

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0304753	(X3) Date Survey Completed 08/26/2026
Name of Provider or Supplier Dothan Medical Associates	Street Address, City, State 1118 Ross Clark Circle Suite 100, Dothan, AL	
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. In addition, retain the following: This STANDARD is not met as evidenced by: Based on a review of the 25-OH Vitamin D (Vit.D) Quality Control (QC) Certificate and an interview with the Testing Personnel 1 (TP1), the laboratory failed to provide the surveyor the worksheets for one of the three 25-OH Vitamin D kits in use in the ELISA testing for approximately nine months. The findings include: 1. A review of the Vit.D QC certificates revealed Kit Lot E250429AY, Expiration of 04-28-26, had no documentation of performance verification when it was put in use, 10-06-25. 2. TP1 confirmed the above findings during the Day 2 exit conference on 08-26-2026 at 4:00 PM.
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 review of the personnel records, and an interview with the Testing Personnel 1 (TP1), the Laboratory Director (LD) failed to assess and document the annual competency for one of the two TP listed on the CMS 209 (Laboratory Personnel

	Report) for 2024-2026. The findings include: 1. A review of the personnel records revealed the LD had not documented the annual competency assessment of TP1 for the Vitros XT 3400 analyzer utilized in the Chemistry specialty. 2. TP1 confirmed the above findings during the Day 1 exit conference on 08-25-2026 at 4:00 PM.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of the American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) and the College of American Pathologists (CAP) Proficiency Testing (PT) records and an interview with Testing Personnel 1 (TP1), the Laboratory Director (LD) failed to document review and evaluation of PT performance. This was noted on one of the three Chemistry events in 2025, and one of the two Special Immunology events had no documentation of review and corrective action for the unsatisfactory scores by the LD. The findings include: 1. A review of the AAB-MLE and CAP PT records revealed no documentation of review on the returned evaluation by the LD, or designee, for the following. A) AAB-MLE Chemistry M3 2025 in Urine Microscopy, 50% B) CAP SB-2 2024 Special Immunology Anti-Centromere Antibody, 0% 2. TP1 confirmed the above findings during the Day 2 exit conference on 08-26-2026 at 4:00 PM.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation during the lab tour, reviews of the Policy and Procedure (P&P) Manuals, the Quality Control (QC) records, maintenance logs and the Temperature and Humidity logs, the laboratory: 1. failed to follow manufacturer's requirement for storage of patient samples with no corrective action documented. 2. failed to record on the vials the open expiration date for the three levels of Complete Blood Count QC. 3. failed to perform maintenance of the plate reader as per manufacturer's requirement. 4. failed to perform pipette annual calibration. Findings include: 1. Refer to D5413. 2. Refer to D5415. 3. Refer to D5431. 4. Refer to D5435
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 reviews of the Temperature Log Sheets, the 25-OH Vitamin D (Vit.D) and Anti-Nuclear Antibody Profile (ANAP) Elisa Test Instructions, and an interview with the Testing Personnel 1 (TP1), the laboratory failed to document the corrective action when the freezer temperature was outside the manufacturer's specified range. It was noted freezer temperature was out of range for 2 of the 16 testing days in July 2024. The findings include: 1. A review of the temperature log revealed the freezer temperature was outside the manufacturer's acceptable range on July 20, 2024, and July 29, 2024, without corrective action documented. 2. A review of the manufacturer's test instructions for the Vit.D and ANAP testing revealed on page four, Preparation and Stability of Patient Samples. "...if samples will be stored beyond 48 hours, samples should be frozen at minus 20 degrees Celsius or lower". 3. TP1 confirmed the above findings during the Day 2 exit conference on 08-26-2026 at 4:00 PM.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on the surveyor's laboratory tour observation, review of manufacturer's package inserts and confirmed in an interview with the Testing Personnel 1 (TP1), the laboratory failed to label Boule Hematology Quality Control (QC) materials with revised expiration dates for three of the three control vials upon opening. Findings Included: 1. During the laboratory tour of the moderate complexity laboratory with TP1 on 08-25-2026 at 9:02 AM, the surveyor observed the following Boule Hematology controls for Medonic M-Series analyzer, stored in the laboratory refrigerator. Levels Low, Normal, High Lot Number: Expiration Date: 22606-31, 22606-32, 22606-33, Expires 11-11-2026 Open Expiration Date: Not written 2. Review of manufacturer's package insert for the Boule Hematology control revealed the following instructions, "Storage and shelf life after first opening Opened and recapped vials ... will retain stability for 14 days if stored at 2-8 C after being recapped." 3. The surveyor inquired if the above QC vials were currently being used prior to patient testing. TP1 confirmed on 08-25-2026 at 9:46 AM the QC vials were currently in use on
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) (a)(2) Function checks as defined by the manufacturer and with at least the frequency

	specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following: This STANDARD is not met as evidenced by: Based on reviews of the laboratory's Policy and Procedure (P&P) manual, the BIOTEK ELX800 ELISA Plate Reader maintenance logs, the Linearity Testing Procedure for the BIOTEK ELX800 ELISA Plate Reader and an interview with the Testing Personnel 1 (TP1), the laboratory failed to perform and document plate calibration required by the manufacturer at least every six months. It was noted there was no documentation of the required calibration from the date of the last survey, 4-16-2024, through the date of the current survey, 08-26-2026. The findings include: 1. A review of the laboratory's P&P manual revealed the Linearity Testing Procedure for the BIOTEK ELX800 ELISA Plate Reader where the manufacturer specification indicated plate calibration of at least every six months. 2. BIOTEK ELX800 ELISA Plate Reader maintenance logs revealed missing documentation that the plate calibration was performed at least every six months for an approximate of 28 months. 3. TP1 confirmed the above findings during the Day 2 exit conference on 08-26-2026 at 4:00 PM.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of the pipette maintenance records and an interview with Testing Personnel 1 (TP1), the laboratory failed to perform and document the annual pipette calibration in 2024 and 2025. This was noted for four of the four pipette volumes available for use in the ELISA laboratory. The findings include: 1. A review of the 2024 and 2025 pipette maintenance records revealed the following pipettes had no documentation of calibration in 2024 and 2025. a) Finnpipette - 3P, 5-50 microliters, SN MU43324 b) Finnpipette - 3P, 20-200 microliters, SN OU15217 c) VWR - 3P, 100-1000 microliters, SN GH23930 d) 3P - Finnpipette Multichannel, 50-300 microliters, SN SH78507 2. A further review of the pipette maintenance records revealed all pipettes were calibrated in 2026. 3. TP1 confirmed the above findings during the Day 2 exit conference on 08-26-2026 at 4:00 PM.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is

authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on reviews of Proficiency Testing (PT) records, the personnel records listed on the CMS 209 Form (Laboratory Personnel Report) and an interview with Testing Personnel 1 (TP1), the Laboratory Director (LD) failed to specify in writing which of the LD's duties and responsibilities were assigned to a designee. The surveyor noted there was no documentation for the delegation of responsibilities from the date of the last survey, 4-16-2024, through the date of the current survey, 08-26-2026. The findings include: 1. A review of PT and the personnel records revealed the LD had no documentation authorizing a qualified designee to perform PT review and evaluations for the returned results. 2. TP1 confirmed the above findings during the Day 2 exit conference on 08-26-2026 at 4:00 PM.