Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2113834	(X3) Date Survey Completed 05/07/2020
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	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 CMS database and review of the American Proficiency Institute (API) proficiency testing reports, it was determined the laboratory failed to successfully participate in a CMS approved proficiency testing program for the specialty of hematology. Findings include: Review of the CMS database and the API proficiency testing reports showed unsatisfactory performance for 2 (3rd 2019 and 1st 2020) of 2 consecutive testing events. Refer to D2123 and D2131.
D2123	HEMATOLOGY

	CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: . Based on review of the CMS database and review of the American Proficiency Institute (API) proficiency testing reports, the laboratory failed to participate in 2 (3rd 2019 and 1st 2020) of 2 testing events for the specialty of hematology, which is unsatisfactory performance resulting in a testing event score of 0%. Findings include: Unsatisfactory performance for 2 of 2 overall testing events for the failure to participate in the speciality of hematology constitutes unsuccessful performance. Hematology PT Events Score 3rd event 2019 0% 1st event 2020 0%
D2131	HEMATOLOGY CFR(s): 493.851(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 CMS database and the American Proficiency Institute (API) proficiency testing reports, the laboratory failed to participate and achieve satisfactory performance for 2 (3rd 2019 and 1st 2020) of 2 testing events for the following overall hematology specialty and for each individual analyte: Cell Identification (ID) or white blood cell diff (WBC Diff), red blood cell count (RBC), hematocrit (HCT), hemoglobin (HGB), white blood cell count (WBC), and platelets. Findings include: For the hematology specialty and for each analyte listed above the following scores: Hematology PT Event Score 3rd event 2019 0% 1st event 2020 0%