

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0184183	<b>(X3) Date Survey Completed</b>  06/14/2023
<b>Name of Provider or Supplier</b>  Metabolic Disease Associates Inc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2015</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) 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. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by:</p> <p>A. Based on review of the Medical Laboratory Evaluation (MLE) proficiency testing (PT) records and interview with the administrative assistant, the laboratory failed to provide 3 of 6 PT attestation statements for clinical chemistry signed by the laboratory director or designee in 2022 and 2023. Findings Include: 1. On the day of the survey, 06/14/2023 at 12:05 PM, the following MLE PT attestation statements were not signed by the laboratory director or designee in 2022 and 2023: - Clinical Chemistry: (Thyroid Stimulating Hormone (TSH), Free Thyroxine (FT4), and Free Triiodothyronine (FT3)) - 2022 Event #3 - 2023 Event #1 - 2023 Event #2 2. The administrative assistant confirmed the findings above on 06/14/2023 around 4:00 PM.</p> <p>B. Based on review of the MLE PT records, the laboratory failed to prepare and examine 5 of 5 PT samples in the same manner as patient samples in 2022 and 2023. Findings Include: 1. On the day of the survey, 6/14/2023 at 12:05 PM, the laboratory records showed each PT sample analyzing TSH, FT4, and FT3 was ran 3 times and the result reported to MLE was the calculated average of the 3 runs. The PT events affected into 2022 and 2023 include: - Clinical Chemistry: (TSH, FT4, and FT3) -</p>

2022 Event #1 - 2022 Event #2 - 2022 Event #3 - 2023 Event #1 - 2023 Event #2 2. The administrative assistant confirmed the findings above on 06/14/2023 around 4:00 PM. C. Based on review of the MLE PT records, the laboratory failed to maintain copies of the proficiency testing program reports that record PT results for 4 of 6 PT events in 2022 and 2023. Findings include: 1. On the day of the survey, 6/14/2023 at 12:10 PM, the following MLE PT events were missing copies of the PT program reports that record PT results in 2022 and 2023: - Clinical Chemistry: (TSH, FT4, and FT3) - 2022 Event #1 - 2022 Event #2 - 2022 Event #3 - 2023 Event #1 - 2023 Event #2 2. The administrative assistant confirmed the findings above on 06/14/2023 around 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 lack of documentation and interview with the administrative assistant, the laboratory failed to follow and establish a complete competency assessment procedure to assess 1 of 2 testing personnel (TP) performing endocrinology tests for their regulatory responsibilities from 7/14/2021 to the date of the survey. Findings include: 1. The Competency Policy states: "The assessment will be performed by the Laboratory Director or Director's designee" and "Staff who perform laboratory testing, will have a competency assessment at 6 months, 12 months and yearly thereafter." 2. On the day of survey, 06/14/2023, the laboratory could not provide competency assessment records for 1 of 2 TP (CMS 209 personnel #2) who performed endocrinology tests on the Architect from 7/14/2021 to the date of the survey. 3. The provided competency assessment for TP#2 did not have a completion date and was not signed off by the laboratory director or laboratory designee. 4. The administrative assistant confirmed the findings above on 06/14/2023 around 4:00 PM. **\*\*Repeat Deficiency\*\***

**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 administrative assistant, the laboratory failed to define criteria for proper storage for the architect reagents and specimen housed in 2 of 2 freezers from 7/14/2021 to the day of survey. Findings Include: 1. On the day of survey, 6/14/2023 at 12:50 PM, review of the laboratory temperature records revealed, 2 of 2 freezers housing endocrinology

reagents and specimen did not have the correct criteria of storage from 07/14/2021 to the date of the survey 2. The administrative assistant confirmed the findings about on 06/14/2023 around 4:00 PM. \*\* Repeat Deficiency \*\*

**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 lack of documentation and interview with the administrative assistant, the laboratory failed to perform the recommended manufacturer maintenance on 1 of 1 Abbott Architect Plus from 07/14/2021 to the date of the survey. Findings include: 1. On the day of survey, 06/14/203 at 2:00 PM, the laboratory failed to provide documentation of recommended manufacturer maintenance for 1 of 1 Abbott Architect Plus from 07/14/2021 to the date of the survey. 2. The administrative assistant confirmed these findings on 6/14/2023 around 4:00 PM.

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:  
Based on lack of documentation and interview with the administrative assistant, the laboratory failed to perform calibration verification at least once every six months as required for 1 of 1 Abbott Architect Plus for Thyroid Stimulating Hormone (TSH) in chemistry from 07/14/2021 to the date of the survey. Findings include: 1. On the date of the survey, 06/14/2023 at 12:30 PM, the laboratory could not provide calibration verification records for the required analytes including TSH. 2. The administrative assistant confirmed the findings above on 06/14/2023 around 4:00 PM.

**D5447**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on Architect Plus quality control (QC) record review and interview with the administrative assistant, the laboratory failed to perform quality control for clinical chemistry analytes (Thyroid Stimulating Hormone (TSH), Free Thyroxine (FT4), and Free Triiodothyronine (FT3)) for 7 of 13 days in January 2022 and 13 of 17 days in February 2023 on 1 of 1 Abbott Architect Plus at least once each day of patient testing. Findings: 1. On the day of the survey, 6/14/2023 at 1:13 PM, the QC was not ran for TSH, FT4, or FT3 on following days of patient testing: - 01/05/2022, 01/06/2022, 01/10/2022, 01/20/2022, 01/25/2022, 01/27/2022, 01/31/2022 - 02/02/2023, 02/02/2023, 02/06/2023, 02/09/2023, 02/13/2023, 02/14/2023, 02/16/2023, 02/20/2023, 02/21/2023, 02/22/2023, 02/23/2023, 02/27/2023, 02/28/2023 2. The administrative assistant confirmed the findings on 6/14/2023 around 4:00 PM

**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 administrative assistant, the Laboratory Director (LD) failed to establish and follow written policies and procedures for an on-going mechanism to monitor, assess, and when indicated, correct problems identified in the laboratory from 7/21/2021 to the day of survey. Findings Include: 1. On the day of survey 06/14/2023 at 3:00 PM, the laboratory could not provide periodic evaluation of the laboratory that assess its pre-analytical, analytical, and post-analytical processes from 07/2021 to the date of the survey. 2. The administrative assistant confirmed the finding above on 06/14/2023 around 4:00 PM. \*\* Repeat Deficiency\*\*

**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 laboratory procedure review and interview with the administrative assistant, at the time of survey the laboratory director failed to ensure that a adequate procedure manual is available to the testing personnel (TP) responsible for performing clinical chemistry testing on 1 of 1 Abbott Architect Plus analyzer from 7/14/2021 to the date of the survey. Findings include: 1. On the day of the survey, 6/14/2023 at 12:45 PM, the laboratory provided a procedure manual from an outside faciliy's microbiology department for the Abbott Architect analyzer from 07/14/2021 to the date of the survey. 2. The provided procedure does not pertain to the chemistry testing performed in the laboratory. 3. The administrative assistant confirmed the findings on 6/14/2023 around 4:00 PM.