Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D2158677	09/02/2021
Name of Provider or Supplier	**Street Address, City, State**	
Ms Medical Associates, Llc	8 Front St, Belmont, MS	

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
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: Based on review of the Centers For Medicare & Medicaid Services (CMS) Casper 155 report and laboratory proficiency test reports available the day of survey and interview with TP #8/clinic owner, the laboratory failed to authorize the proficiency testing program to release to HHS (Department of Health & Human Services) all data and results to determine if the laboratory had successfully completed proficiency testing. Findings include: 1. The CMS Casper 155 report revealed no proficiency scores for hematology were released for this laboratory to the CLIA program (HHS) for review the 2nd event of 2021. 2. Interview with TP #8/clinic owner on 9/2/21 at 5: 00 p.m. confirmed the lab did not ensure scores were released to the HHS for 2021.
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 review of the laboratory procedure manual and confirmation with TP#8 /clinic owner at 3:30 p.m. on 9/2/21, the laboratory did not have available on the day of survey written approved procedures that included all required elements. Findings include: The procedure manual available for review did not include the following elements. 1. Requirements for patient preparation; specimen storage, preservation, transportation, processing and referral; and criteria for specimen acceptability and rejection. 2. The laboratory's system for entering results in the patient record and reporting patient results including the protocol for reporting imminent life threatening results (panic or alert) values. 3. Written procedures for the steps that are taken when the Abbott Cell Dyn Emerald hematology analyzer becomes inoperable.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of laboratory records since installation of the Abbott Cell Dyn Emerald on 1/16/21 and confirmation with testing personnel (TP) #8/clinic owner at 2: 30 p.m. on 9/2/21, the laboratory failed to monitor and document the room temperature for the laboratory where hematology testing was performed. Findings include: 1. Observation of the laboratory room where hematology testing was performed revealed no thermometer to monitor the room temperature for optimal performance of the Abbott Cell Dyn Emerald hematology analyzer. 2. No room temperature logs were available for review. 3. Manufacturer's instructions for the Cell Dyn Emerald require: a) The Cell Dyn Emerald reagent, lyse and detergent should be stored at a temperature range of 18-32 degrees Celsius. b) Operating specifications for the Cell Dyn Emerald hematology analyzer instrument require a room temperature of 18-32 degrees Celsius. c) Quality control and calibration materials for the Cell Dyn Emerald must be allowed to come to room temperature before testing. 4. Interview with the TP #8/clinic owner at 2:30 p.m. on 9/2/21 confirmed no room temperatures were being monitored and documented.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing records, Centers of Medicare and Medicaid Services (CMS) database proficiency testing report and confirmation with TP #8/clinic owner at 3:30 p.m. on 9/2/21, the laboratory director failed to ensure the laboratory was enrolled and participated in an HHS approved proficiency testing (PT) program for CBC (complete blood count) performed on the Abbott Cell Dyn Emerald hematology analyzer for the first event of 2021. Findings include: 1. Review of the CMS database proficiency testing report revealed no scores for CBC for 2021. 2. Review of the laboratory proficiency records since installation of the Abbott Emerald on 1/16/21 through 9/2/21 revealed no evidence of proficiency testing participation for the first event of 2021. 3. Interview with TP #8/clinic owner at 3:30 p.m. on 9/2/21 revealed the laboratory did not enroll and participate in proficiency testing for CBC for the first event of 2021.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of laboratory testing personnel records available on 9/2/21, the CMS (Centers for Medicare and Medicaid Services) 209 form and interview with TP #8 /clinic owner, the laboratory director had not ensured that TP #2, and TP#4 through #8 (as listed on the CMS 209 personnel form) had received the appropriate training with documentation to perform CBC (complete blood count) testing with the Abbott Cell Dyn Emerald hematology analyzer prior to testing patients. Findings Include: 1. Based on lack of documentation available the day of survey, TP #2 and TP#4 through TP #8 had no documented training prior to performing CBC on patients beginning on 1/16/21. There was no documentation to indicate TP #2 and TP#4 through TP #8 had demonstrated adequate performance of the testing procedure, quality control performance and maintenance required for the Cell Dyn Emerald. 2. Interview with the TP #8/clinic owner at 5:30 p.m. on 9/2/21 confirmed that initial training for TP #2 and TP#4 through #8 had not been documented for the Cell Dyn Emerald hematology analyzer.

D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of laboratory testing records from 1/16/21 through 9/2/21 and interview with testing personnel (TP) #8/clinic owner as listed on the Centers for Medicare & Medicaid Services 209 form at 3:30 p.m. on 9/2/21, the following records had not been documented as reviewed by the technical consultant: Findings Include: 1. Review of the laboratory records from 9/2/21 through 7/28/21 revealed the following records were not documented as reviewed by the technical consultant: a. Abbott Cell Dyn Emerald hematology quality control (QC) from 1/16/21 through 9/2 /21 b. Abbott Cell Dyn Emerald hematology calibration records from 1/16/21 through 8/22/21 c. Abbott Cell Dyn Emerald maintenance from 1/16/21 through 9/2/21 d. Temperature records (room, refrigerators, freezers) from 1/16/21 through 9/2/21 2. Interview with the TP #8/clinic owner at 3:30 p.m. on 9/2/21 confirmed there was no documented review of these records by the technical consultant