

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0957045	(X3) Date Survey Completed 05/01/2025
Name of Provider or Supplier Wellmont Medical Associates Of Gray	Street Address, City, State 115 Judge Gresham Rd, Gray, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) 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 laboratory observation, a review of the laboratory procedure manual, a lack of documentation, and an interview, the laboratory failed to follow the procedure for reviewing Levy-Jennings charts to detect shifts and trends for eleven out of twenty months reviewed from August 2023 through March 2025. 1. Observation of the laboratory on 05.01.2025 at 9:15 a.m. revealed the Cell-Dyn Emerald hematology analyzer (serial number 030914-005680) used for complete blood count patient testing. 2. A review of the laboratory's Quality Control Plan procedure revealed the following statement: "On a monthly basis, the supervisor reviews QC LJ charts. The monthly review will include examination of QC performance and review of SD's and CV's to detect control shifts and trends." 3. There was no documentation that the laboratory reviewed the Cell-Dyn Emerald Levy Jennings data for December 2023, January 2024, February 2024, March 2024, May 2024, June 2024, July 2024, August 2024, December 2024, January 2025, and March 2025. 4. An interview with the technical consultant on 05.01.2025 at 11:45 a.m. confirmed the above survey findings. Word key: CBC = complete blood count LJ = Levy-Jennings QC = quality control SD = standard deviation CV = coefficient of variation</p>