Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1039230	05/21/2026
Name of Provider or Supplier	**Street Address, City, State**	
Wellmont Health System	851 Locust Street, Rogersville, 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
D0000	An onsite validation survey was conducted on May 21, 2026. The laboratory was found to be in compliance with condition level deficiencies. The following standard-level deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy, procedures, lack of a supervisory competency assessment procedure, and an interview with the technical consultant (TC), the laboratory failed to have a policy or procedure in place to assess the competency of 1 of 1 TC. Findings: 1. Review of laboratory policies and procedure on May 21, 2026, revealed that competency assessment procedures were for testing personnel performing blood gas testing on the Radiometer ABL 90 Flex. 2. The laboratory failed to provide a policy or procedure for the assessment of competency for the TC. 3. By interview on May 21, 2026, at 9:00 am, the TC confirmed that a supervisory competency assessment was performed for delegated responsibilities, but there was no policy or procedure in place for the assessment of the TC.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic

	examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory procedures and an interview with the technical consultant (TC), the laboratory failed to include procedures for controls, calibrations, and corrective action to take when control and calibration results fail to meet acceptable criteria for the Radiometer ABL 90 Flex used for blood gas testing for 2 of 2 years (May 2024 to May 2026). Findings: 1. Review of the Radiometer ABL 90 Flex policy/procedure revealed the following procedural sections were not stated in the procedure for 2 years: a. Calibration. b. Control procedures. c. Corrective actions to take when calibration or control results fail to meet the acceptable criteria. 2. By interview on May 21, 2026, at 11:00 am, the TC confirmed the above procedural sections were not stated in the procedure signed by the laboratory director.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the Radiometer ABL 90 Flex Instructions for use, lack of cleaning records, and interview with the technical consultant (TC), the laboratory failed to document maintenance as defined by the manufacturer for 2 of 2 Radiometer ABL 90 Flex analyzers used for blood gases testing. Findings: 1. The Radiometer ABL 90 Flex Instructions for use stated on page 52 under Maintenance, Cleaning, "Cleaning - when is it necessary? The analyzer must always be kept clean. Exterior surfaces, the Inlet Gasket, and other parts of the analyzer must be cleaned when they are contaminated with blood and/or other liquids. To clean the inlet gasket - Prerequisite: A lint-free cloth". 2. On May 21, 2026, the laboratory was unable to provide cleaning records for the 2 Radiometer ABL 90 Flexes in use (serial numbers 092R0583N024 and 092R583N025 as defined by the manufacturer. 3. By interview on May 21, 2026, at 10:30 am, the TC confirmed cleanings were performed daily, but they were not documented.