

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D1004150	<b>(X3) Date Survey Completed</b>  06/20/2024
<b>Name of Provider or Supplier</b>  Grace Primary Care A Division Of Summit Medical	<b>Street Address, City, State</b>  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.		

<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: Based on observation of the laboratory, review of the laboratory procedure manual, review of calibration verification records, and staff interview, the laboratory failed to follow its written policy for calibration verification frequency in 2024. The findings include: 1. Observation of the laboratory on 06.20.2024 at 9:00 a.m. revealed a Cell-Dyn Emerald hematology analyzer (Serial Number: 8394) in use for patient Complete Blood Count (CBC) testing. 2. A review of the laboratory's hematology procedure revealed calibration verification is performed and documented at least every six months. 3. A review of laboratory calibration verification records revealed calibration verification was not performed every six months in 2024. 4. Interview on 06.20.2024 at 10:40 a.m. with the site manager confirmed the above survey findings.</p>