count (CBC) testing in the specialty of Hematology. 2 laboratory's maintenance log for the Sysmex XP-300 hematology analyzer revealed the following were performed: a) Weekly: Clean SRV Tray 3. Further review of the maintenance records for the Sysmex January 2022 through November 2023 revealed the laboratory did not perform the weekly maintenance three (3) of ninety six (96) weeks reviewed: a) November 10, 2023 b) November 17, 2023 c) November 24, 2023. Interview on November 29, 2023 at 10:24 am, the laboratory supervisor confirmed the weekly maintenance was not performed for the identified weeks.

**D6014** LABORATORY DIRECTOR RESPONSIBILITIES  
CFR(s): 493.1407(e)(3)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, in employment of personnel who are competent to perform test procedures, and record and report test results accurately, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director shall ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy and records along with interview with personnel, the Laboratory failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to ensure the weekly maintenance on the Sysmex XP-300 was performed as required by the manufacturer. Refer to D5429.

**D6018** LABORATORY DIRECTOR RESPONSIBILITIES  
CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, in employment of personnel who are competent to perform test procedures, and record and report test results accurately, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director shall ensure that-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on review of laboratory policy and proficiency testing records and interview with personnel, the laboratory failed to ensure proficiency testing attestation statements were signed by the appropriate personnel. The laboratory failed to ensure testing personnel and laboratory director signed the attestation statement for proficiency testing (PT) events reviewed in 2022 and 2023. Refer to D2009.