Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0971816	11/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Sfmg Pediatrics	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Certification Survey was performed on November 22, 2019 at Rosales Children's Clinic, CLIA ID # 19D0971816. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to document remedial action for unacceptable Hematology scores. Findings: 1. Review of the laboratory's 2018 and 2019 Proficiency Testing (PT) results revealed the laboratory received the following unacceptable results: a) Q2 Nonchemistry 2019: HMDD Erythrocytes - Module D Sample 2 - 80% b) Q2 Nonchemistry 2019: HMDD Hematocrit - Module D Sample 2 - 80% c) Q2 Nonchemistry 2019: HMDD Hemoglobin - Module D Sample 2 - 80% 2. Further review of PT records revealed the laboratory did not have any documentation of corrective action, investigation, or remedial action of the unacceptable scores. 3. In interview on November 22, 2019 at 10:47 am, Personnel 2 stated the laboratory does not investigate PT results unless the event or analyte is less than 80%.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

	CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to have complete performance specification verification studies for the Sysmex XP-300 Hematology analyzer. Findings: 1. Observation by surveyor during the laboratory tour on November 22, 2019 revealed the laboratory utilizes the Sysmex XP-300 Hematology analyzer for Complete Blood Count (CBC) testing. 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a policy for performance verification studies for new analyzers. 3. Review of the laboratory's installation records revealed the laboratory did have studies to include accuracy, precision, reportable range, and reference range; however, the laboratory did not include complete precision studies (day-to-day) and the raw data to support these studies. 4. In interview on November 22, 2019 at 11:05 am, Testing Personnel 2 confirmed the installation records did not include complete precision studies.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by:

	Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory followed the corrective action plan for unacceptable proficiency testing results. Refer to D2128.