

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D1032343	<b>(X3) Date Survey Completed</b>  12/20/2021
<b>Name of Provider or Supplier</b>  Tri-Parish Pediatrics	<b>Street Address, City, State</b>  4937 Hearst Street Suite 2a, Metairie, 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 Recertification survey was performed on December 20, 2021 at Tri-Parish Pediatrics, CLIA ID # 19D1032343. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5211</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, proficiency test records, and interview with personnel, the laboratory failed to ensure the Laboratory Director reviewed the proficiency testing performance evaluation results for two (2) of five (5) events reviewed. Findings: 1. Review of the laboratory's "Evaluation Proficiency Testing Performance" policy revealed "Employees and the laboratory director review and evaluate the results from the proficiency testing. If all results are acceptable, the laboratory director will then sign off on the results." 2. Review of the American Proficiency Institute (API) proficiency testing records for 2020 and 2021 revealed the laboratory did not have documentation of review of their results by the Laboratory Director for the following events: 2020 Microbiology 2nd Event: Date not documented by Laboratory Director 2020 Microbiology 3rd Event: no signature and date by Laboratory Director 3. In interview on December 20, 2021 at 9:52 am, Testing Personnel 1 stated the Laboratory Director reviewed the proficiency testing results. Testing Personnel 1 further stated the Laboratory Director did not sign/date the identified proficiency testing results.</p>
<b>D5221</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p>

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's proficiency testing records, policies, and interview with personnel, the laboratory failed to establish and document proficiency testing assessment activities for one (1) of five (5) events reviewed. Findings: 1. Review of the laboratory's "Evaluation Proficiency Testing Performance" policy revealed "If any results are acceptable, we will perform corrective action as required, which may or may not include repeating the proficiency testing. Our corrective action is then reviewed with all employees and the laboratory director. The corrective action is documented and signed off by the laboratory director." 2. Further review of the laboratory's "Evaluation Proficiency Testing Performance" policy revealed the laboratory did not include the specific actions the laboratory performs to evaluate unacceptable results. 3. Review of the American Proficiency Institute (API) testing records for Microbiology for 2020 and 2021 revealed the following unacceptable result: 2020 Microbiology 2nd Event Urine Identification: Sample UR-7 "Unacceptable;" Score: 50% 4. Review of the laboratory's performance evaluation form for that event revealed the following: a) Corrective action "Called for unacceptable. No consensus met. Ok per API." b) Laboratory Director signed the performance review; however no date was included 5. In interview on December 20, 2021 at 9:52 am, Testing Personnel 1 confirmed the laboratory's policy did not specify actions to take for unacceptable proficiency test results received.

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation, review of expiration check logs, and interview with personnel, the laboratory failed to ensure supplies did not exceed expiration dates. Findings: 1. Observation by surveyor during laboratory tour on December 20, 2021 at 9:09 am revealed the following expired item: Siemens Multistix 10 SG Reagent strips, lot 002043, Expiration Date: 2021-07-31, Quantity: one (1) bottle. 2. Review of the laboratory's "Monthly Quality Assurance Checklist" revealed the following monitor "All reagents, controls, kits, etc. that exceeded their expiration date were discarded." 3. Review of the laboratory's "Expired Product Check Log" revealed "Every Friday Check lab for any expired products and dispose of per manufacturer and CLIA standards date and initial by personnel and lab director." 4. Further review of the laboratory's "Expired Product Check Logs" for May 29, 2020 through December 15, 2021 revealed the laboratory documented performance of a weekly check; however, the laboratory did not identify the expired item indicated above. 5. In interview on December 20, 2021 at 9:16 am, Testing Personnel 1 stated the identified bottle of Multistix strips were not in use and confirmed their expiration.

**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, 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)(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 observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5417.

**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 are reviewed by the appropriate staff. Refer to D5211.

**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 established and documented corrective actions for unacceptable proficiency testing results. Refer to D5221.