Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1004150	01/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Grace Primary Care A Division Of Summit Medical	950 Baker Hwy, Ste 4, Huntsville, 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 review of the Proficiency Testing (PT) Attestation records for 2016 and 2017, documented competencies for 11 of 12 testing personnel and upon interview with the Primary and Assistant Laboratory Leaders, determined the PT samples were not rotated among all testing personnel as listed on the Laboratory Personnel Report Form 209 for the patient testing they are currently performing as noted on their competency forms. The findings include: 1. A review of the 2016 and 2017 PT attestation records for Chemistry and Microbiology revealed only 1 of 4 testing persons showed participation in testing PT samples. 2. A review of the 2016 and 2017 PT attestation records for CBC testing revealed only 4 of 11 testing persons showed participation in testing PT samples. 3. A review of documented competencies for 2016 and 2017 showed 4 of 12 testing personnel competent for performing Chemistry and Microbiology testing and 11 of 12 testing personnel competent for performing CBC testing. 4. An interview with the Primary Laboratory Leader at approximately 1:00 p.m. January 24, 2018 confirmed that all testing personnel had not been participating in the PT for which they are currently performing patient testing in. _____
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the

	laboratory's routine methods. This STANDARD is not met as evidenced by: _____ Based on lack of director's signature on attestation sheets for Hematology testing events 3 of 2016 and 1 of 2017 and interview with the Primary Laboratory Leader, the Laboratory Director failed to attest to integration of proficiency testing (PT) samples into the routine patient workload for these 2 events. The findings include: 1. Lack of director's signature on attestation sheets for Hematology testing events 3 of 2016 and 1 of 2017. 2. Interview at approximately 12:00 p.m. January 24, 2018 with the Primary Laboratory Leader confirmed the Laboratory Director failed to attest to integration of PT samples into the routine patient workload by lack of signature on events 3 of 2016 and 1 of 2017. _____
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: _____ Based on a review of the Laboratory's protocol for performing the Calibration Verification every 6 months on the Hematology analyzer, lack of calibration verification documentation since 5/20/16 and an interview with the Primary Laboratory Leader, determined the laboratory failed to ensure calibration verification was performed every six months per protocol. The findings include: 1. Review of the Laboratory's protocol for performing calibration verification every 6 months on the Hematology analyzer. 2. Lack of calibration verification documentation since 5/20/16. 2. Interview at approximately 2: 00 p.m. January 24, 2018 with the Primary Laboratory Leader confirmed the laboratory failed to follow protocol for performing calibration verification on the Hematology analyzer every 6 months since 5/20/16. _____

D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: _____ Based on lack of the 6 competency assessment criteria upon review of 12 of 12 testing personnel competency evaluations and interview with the Primary and Assistant Laboratory Leaders, determined the Technical Consultant failed to include all 6 required competency assessment criteria for 2016 and 2017. The findings include: 1. Upon review of competency evaluations for 12 of 12 testing personnel, it was revealed they lacked the 6 required competency criteria for 2016 and 2017. 2. An interview at approximately 1:00 p.m. January 24, 2018 with the Primary and Assistant Laboratory Leaders, confirmed the Technical Consultant failed to include the 6 criteria for assessing competency for 12 of 12 testing personnel for the two year period. _____