

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2046132	(X3) Date Survey Completed 02/13/2018
Name of Provider or Supplier Grace Pediatrics, Plc	Street Address, City, State 238 Centre Street, Suite 100, Pleasant View, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on a lack of proficiency testing (PT) records and an interview with the office manager, the laboratory failed to enroll in PT for the specialty of hematology analytes in complete blood count (CBC) for any events in 2017. Findings include: 1. No PT records for the specialty of hematology analytes of red blood cells (RBC), white blood cells (WBC), hemoglobin (hgb), hematocrit (hct), platelets (plt), and differentials (diff) in complete blood count (CBC) for events in 2017 were available to review. 2. Interview with the office manager on February 13, 2018, confirmed the lab did not participate in proficiency testing for the CBC analytes in 2017.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p>

This STANDARD is not met as evidenced by:

Based on review of the October 21, 2017 through January 2, 2018 hematology instrument quality control (QC) records and interview with the office manager, the laboratory failed to maintain the hematology instrument QC printouts for the following analytes: red blood cells (RBC), white blood cells (WBC), hemoglobin (hgb), hematocrit (hct), platelets (plt), and differentials (diff) for designated period in 2017-18. The findings include: 1) Review of the October 21, 2017 through January 2, 2018 hematology instrument quality control (QC) records for the daily actual measurement(s) of the hematology analytes QC levels for low, normal, and high were not maintained from October 21, 2017 through January 2, 2018. 2) Interview on February 13, 2018, at 10:00am, with the office manager confirmed the daily actual measurements of the hematology QC levels for low, normal, and high were not maintained from October 21, 2017 through January 2, 2018., when testing person #1 deleted the information on the hematology analyzer by accident on January 11, 2018.