Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0184183	07/14/2021
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the Medical Laboratory Evaluation (MLE) proficiency testing (PT) Records and Interview with the Practice Manager and Lab Supervisor, the laboratory failed to obtain signatures of testing personnel and the laboratory director on the PT attestation statements form 2020 and 2021. Findings Include: 1. On the day of survey, 07/14/2021, review of the MLE PT records revealed, the individuals testing the PT samples and the laboratory director did not sign the attestation statements for the following event in 2020 and 2021. 2020 MLE - Event #1. 2021 MLE - Events #1 and #2. 2. The Practice Manager and Lab Supervisor confirmed the findings above on 07/14/2021 around 10:15 am.
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 laboratory procedure manuals and interview with the Practice Manager and Lab Supervisor, the laboratory failed to follow and establish a complete competency assessment procedure to assess 5 of 5 testing personnel (TP) performing

	endocrinology tests, fine needle aspirate (FNA) examinations and 2 of 3 technical consultant (TC) for their regulatory responsibilities in 2019 to the day of survey. Findings include: 1. The Competency Policy states, "Staff who perform laboratory testing, will have a competency assessment at 6 months, 12 months and yearly thereafter." 2. On the day of survey, 07/14/2021, the laboratory could not provide competency assessment records for 4 of 4 testing personnel including the 6 points of competency assessment who performed endocrinology tests on the Architect in 2019, 2020 and 2021. 3. The laboratory could not provide competency assessment records for 1 of 1 TP performing FNA examinations in 2020 and 2021. 4. The laboratory could not provide a complete policy to assess the competency of 2 of 3 TC (#2 and #3) for their regulatory responsibilities in 2019, 2020 and 2021. 5. The Practice Manager and Lab Supervisor confirmed the findings above on 07/14/2021 around 9: 30 am.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with the Practice Manager and Lab Supervisor, the laboratory failed to establish a Fine Needle Aspiration (FNA) and Architect Chemistry analyzer procedure for 2019 to the day of survey. Findings include: 1. On the day of survey, 07/14/2021, the laboratory could not provide a FNA or Architect Chemistry analyzer procedure in place from 07/14 /2019 to 07/14/2021. 2. The Practice Manager and Lab Supervisor confirmed the finding above on 07/14/2021 around 10:00 a.m.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with the Practice Manager and Lab Supervisor, the Laboratory Director failed to approve the laboratory procedures in use from 07/14/2019 to the day of survey. Findings include: 1. On the day of survey, 07/14/2021, review of the laboratory procedures revealed, the current Laboratory Director failed to sign and date laboratory procedures prior to use from 07 /14/2019 to 07/14/2021. 2. Practice Manager and Lab Supervisor confirmed the above findings on 07/14/2021 around 10: 50 pm.
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 temperature records and interview with the Practice Manager and Lab Supervisor, the laboratory failed to define criteria for proper storage for the architect reagents and specimen housed in 2 of 2 freezers from 2019 to the day of survey. Findings Include: 1. On the day of survey, review of the laboratory temperature records revealed, 2 of 2 freezers housing endocrinology reagents and specimen did not have defined criteria of storage from 2019 to June 2021. 2. The Practice Manager and Lab Supervisor confirmed the findings about on 07/14/2021 around 11:05 am.
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, lack of documentation and interview with the Practice Manager and Lab Supervisor, the laboratory failed to perform maintenance of laboratory equipment from 2019 to the day of survey. Findings include: 1. On the day of survey, 07/14/2021, observation of the laboratory revealed the following laboratory equipment was due for maintenance: Freezer A thermometer, service sticker stated, " Calibration Due 08/20/2015". 1 of 1 Quest Diagnostic Horizon mini E centrifuge, service sticker stated, " Calibration Due 04/17". 2. The laboratory could not provide a maintenance procedure policy . 3. The Practice Manager and Lab Supervisor confirmed the findings about on 07/14/2021 around 11:06 am.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of a sampling of temperature logs (refrigerator B) and interview with the The Practice Manager and Lab Supervisor, the laboratory failed to document all

