

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2011677	(X3) Date Survey Completed 02/19/2019
Name of Provider or Supplier Elite Pediatric And Adolescent Medicine, Llc	Street Address, City, State 201 Lakeview Dr, Suite A, Somerville, TN	
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
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory quality assessment (QA) plan, the 2017 proficiency testing (PT) records, the 2017 and 2018 QA records and interview with the lead testing personnel, the laboratory failed to follow the QA plan in 2017 and 2018. The findings include: 1) Review of the laboratory QA plan revealed the following: "Proficiency Testing Evaluations. ... The accuracy test results are reviewed and retained for a period of at least two years. ... Record Retention. ...All monthly QC reviews are performed by the Technical Consultant or Laboratory Director and include initials or signatures to verify the review. ...Elite Pediatric and Adolescent Laboratory Checklist of Review. ... Elite Pediatric and Adolescent Medicine Monthly Quality Assessment Checklist". 2) Review of the 2017 PT records revealed the 2017 event one comparative evaluation form and performance summary were missing; the 2017 event two comparative evaluation report was missing. 3) Review of the 2017 and 2018 QA records revealed the Elite Pediatric and Adolescent Laboratory Checklist of Review form and the Elite Pediatric and Adolescent Medicine Monthly Quality Assessment Checklist form was missing for January 2017 to present survey date February 19, 2019. 4) Interview on February 19, 2019 at 11:40 a.m. with the lead testing personnel confirmed the 2017 PT records were not available for review and that the Checklist of Review form and the Monthly QA Checklist were not in use for documenting the monthly QA processes from January 2017 to present survey date.</p>