Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0957045	07/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Wellmont Medical Associates Of Gray	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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 lack of procedure's for performing and reporting Complete Blood Counts (CBC's) and Cold Agglutinin's, lack of patient reference ranges and alert values and no course of action if CBC test system becomes inoperable and upon interview with MLT (Medical Laboratory Technician) and Laboratory Director, determined the laboratory failed to have current procedures for CBC's, Cold Agglutinin's, reference and alert values and course of action if CBC test system becomes inoperable, since 2018. The findings included: 1. Lack of procedure's for performing and reporting CBC's and Cold Agglutinins. 2.

	Lack of patient reference ranges and alert values for CBC's. 3. Lack of course of action if CBC test system becomes inoperable. 4. Interview with MLT and Laboratory Director at approximately 2:30 p.m. July 15th, 2019 confirmed there were no procedures for CBC and Cold Agglutinin testing and reporting, reference and alert values and course of action if CBC test system becomes inoperable, since 2018. ==========
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 observation of microscope, lack of professional service documentation and interview with MLT, determined the laboratory failed to define maintenance protocol since installation date in 2018. The findings include: 1. Observed used microscope for reading microscopic urines and wet prep analysis at approximately 9:15 a.m. July 15, 2019. 2. Lack of professional service documentation for microscope since installation in 2018. 3. Interview at approximately 9:15 a.m. July 15, 2019 with MLT confirmed laboratory failed to define maintenance protocol and microscope had not been serviced since installation date in 2018. ==========
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: ========== Based on review of CBC Proficiency Testing results for the 3rd event of 2018 and upon interview with the MLT, determined the Laboratory Director failed to ensure an approved corrective action plan is followed when PT results are found to be unacceptable. The findings include: 1. Review of CBC Proficiency Testing results for the 3rd event of 2018 revealed unacceptable results for hemoglobin and platelets with no corrective action documented. 2. An interview at approximately 2:30 p.m. July 15, 2019 confirmed the Laboratory Director failed to ensure corrective action was documented for unacceptable results for hemoglobin and platelets for the 3rd event of 2018. ==========
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification

	requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: ========== The Technical Consultant is not met due to failing to provide documentation of the qualification requirements and provide technical oversight in accordance with $493.1413. (Refer to D6035) ==========
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: ========== Based on review of the CMS-209 Laboratory Personnel Report Form, lack of personnel records for the named Technical Consultant and upon interview with the Office Manager and Laboratory Director, the Technical Consultant failed to provide technical consultant qualification documentation and failed to fulfill the duties of the technical consultant since 2018 (Reference D-tags: D-6019; D-6040; D-6041; D-6042; D-6046). The findings include:

	1. Review of the CMS-209 Laboratory Personnel Report Form revealed one Technical Consultant listed. 2. Review of the personnel records revealed no records available for review for the technical consultant listed. 3. Interview at approximately 2:30 p.m. July 15, 2019 with the Office Manager and Laboratory Director confirmed the technical consultant listed on the CMS-209 Laboratory Personnel Report Form revealed documentation of 1 year requirement of laboratory training or experience was not available for review and did not fulfill the duties of a technical consultant. ==========
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: ========== Based on test menu to include urine microscopic analysis, test procedure, lack of urine centrifuge and upon interview with MLT, determined the Technical Consultant failed to establish correct verification and test performance of urine microscopic testing according to procedure since 2018. The findings include: 1. Test menu included urine microscopic analysis. 2. Test procedure for urine microscopic analysis states to centrifuge urine at 1500 RPM's (revolutions per minute) for 5 minutes. 3. Lack of urine centrifuge with urine being spun in the blood separation centrifuge at 3400 RPM's for 10 minutes. 4. Interview at approximately 2:30 p.m. July 15, 2019 with MLT confirmed the Technical Consultant failed to establish correct verification and test performance for urine microscopic testing since 2018. ==========
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: ========== Based on lack of Proficiency Testing (PT) enrollment for CBC testing for the first event of 2019 and upon interview with the MLT, determined the Technical Consultant failed to ensure enrollment for CBC testing for the first event of 2019. The findings include: 1. Lack of PT enrollment for CBC testing until May 2019, missing the first event. 2. Interview at approximately 2:30 p.m. July 15, 2019 with MLT confirmed Technical Consultant failed to ensure PT enrollment for CBC testing until May 2019, missing the first event. ==========
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for

	acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: ========== Based on the Laboratory's test menu to include Cold Agglutinins, Urine Microscopics and Wet Prep Analysis, lack of quality control (QC) plan and control documentation, lack of accuracy verification policies and documentation and upon interview with the MLT, Laboratory Director and Office Manager, determined the Technical Consultant failed to establish parameters for acceptable levels of performance throughout entire testing process for Cold Agglutinin Testing, Urine Microscopic Testing and Wet Prep Analysis since 2018. The findings include: 1. Laboratory's test menu includes Cold Agglutinins, Urine Microscopics and Wet Prep Analysis. 2. Lack of QC plan and control documentation for the Cold Agglutinin testing since 2018. 3. Lack of accuracy verification policies and documentation for Cold Agglutinin, Urine Microscopic and Wet Prep Analyis since 2018. 4. Interview at approximately 2:30 p.m. July 15, 2019 with the MLT, Laboratory Director and Office Manager confirmed the Technical Consultant failed to establish parameters for acceptable levels of performance throughout the testing process for Cold Agglutinins, Urine Microscopic Testing and Wet Prep Analyis since 2018. ==========
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: ========== Based on review of the MLT's training and competency records from hire date 10/09/2017, CMS Personnel Form 209 and interview with the MLT, Laboratory Director and Office Manager, determined the Technical Consultant failed to evaluate the testing personnel to assure competency using the 6 CLIA assessment criteria, since hire date. The findings include: 1. Review of MLT's records from hire date 10/09/2017 failed to show documentation of training or 6 month competency for CBC testing, urine microscopic testing, wet prep analyis and cold agglutinin testing. 2. Review of MLT's records showed annual competency documented 5/3/19 by Registered Nurse (AS) who is not listed on the CMS Personnel Form 209 and did not use all 6 competency criteria for assessment to include: direct observation of speciment handling and processing; monitoring the recording and reporting of test results; review of quality control records, proficiency testing results and preventive maintenance records; direct observation of performance of instrument maintenance and function checks and assessment of test performance through testing previously analyzed specimens or external proficiency testing samples. 3. Interview at approximately 2:30 p.m. July 15, 2019 with the MLT, Laboratory Director and Office Manager confirmed the Technical Consultant failed to assess the training and competency of the MLT upon hire date 10/09/2017. ==========