

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2030207	<b>(X3) Date Survey Completed</b>  09/15/2020
<b>Name of Provider or Supplier</b>  Andrew Chung Md, Pllc	<b>Street Address, City, State</b>  3600 Gaston Ave #755, Dallas, TX	
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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by:                      ++++++ Revisit Conducted 09/14/2020-09/15/2020 New Finding Based on review of laboratory policy, quality control (QC) records and confirmed in interview, the laboratory failed to follow it's own written policy for repeating QC when all parameters were not within range or had flags for 5 of 45 days in 2020 (random review Jun-Aug). Findings included: 1. Review of Hematology Analyzer (AcT Diff 2) laboratory policy, approved on 01/2020 revealed: "QUALITY CONTROL... 6. Successful control runs will have all parameters within range with no flags present. All out of range controls will be flagged with a (L) or (H). The only acceptable flags for 4C+ control is the * for PLT count on Low control and * on MO# and Mo/o on High Control. All other flags must be investigated, and controls repeated until no flags are present." 2. Review of QC data from 06/24/20 through 08/25/2020 revealed the following dates QC was not repeated when flags or failures were obtained during a QC run: QC normal level lot #077700 expiration date 09/03/2020 WBC acceptable range: 7.1-8.7*10<sup>3</sup>/uL Lymphocyte% acceptable range: 38.2-44.2 % RBC acceptable range: 3.84-4.4*10<sup>6</sup>/uL HCT acceptable range: 32-36.6 % QC high level lot #087700 expiration date 09/03/2020 RBC acceptable range: 4.89-5.11 *10<sup>6</sup>/uL 07/01/2020 normal control RBC: 3.70 L HCT: 30.7 L 07/16/2020 normal control Lymphocyte %: 37.4 L 07/28/2020 high control RBC: 4.85 L 08/03/20 normal control WBC: 7.7 L 08/06/2020 normal control RBC: 3.84 L QC was not repeated for any of the above dates. The laboratory failed to follow thier own written policy for repeating QC when failures or flags were obtained for all parameters. 3. During an</p>

interview on 09/15/2020 at 11:00 am, the technical consultant confirmed the above findings. ++++++