

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D0972445	<b>(X3) Date Survey Completed</b>  11/21/2019
<b>Name of Provider or Supplier</b>  Grace Medical Clinics, Pa	<b>Street Address, City, State</b>  2317 Concord Lake Road, Concord, NC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2010</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedures, review of 2017, 2018, and 2019 American Proficiency Institute (API) proficiency testing (PT) records, and testing personnel (TP) interview 11/21/19, the laboratory failed to test PT specimens the same number of times as they test patient specimens. Findings: The laboratory's "Proficiency Testing" procedure states, "The laboratory shall test PT samples using the same procedures/methodologies used for patient testing..." The Procedure also states under "PT Specimen Processing", "PT specimens are processed identical to patient specimens." Review of the laboratory's procedure, "Cell-Dyn Emerald Hematology Analyzer", under section "Critical Values Critical/Alert Values", revealed the following: "Critical values are those results demonstrating such variance from normal as to represent a pathophysiological state with potential of being life threatening unless action is taken quickly. Results should be verified by repeat testing...." The laboratory's procedure, "Cell-Dyn Emerald Hematology Analyzer", also revealed the following hematology critical values: a. White Blood Cell (WBC) (K/mm<sup>3</sup>)- less than or equal to 2.0, or greater than or equal to 20.0. b. Hemoglobin (HGB) (g/dL)- less than or equal to 7.0, or greater than or equal to 20.0. c. Hematocrit (HCT)(%)- less than or equal to 20.0, or greater than or equal to 60.0. d. Platelet (PLT) (K/mm<sup>3</sup>) - less than or equal to 30.0. Review of 2017, 2018, and 2019 API PT records revealed the following PT specimens had critical values that were not repeated. 1. 2017 API 3rd event: Sample HEM-13, WBC result 20.7 and Sample HEM-15, WBC result 1.9, HGB result 5.2, and HCT result 17.3. 2. 2018 API 1st event: Sample HEM-01, HGB result 5.5 and HCT result 18.2. 3. 2018 API 2nd event: Sample HEM-08, HGB result 5.5, and HCT result 19.7. 4. 2019 API 1st event: Sample HEM-01, WBC result 20.2</p>

and Sample HEM-02, HGB result 5.4, and HCT result 19.3. During interview at approximately 11:20am, TP#3 confirmed it is the laboratory's policy to repeat critical values on patient specimens before reporting the results to the provider. She also stated PT specimens are not always repeated for Critical Values. Deficiency previously cited 11/18/2015.