

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0184183	(X3) Date Survey Completed 02/05/2026
Name of Provider or Supplier Metabolic Disease Associates Inc	Street Address, City, State 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
D0000	A desk review for proficiency testing results was conducted by the Pennsylvania State Agency for Metabolic Disease Associates Inc on 02/05/2026. The laboratory was found out of compliance with the following conditions: 493.803 Condition: Successful participation. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the CASPER 0155 report and graded results from the proficiency testing (PT) organization, American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE), the laboratory failed to successfully participate in PT for

	Thyroid Stimulating Hormone (TSH), Free Thyroxine (FT4), and the sub-specialty of Endocrinology. The laboratory had unsatisfactory scores for the 3rd event of 2024, and the 1st, 2nd, and 3rd Events of 2025. Refer to D2107 and D2108.
D2107	ENDOCRINOLOGY CFR(s): 493.843(f) (f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the CASPER 0155 Report and graded results from the proficiency testing organization, American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE), the laboratory failed to achieve an overall testing score of satisfactory performance for the Thyroid Stimulating Hormone (TSH) and Free Thyroxine (FT4) analytes and has sustained a subsequent occurrence of unsuccessful performance. The laboratory had unsatisfactory scores for the 3rd Event of 2024, and the 1st, 2nd, and 3rd Events of 2025. Findings include: 1. Review of the CASPER 0155 report revealed the following unsatisfactory scores: - 2024 Event 3: TSH: 0% FT4: 0% - 2025 Event 1: TSH: 60% - 2025 Event 2: TSH: 0%, FT4: 0% - 2025 Event 3: TSH: 0% FT4: 0% 2. Further review of the laboratory's 2024 and 2025 AAB-MLE PT agency's graded results confirmed the above findings, resulting in non-initial unsuccessful participation for the analytes: TSH and FT4.
D2108	ENDOCRINOLOGY CFR(s): 493.843(g) (g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the CASPER 0155D Report and graded results from the proficiency testing organization, American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE), the laboratory failed to achieve an overall testing score of satisfactory performance for the sub-specialty: Endocrinology and has sustained a subsequent occurrence of unsuccessful performance. The laboratory had unsatisfactory scores for the 3rd Event of 2024, and the 1st, 2nd, and 3rd Events of 2025. Findings include: 1. Review of the CASPER 0155 report revealed the following unsatisfactory scores: - 2024 Event 3 Endocrinology: 0% - 2025 Event 1 Endocrinology: 70% - 2025 Event 2 Endocrinology: 0% - 2025 Event 3 Endocrinology: 0% 2. Further review of the laboratory's 2024 and 2025 AAB-MLE PT agency's graded results confirmed the above findings resulting in non-initial unsuccessful participation for the sub-specialty of Endocrinology.
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 review of the CASPER 0155 report and graded results from the proficiency testing (PT) organization, American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) the laboratory director failed to provide overall management and direction in accordance with 493.1407. Findings include: The laboratory failed to successfully participate in proficiency testing for the following: - Subspecialty: Endocrinology: 3rd Event 2024 AAB-MLE, 1st, 2nd and 3rd Events of 2025 AAB-MLE. - Thyroid Stimulating Hormone (TSH): 3rd Event 2024 AAB-MLE, 1st, 2nd and 3rd Events of 2025 AAB-MLE. - Free Thyroxine (FT4): 3rd Event 2024 AAB-MLE, 2nd and 3rd Events of 2025 AAB-MLE. Refer to D6016.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on a desk review of the laboratory's proficiency testing results from the American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) and the CASPER 0155D report, the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in a HHS approved proficiency testing program. Refer to D2107, and D2108.