Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2002945	03/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Grace Pediatrics, Pllc	1335 Rock Springs Road, Smyrna, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of 2016 and 2017 Proficiency Testing (PT) attestation records and an interview with the primary testing person, it was determined the laboratory did not involve all 7 testing personnel in rotating PT samples for complete blood counts during the 2 year period. Findings include: 1. A review of PT records from 2016 and 2017 disclosed 5 of 7 testing persons (TP#1, 3-6) did not rotate in testing of PT samples. 2. An interview with the primary testing person at 11 AM on March 8, 2018, confirmed 5 of 7 TP (#1, 3-6) did not run PT samples for the 2 year period from 2016-17.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

	This STANDARD is not met as evidenced by: Based on a review of Proficiency Testing (PT) records from 2016-2017 and interview with the lead nurse testing person, determined the laboratory failed to have PT attestation statement signed by testing person/analyst #2 for the first event 2017 for hematology in complete blood count. Findings include: 1. A review of PT records for 2016 to 2017 disclosed the analyst#2 did not sign the attestation statement the first event 2017 for hematology in complete blood count. 2. An interview with the lead nurse testing person at approximately 9:45 AM on March 8, 2018, confirmed the analyst#2 did not sign the attestation statement the first event 2017 for hematology in complete blood count.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: The laboratory failed to maintain satisfactory participation in two out of three events for the automated red blood cell (RBC) differential, resulting in the first unsuccessful proficiency testing (PT) occurrence for the automated RBC differential analyte. (Refer to D2130)
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a desk review of the CMS 155 report and the laboratory's 2016 and 2017 proficiency testing (PT) records, the laboratory failed to maintain satisfactory performance for the automated red blood cell (RBC) analyte in 2016 event three and 2017 event one, resulting in the first unsuccessful occurrence. The findings include: 1) Review of the CMS 155 report revealed the automated RBC 2016 event three score is

	60% and the 2017 event one score is 40%. 2) Review of the laboratory's 2016 event three PT reports revealed 2 of 5 sample numbers had unacceptable grades for automated RBC analytes resulting in a score of 60%. 3) Review of the laboratory's 2017 event one PT reports revealed 3 of 5 sample numbers had unacceptable grades for automated RBC analytes resulting in a score of 40%.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of the procedure manual, employee training records for 2016-17, and an interview with the lead testing person, the laboratory failed to document all competencies and training procedures performed initially for new hire personnel. Findings include: 1. Review of the procedure manual revealed competencies and training was required for new hire lab personnel upon hire. 2. Review of the employee training records for 2016-17 revealed no competencies and training was documented for one new hire lab testing person. 3. In an interview, March 8, 2018, at approximately 11:00 AM, the lead testing person confirmed the employee training records for 2016-17 were incomplete by missing the competencies and training for the new lab tech upon hire. 2nd citation: Based on a review of the procedure manual, employee training records for 2016-17, and an interview with the lead testing person, the laboratory failed to document the six minimum areas of competencies and procedures for the complete blood cell (CBC) instrument performed for 7 of 7 testing persons (TP). Findings include: 1. Review of the procedure manual revealed competencies and training was required for all lab personnel. 2. Review of the employee training records for 2016-17 revealed no documentation for the six minimum areas of competencies and training documented for 7 of 7 lab testing persons on the complete blood cell (CBC) instrument. 3. In an interview, March 8, 2018, at approximately 11:00 AM, the lead testing person confirmed missing the six minimum areas of competencies and training documented for 7 of 7 lab testing persons on the complete blood cell (CBC) instrument.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of five of five hematology complete blood cell (CBC) patient final test results, the Centers for Medicare and Medicaid Services (CMS)-116 form and

	interview with the lead testing person, the laboratory name and address were not correct on the final laboratory reports for the chart audit of patient records for 2016-18. The findings include: 1) Review of 5 of 5 audited patient final test results (X1 dated 040416, X2 101216, X3 021017, X4, 091117, and X5 020918) revealed the following name and address: Grace Pediatrics, 699 Presidents Place, Smyrna, TN. 2) Review of the CMS -116 form revealed the laboratory name and address is Grace Pediatrics, 1335 Rock Springs Road, Smyrna, TN. 3) Interview on March 8, 2018 at 1: 00 p.m. with the lead testing person confirmed the address incorrect on the laboratory final reports, since the move of the office/lab to the new address.
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 review of the complete blood count (CBC) proficiency testing (PT) performance summary and corrective action records for 2016-17 and an interview with the lead nurse testing person, the laboratory director failed to review and sign 5 of 6 performance summary records for events 2016-17. Findings include: 1. Review of the CBC PT performance summary records for events during the 6 events for 2016-17 revealed 5 of 6 events (2-3 2016 and 1, 2, & 3 2017) were missing the laboratory director's review and signature for PT performance and corrective actions during 2016-17. 2. Interview on March 8, 2018, at 11:00am with the lead nurse testing person confirmed the 5 of 6 events (2-3 2016 and 1, 2, & 3 2017) were missing the laboratory director's review and signature for PT performance and corrective actions during 2016-17.