

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1032343	(X3) Date Survey Completed 06/28/2019
Name of Provider or Supplier Tri-Parish Pediatrics	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Certification Survey was performed on June 28, 2019 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.
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to retain all proficiency testing records for at least two years for one (1) of five (5) events reviewed. Findings: 1. Review of the laboratory's Hematology American Proficiency Institute (API) proficiency testing (PT) records for 2017 (3rd event), 2018 (all three events), and 2019 (1st event) revealed the laboratory did not maintain the following records: a) 2018 2nd Event remedial action records for API reported "unacceptable" result for WBC sample 10: score 80% b) 2018 2nd Event instrument printouts 2. Review of the laboratory's "Proficiency Testing" policy revealed "Corrective action: The laboratory director will perform corrective action if needed on any event that may be unacceptable. The documentation will be filed in a binder labeled 'Proficiency testing' and will be kept for 5 years (office policy)." 3. Review of the laboratory's Hematology API PT records for the 2018 2nd event revealed the following actions were taken: a) "Retrained all employees on proper collection, processing, handling, interpretation of results" b)" Machine recalibrated, daily controls performed all within normal limits" 4. In interview on June 28, 2019 at 11:46 am, Testing Personnel 1 confirmed the laboratory did not have documentation the identified remedial actions were performed. Testing Personnel 1 stated she could not find the instrument printouts for the 2018 API PT Hematology 2nd Event.</p>
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 regarding record retention for unacceptable proficiency testing results. Refer to D3037.