Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D2136510	01/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Mays Medical Wellness, Llc	3964 Goodman Rd E Ste 128, Southaven, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the AcT Diff analyzer records from installation, 5/2/18 through 1 /17/19 (day of survey) and confirmation with technical consultant at 10:30 am, the laboratory failed to retain the quality control (QC) assay sheets to include but not limited to acceptable ranges, storage requirements, lot numbers and standard deviations for at least 2 years. Findings include: Review of the AcT Diff QC assay sheet (in use the day of survey) and other hematology records indicated the laboratory did not retain all QC assay sheets with the change of a new lot number of hematology low, normal and high controls.
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 interview with the technical consultant on 5/21/18, the procedure manual did not include the procedure for calibration of the AcT Diff hematology analyzer, to include type of calibration material, frequency of calibration, and corrective action to take when calibration results fail to meet the laboratory's criteria for acceptability.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on AcT Diff records available the day of survey and interview with technical consultant at 10:30 am, the laboratory director failed to ensure that verification procedures were used during installation of the AcT Diff hematology analyzer to determine the accuracy, precision and linearity of the hematology analyzer, which was installed for CBC (complete blood count) testing in May 2018. Findings: Review of records during installation of the AcT Diff hematology analyzer revealed that calibration only was performed on 5/21/18. No documentation of verification of performance, such as accuracy, precision, or linearity was available on the day of survey to ensure the analyzer was properly installed and adequate for patient testing. Patient testing began 9/6/18 according to testing personnel.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records for the AcT Diff hematology analyzer from 9/6/18 through 1/17/19 and review of the clinic LMS patient report, 2 of the 3 levels of QC material performed were outside of the manufacturer's acceptable range when patients were tested and results reported. Findings include: 2

	of 3 QC results were out of range on these days when patient samples were also tested and reported: 9/7/18 9/8/18 9/9/18 9/10/18 9/11/18 9/13/18 9/14/18 9/18/18 9/19/18 9 /20/18 9/24/18 9/25/18 9/26/18 9/27/18 9/28/18 Twenty two patients were tested on these days without acceptable QC.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the deficiencies cited for laboratory director responsibilities, the laboratory director was not providing overall management and direction of the laboratory in accordance with paragrah 493.1407 of this subpart. Refer to D6013 (Failure to ensure verification of performance specifications was performed.) Refer to D6015 (Failure to ensure the laboratory was enrolled in an HHS approved proficiency testing program). Refer to D6029 (Failure to ensure testing personnel received appropriate training). Refer to D6031 (Failure to ensure an approved procedure manual was available to staff).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on AcT Diff records available the day of survey and interview with the technical consultant at 10:30 am, the laboratory director failed to ensure that verification procedures were used during installation of the AcT Diff hematology analyzer to determine the accuracy, precision and linearity of the hematology analyzer, which was put in use for CBC (complete blood count) testing in May 2018. Findings: Review of records from the installation of the AcT Diff hematology analyzer revealed only a calibration was performed on 5/21/18. No documentation of verification of performance, such as the accuracy, precision, or linearity was available on the day of survey to ensure the analyzer was properly installed and adequate for patient testing. Patient testing was begun on 9/6/18 according to testing personnel.
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 surveyor review of the laboratory proficiency testing records, Centers of Medicare and Medicaid Services database proficiency testing report and confirmation by testing personnel at 1:30 pm on 1/17/19, 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 AcT Diff hematology analyzer for the third testing event of 2018. The laboratory director must ensure the laboratory is enrolled and participates in proficiency testing for all testing performed.
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 testing personnel records available the day of survey, the testing personnel listed on the CMS (Centers For Medicare & Medicaid Services) 209 personnel form as #1 and #2, the laboratory director failed to ensure the testing personnel reviewed appropriate training for performing complete blood count (CBC) testing with the Beckman Coulter AcT DIff hematology analyzer prior to testing patients. There was no documentation of training for the entire laboratory testing process to include preanalytic, analytic and postanalytic phases of the laboratory. Findings include: Documentation of training available the day of survey revealed both testing personnel, #1 and #2 were trained on the AcT Diff hematology analyzer on 1/3/19. According to staff and patient records, patient testing began on 9/6/18. According to personnel records, the testing personnel did not have the following laboratory training prior to collecting, performing and reporting patient testing: a. Skills required for proper specimen collection, including patient preparation b. Skills required for implementing all standard laboratory procedures c. A working knowledge of reagent of reagent stability and storage d. Skills required to implement the quality control policies and procedures of the laboratory e. Skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values to prior to reporting patient test results d. Knowledge of how to report patient results (paper chart, electronic, etc.) e. AcT Diff training (testing quality controls, troubleshooting, maintenance, calibrating, etc.) .
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of the manufacturer's procedure manual for the Beckman Coulter hematology analyzer and the written laboratory procedure manual put into use for patient testing in May 2018, the laboratory director failed to approve either manual for use by testing personnel as of the day of survey, 1/17/19.
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 records (including quality control, calibrations, temperatures and maintenance) from 5/21/18 through 1/17/19 (day of survey) and confirmation with testing personnel at 3:30 pm, the technical consultant failed to document as reviewed the following laboratory records. The following records were not reviewed by the technical consultant appointed during that time: 1. AcT Diff hematology calibration on 5/21/18 2. AcT Diff hematology QC records from 9/6/18 through 1/2/19 3. Temperature logs (room, freezer, refrigerator) from 8/16/18 through 1/2/19 4. Laboratory Cleaning Schedule- 8/10/18 through 1/2/19