

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2113834	(X3) Date Survey Completed 08/12/2024
Name of Provider or Supplier Tox Testing Inc	Street Address, City, State 16100 19 Mile Road Suite 200, Clinton Township, MI	
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 record review and interview, the laboratory failed to successfully participate in the virology proficiency testing program. Refer to D2064.</p>
D2064	<p>VIROLOGY CFR(s): 493.831(e)</p> <p>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</p>

unsuccessful performance.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the General Supervisor, the laboratory failed to successfully participate in the virology proficiency testing program for two (2023 event 3 and 2024 event 2) of three consecutive proficiency testing events.

Findings include: 1. A review of the laboratory's American Proficiency Institute (API) revealed the following scores for the virology specialty: a. 2023 event 3 had a score of 73%. b. 2024 event 2 had a score of 0%. 2. A phone interview on 8/12/24 at 9:00 am with the General Supervisor confirmed the score for 2023 event 3 and nonparticipation in 2024 event 2.