

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D0906813	<b>(X3) Date Survey Completed</b>  09/12/2019
<b>Name of Provider or Supplier</b>  Center For Pediatric & Adolescent Medicine	<b>Street Address, City, State</b>  5040 West Main Street, Houma, 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>	A Certification survey was conducted at Center for Pediatric and Adolescent Medicine-CLIA ID # 19D0906813 on September 12, 2019. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
<b>D5221</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to perform and assessment for unsatisfactory Hematology proficiency test (PT) results. Findings: 1. Review of the laboratory's 2017, 2018, and 2019 American Proficiency Institute (API) PT results revealed the laboratory received the following "unacceptable" results: 2018 Hematology/Coagulation 2nd Event: Sample HEM-09 for Red Blood Cell Count, API grade: "unacceptable" 80% 2018 Hematology/Coagulation 3rd Event: Sample HEM-15 for Red Blood Cell Count, API grade: "unacceptable" 80% 2. Review of the laboratory's PT records revealed the laboratory did not perform assessments for the "Unacceptable" by API results identified above. 3. In interview on September 12, 2019, the Technical Consultant stated the laboratory did not perform assessments for the identified PT events.</p>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p>

This STANDARD is not met as evidenced by:  
Based on record review and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have written policies and procedures that included: a) Complete Blood Counts (CBC) flags, to include manufacturer requirements for platelet flags b) Proficiency Testing, to include assessment of unacceptable results 2. In interview on September 12, 2019, the Technical Consultant confirmed the laboratory's policy and procedure manual did not include the identified policies.

**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, 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:  
Based on record review and interview with personnel, the Laboratory Director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Refer to D5221.

**D6031**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(13)

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. Refer to D5401.