

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D1044662	(X3) Date Survey Completed 04/01/2022
Name of Provider or Supplier Medical Assay Laboratory I	Street Address, City, State 8205 S Cass Ave, Ste 108, Darien, IL	
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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the CASPER Report 0155D and interview with an American Proficiency Institute (API) representative the laboratory failed to successfully participate in proficiency testing (PT) for the endocrinology analyte Thyroxine (TY) during events two of 2021 and one of 2022. See D2107.</p>
D2107	<p>ENDOCRINOLOGY CFR(s): 493.843(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two</p>

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 Report 0155D (Individual Laboratory Profile) and interview with an American Proficiency Institute (API) representative the laboratory failed to successfully participate in proficiency testing (PT) for the endocrinology analyte Thyroxine (TY) in the PT events two of 2021 and one of 2022. Findings include: 1. Review of the CASPER 0155D report revealed that the initial unsuccessful PT performance occurred during API PT event two of 2021 and one of 2022, as listed below. ENDOCRINOLOGY EVENT -2, 2021 TY - 60% Unsatisfactory EVENT -1, 2022 TY - 60% Unsatisfactory 2. Interview via phone with the API representative on 4-1-22 at 9:15 am confirmed the initial unsuccessful PT performance for TY in events two of 2021 and one of 2022.