

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0971816	(X3) Date Survey Completed 01/10/2018
Name of Provider or Supplier Sfmg Pediatrics	Street Address, City, State 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 Recertification Survey was performed at Rosales Children's Clinic - CLIA # 19D0971816 on January 10, 2018. Rosales Children's Clinic was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1403 CONDITION: Laboratories Performing Moderate Complexity Testing; Laboratory Director 42 CFR 493.1421 CONDITION: Laboratories Performing Moderate Complexity Testing; Testing Personnel
D5205	<p>COMPLAINT INVESTIGATIONS CFR(s): 493.1233</p> <p>The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel the laboratory failed to have a system in place to ensure that it documents all complaints and problems reported to the laboratory. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the manual did not include written policy or procedure detailing how the laboratory is to address, document, and handle complaints or problems reported to the laboratory. 2. Interview with Personnel 1 and 2 on January 10, 2018 revealed they were unaware of all the policies and procedures that were required. Personnel 1 and 2 confirmed the laboratory did not have a complete policy and procedure manual.</p>
D5207	<p>COMMUNICATIONS CFR(s): 493.1234</p> <p>The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an</p>

authorized person who orders or receives test results.

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory personnel the laboratory failed to have a system in place to ensure that it documents all complaints and problems reported to the laboratory. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to have written policies and procedure to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. 2. Interview with Personnel 1 and 2 on January 10, 2018 revealed they were unaware of all the policies and procedures that were required. Personnel 1 and 2 confirmed the laboratory failed to have a complete policy and procedure manual.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy and procedure manual, and interview with personnel, the laboratory failed to establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to establish written policies and procedures that include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel involved in any phase of laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting of test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. Interview with Personnel 1 and 2 on January 10, 2018 confirmed the laboratory failed to have a detailed written policy and procedure that included the six (6) mandated items.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy and procedure manual and interview with

personnel, the laboratory failed to establish a laboratory policy and procedure manual that contained complete policies and procedures. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory failed to have policies and procedures for: Proficiency Testing (PT): a) Ordering and ensuring that you are enrolled for Proficiency Testing. b) What to do when you receive samples from the PT Provider. c) How to handle the samples; who will test, when to test, how do you assure no inter and intra laboratory communication takes place d) How to record results to send into the PT Provider to be scored. e) What records to maintain. f) How to evaluate when you receive your scores from the PT Provider. g) what steps to take if corrective action is needed. Quality Assurance (QA) to include: a) What is being done to ensure quality of testing b) Who is performing quality checks c) Frequency and documentation of quality checks Record Retention 2. Interview with Personnel 1 and 2 on January 10, 2018 revealed they were unaware of all the written policies and procedures needed in the laboratory. Personnel 1 and 2 confirmed the policy and procedure manual was incomplete.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on observation, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D6021. 2. The Laboratory Director failed to ensure that testing personnel performing non-waived testing met the licensing, and educational requirements for qualify for performing moderate complexity testing. Refer to D6029. 3. The Laboratory Director failed to ensure policies and procedures were maintained for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D6030. 4. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D6031.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on observation, record review and interview with laboratory personnel, the

	<p>Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D5401.</p>
<p>D6029</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Personnel Records and interview with personnel, the Laboratory Director failed to ensure that testing personnel performing non-waived testing met the licensing, and educational requirements for qualify for performing moderate complexity testing. Findings: 1. The laboratory failed to ensure that the laboratory maintained documentation of a current Louisiana state license for one (1) of five (5) testing personnel performing moderate complexity testing. Refer to D 6064. 2. The laboratory failed to provide documentation that testing personnel met the educational qualifications for performing moderate complexity testing for four (4) of five (5) testing personnel. Refer to D6065. 3. Personnel 1 and 2 on January 10, 2018 confirmed the above findings.</p>
<p>D6030</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were maintained for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D5209</p>
<p>D6031</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)</p>

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Findings: 1. The laboratory failed to have a system in place to ensure that it documents all complaints and problems reported to the laboratory. Refer to D5205. 2. The laboratory failed to have a system in place to ensure that it documents all complaints and problems reported to the laboratory. Refer to D5207. 3. The laboratory failed to establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. Refer to D5209. 4. The laboratory failed to establish a laboratory policy and procedure manual that contained complete policies and procedures. Refer to D5401.

D6063

LABORATORY TESTING PERSONNEL

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on record review and interview the laboratory failed to provide documentation of current state licenses and education for individuals performing moderate complex testing. Findings: 1. The laboratory failed to ensure that the laboratory maintained documentation of a current Louisiana state license for one (1) of five (5) testing personnel performing moderate complexity testing. Refer to D6064. 2. The laboratory failed to provide documentation that testing personnel met the educational qualifications for performing moderate complexity testing for four (4) of five (5) testing personnel. Refer to D6065.

D6064

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(a)

Each individual performing moderate complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's personnel records, and interview, the laboratory failed to ensure that the laboratory maintained documentation of a current Louisiana state license for one (1) of five (5) testing personnel performing moderate complexity testing. Findings: 1. Review of personnel folders for laboratory personnel on January 10, 2018 revealed the laboratory had a copy of the 2017 state license but did not obtain a copy of the 2018 state license for Personnel 4. 2. Interview with Personnel 1

and 2 on January 10, 2018 confirmed the laboratory did not maintain documentation of a current license for Personnel 4.

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to provide documentation that testing personnel met the educational qualifications for performing moderate complexity testing for four (4) of five (5) testing personnel.

Findings: 1. Review of personnel records on January 10, 2018 revealed the laboratory failed to maintain documentation of at least a High School Diploma or equivalent for moderate complexity laboratory testing for Personnel 3, 4, 5, and 6. 2. Interview with Personnel 1 and 2 on January 10, 2018 confirmed the laboratory failed to maintain documentation of the highest level of education for personnel cited above.