Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0184183	07/15/2025
Name of Provider or Supplier	**Street Address, City, State**	
Metabolic Disease Associates Inc	240 West 11th Street, Erie, PA	

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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) (b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records and interview with the Technical Consultant (TC), the laboratory failed to ensure PT samples were tested the same number of times as patient specimens as required under subpart H for 1 of 2 AAB-MLE PT chemistry testing events in 2025. Findings include: 1. On the day of survey, 07/15/2025 at 9:06 am, review of the laboratory's AAB-MLE PT records revealed the laboratory failed to examine PT samples in the same manner as patient specimens for the following 1 of 2 AAB-MLE PT testing events in 2025: - AAB-MLE M2 2025 Thyroid Profile; CH 2. During interview with the TC, 07/15 /2025 at 11:00am, the TC stated "PT samples for Thyroid Stimulating Hormone (TSH) Free Thyroxine (FT4) and Free Triiodothyronine (FT3) were analyzed 3 times and the final result reported was based on the calculated average". 3. The laboratory could not provide documentation stating TSH, FT4 and FT3 were included in the laboratory's patient repeat criteria. 4. The TC confirmed the findings above on 07/15 /2025 at 1:00 pm. *REPEAT DEFICIENCY
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT

	program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records, lack of documentation and interview with the Technical Consultant (TC), the Laboratory Director (LD)/designee and testing personnel (TP) failed to attest that PT samples were tested in the same manner as patient specimens as required under subpart H for 6 of 6 AAB-MLE PT events performed in 2023, 2024 and 2025. Findings Include: 1. On the day of survey, 07/15/2025 at 9:06 am, the laboratory failed to provide attestation statements signed by the LD/designee and TP to document that PT samples were tested in the same manner as patient specimens for the following 6 of 6 AAB-MLE chemistry PT events performed in 2023, 2024 and 2025: - 2023 AAB-MLE Chemistry M3 Thyroid Profile - 2024 AAB-MLE Chemistry M1, M2 & M3 Thyroid Profile - 2025 AAB-MLE Chemistry M1 & M2 Thyroid Profile 2. The laboratory reported an estimated annual test volume of 7163 chemistry examinations performed in 2024 (CMS 116, dated 07/09/2025). 3. The TC confirmed the findings above on 07 /15/2025 at 1:00 pm. *REPEAT DEFICIENCY
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 of the laboratory, lack of documentation, and interview with the Technical Consultant (TC), the laboratory failed to meet applicable analytic systems requirements in 493.1251 through 493.1283 for 2 of 2 years when moderate complexity chemistry testing was performed from 06/14/2023 to 07/15/2025. Findings include: 1. The laboratory failed to monitor and document room temperature and humidity to ensure proper reagent storage and operating conditions were met. Refer to D5413. 2. The laboratory failed to perform and document maintenance and function checks as defined by the manufacturer. Refer to D5429.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) (c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by:

	Based on record review, lack of documentation, and interview with the Practice Manager (PM), the laboratory failed to have a complete written procedure manual for endocrinology testing performed on 1 of 1 Abbott Architect i1000 SR immunoassay analyzer that met the requirements of 493.1251 (b)(1) through (b)(12) from 06/14 /2023 to the date of the survey. Findings include: 1. On the day of the survey, 07/15 /2025 at 11:00 am, review of the procedure manuals for endocrinology testing revealed the operator's manuals were used to perform testing on 1 of 1 Abbott Architect i1000 SR immunoassay analyzer from 06/14/2023 to 07/15/2025. 2. Review of the operator's manual revealed that the test system instructions used failed to include the following requirements of 493.1251 (b)(1) through (b)(12) that are specific to the laboratory: - Step by step performance of the procedure including test calculations and interpretation of results. - Preparation of slides, solution, calibrators, controls, reagents, stains, and other material used in testing. - Control procedures. - Calibration and calibration verification procedures. - Corrective action to take when calibrations or control results fail to meet the laboratory criteria for acceptability. - Limitations in the test methodology, including interfering substances. -The reportable range for test results for the test system as established or verified in 493.1253. - Reference intervals (normal values). - Imminently life-threatening test results, or panic or alert values. - 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. - Description of the course of action to take if a test system becomes inoperable. 3. The operators manuals were not approved for use by the current laboratory director prior to the start of patient testing. 4. The PM confirmed the findings on 07/15/2025 at 01:00 pm *REPEAT DEFICIENCY
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 observation of the laboratory, lack of documentation and interview with the Technical Consultant (TC), the laboratory failed to document and define acceptable criteria for room temperature and humidity to ensure proper test system operating conditions and proper reagent storage were met for 1 of 1 Abbott Architect i1000 SR immunoassay analyzer used to perform chemistry testing for 762 of 762 days from 06 /14/2023 to 07/15/2025. Findings include: 1. On the day of survey, 07/15/2025, review of the laboratory's temperature logs revealed the laboratory failed to document and define acceptable criteria for room temperature (manufacturer's acceptable range 15 to 30 degrees Celsius) and humidity (manufacturer's acceptable range 20 to 80 %) for 1 of 1 Abbott Architect i1000 SR immunoassay analyzer used to perform the following endocrinology tests for 762 of 762 days from 06/14/2025 to 07/15/2025: - Thyroid Stimulating Hormone (TSH) - Free Triiodothyronine (FT3) - Free Thyroxine (FT4) 2. The laboratory performed 7163 endocrinology tests in 2024 (CMS 116, dated

