

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1058465	(X3) Date Survey Completed 10/05/2022
Name of Provider or Supplier Memorial Health Partners Foundation, Inc	Street Address, City, State 6401 Mountain View Rd, Suite 109, Ooltewah, 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 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's policy, quality control (QC) records (12.2020, 11.2021, and 07.2022), and interview with the Clinical Compliance Manager, the laboratory failed to follow the quality control policy for three of three months reviewed in 2020, 2021, and 2022. The findings include: 1. Observation of the laboratory on 10.05.2022 at approximately 9:45 a.m. revealed a Sysmex XN-430 instrument in use for patient testing for complete blood count (CBC). 2. Review of the laboratory policy titled "Sysmex XN430 Quality Control" stated, "Three levels of Assayed Controls are run daily two times a day". 3. Review of laboratory quality control records for 12.2020, 11.2021 and 07.2022 revealed three levels of assayed controls were not run two times a day. 4. Interview with Clinical Compliance Manager at approximately 12:30 p.m. confirmed the laboratory failed to follow the policy for running three levels of assayed controls two time a day on the Sysmex XN-430 CBC analyzer for three of three months reviewed in 2020, 2021, and 2022. =====</p>