	corrective actions taken when the acceptable temperature range (2 - 8 degrees Celsius (C)) was exceeded from 07/18/2019 to the day of survey. Findings include: 1. On the day of survey, 07/14/2021, review of a sampling of temperature logs (Freezer B) from 07/18/2019 to 07/14/2021 revealed, the following number of days each month temperatures were below the acceptable temperature range (2 - 8 degrees C): 2019 July - 12 of 14. August - 18 of 19. September - 8 of 16. October - 11 of 19. November - 8 of 15. December - 13 of 16. 2020 January - 5 of 17. February - 7 of 16. March - 8 of 19. April - 16 of 18. May - 11 of 15. June - 17 of 18. July - 03 of 03. August - 01 of 01. September - 17 of 17. October - 12 of 13. November - No temperatures documented. December - 6 of 7. 2021 January - 13 of 16. February - 14 of 16. March - 18 of 19. April - 17 of 17. May - 16 of 16. June - 15 of 17. July - 7 of 7. 2. Corrective actions were not documented on the temperature log when temperatures fell below acceptable range. 3. The Practice Manager and Lab Supervisor confirmed the finding above on 07/14/2021 at 10:30 a.m.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the Medical Laboratory Evaluation (MLE) proficiency testing (PT) records and interview with the Practice Manager and Lab Supervisor, the Laboratory Director failed to ensure that all proficiency testing reports received, identified problems that require corrective actions in 2020. Findings include: 1. On the day of survey, 07/14/2021, review of the 2020 MLE PT records revealed, the laboratory did not perform or document corrective actions for the following failed PT events in 2020: MLE Endocrinology event 1 - score of 0% for TSH and Free TY. MLE Endocrinology event 1 - score of 80% for Free TY. 2. The Practice Manager and Lab Supervisor confirmed the findings above on 07/14/2021 around 10:05 am.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Practice Manager and Lab Supervisor, the Laboratory Director (LD) failed to ensure Quality Assessment (QA) program were maintained to ensure the quality of laboratory services provided from

	2019 to the day of survey. Findings Include: 1. On the day of survey 07/14/2021, the laboratory could not provide periodic evaluation of the laboratory that assess its pre-analytical, analytical, and post-analytical processes from 07/2019 to 07/2/2021 2. The Practice Manager and Lab Supervisor confirmed the finding above on 07/14/2021 at 10:30 a.m.
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: Based on lack of personnel qualification records, review of laboratory documents and interview with the Practice Manager and Lab Supervisor, the laboratory failed to ensure 2 of 3 Technical Consultant (TC) meet qualification requirements of a moderate complexity TC from 2019 to the day of survey. Refer to: 6034
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on lack of personnel qualification records, review of laboratory documents and interview with the Practice Manager and Lab Supervisor, the laboratory failed to ensure 2 of 3 Technical Consultant (TC) meet qualification requirements of a moderate complexity TC from 2019 to the day of survey. Findings include: 1. On the Laboratory Personnel Report (CMS 209 form) individuals #4 and #5 were listed as TC for the speciality of chemistry. 2. On the date of survey, 07/14/2021, the laboratory was unable to provide 2 of 3 TC educational credentials who performed the following TC responsibilities for the speciality of chemistry from 209 to 2021: a). TC#2 - Signed 1 of 4 Testing personnel competency assessment records in 2021. b). TC#3 - Signed as the laboratory director/designee on the following Medical Laboratory Evaluation proficiency testing attestation records: 2019 MLE - Events 1, 2 and 3. 2020 MLE - Events 2 and 3. 3. The laboratory was given until 7/21/2021 to provide the educational records for TC #2 and #3 listed on the CMS 209 form. 4. By 7 /22/2021 the requested educational records were not received. 5. The Practice Manager was emailed 7/22/2021, that educational records were not received at 7:10 am.