	07/09/2025). 3. The TC confirmed the above findings on 07/15/2025 at 12:03 pm. *REPEAT DEFICIENCY
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 lack of documentation and interview with the Technical Consultant (TC), the laboratory failed to perform and document the maintenance and function checks as defined by the manufacturer for 7 of 24 months when chemistry testing was performed on 1 of 1 Abbott Architect i1000 SR immunoassay analyzer from 06/14 /2023 to 07/15/2025. Findings include: 1. On the day of survey 07/15/2025, the laboratory could not provide maintenance/function check records for 1 of 1 Abbott Architect i1000 SR immunoassay analyzer used to perform endocrinology testing for the following 7 of 24 months from 06/14/2023 to 07/15/2025: - January 2024 - February 2024 - March 2024 - April 2024 - May 2024 - June 2024 - July 2024 2. The laboratory performed 7163 endocrinology tests in 2024 (CMS 116, dated 07/09/2025). 3. The TC confirmed the findings above on 07/15/2025 at 1:00 pm. *REPEAT DEFICIENCY
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 observation of the laboratory, review of records, and interview with the Practice Manager (PM), the laboratory director failed to provide overall management and direction of the laboratory in accordance with 493.1407 for 2 of 2 years when moderate complexity chemistry testing was performed from 06/14/2023 to 07/15 /2025. Refer to D6020
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Practice Manager (PM), the Laboratory Director (LD) failed to ensure Quality Assessment (QA) programs were established and maintained to assure the quality of laboratory services provided when chemistry testing was performed for 2 of 2 years from 06/14/2023 to the date of the survey. Findings include: 1. On the day of survey 07/15/2025, the laboratory could

	not provide documentation of QA activities to assess the laboratory's pre-analytical, analytical and post-analytical processes for 2 of 2 years when chemistry testing was performed from 06/14/2023 to 07/15/2025. 2. The laboratory could not provide a written QA policy for the continuous monitoring, assessing and correcting of problem identified in the general laboratory systems when chemistry testing was performed from 06/14/2023 to 07/15/2025. 3. The PM confirmed the above findings on 07/15 /2025 at 1:00 pm. *REPEAT DEFICIENCY
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY 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: Based on review of the CLIA Laboratory Personnel Report (Form CMS-209), lack of personnel qualification records and interview with the Practice Manager (PM), the laboratory failed to ensure 1 of 1 Technical Consultant (TC) met the minimum requirements of 493.1411 to perform technical consultation for moderate complexity chemistry examinations performed from 06/14/2023 to 07/15/2025. Refer to 6035
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 (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 1 year of laboratory training or experience, or both, in nonwaived 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)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in

	nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. This STANDARD is not met as evidenced by: Based on review of the CLIA laboratory Personnel Report (Form CMS-209), lack of Personnel Qualification records, and interview with the Practice Manager (PM), the laboratory failed to ensure that 1 of 1 Technical Consultant (TC) met the minimum requirements of 493.1411 to perform technical consultation for moderate complexity chemistry examinations performed from 06/14/2023 to 07/15/2025. Findings Include: 1. On the day of survey, 7/15/2025, the laboratory failed to provide education credentials for 1 of 1 TC (CMS 209 personnel #2) who performed technical consultation for moderate complexity endocrinology (chemistry) examinations performed from 06/14/2023 to 07/15/2025. 2. The PM confirmed the findings above on 07/15/2025 at 09:49 am.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the CLIA ' s laboratory Personnel Report (Form CMS-209), lack of Personnel Qualification records, and interview with the Practice Manager (PM), the laboratory failed to ensure 1 of 2 TP (CMS 209, personnel #3) performing moderate complexity testing meet the minimum qualification requirements of 493.1423. Refer to D6065
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50

	weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the CLIA laboratory Personnel Report (Form CMS-209), lack of Personnel Qualification records, and interview with Practice Manager (PM), the laboratory failed to ensure that 1 of 2 TP met the minimum requirements to perform moderate complexity testing from 06/14/2023 to 07/15/2025. Findings Include: 1. On the day of survey, 7/15/2025, the laboratory failed to provide education credentials for 1 of 2 TP (CMS 209 personnel #3) who performed moderate complexity endocrinology (chemistry) examinations from 06/14/2023 to 07/15/2025. 2. The PM confirmed the findings above on 07/15/2025 at 09:49 am.