

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2040304	(X3) Date Survey Completed 01/25/2021
Name of Provider or Supplier Md Tox Laboratory	Street Address, City, State 1565 Mcgaw Ave Ste B, Irvine, CA	
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 with the laboratory's American Proficiency Institute (API) proficiency testing (PT) result reports for Hematology from Q3 2018 thru Q3 2020 shown unsuccessful (2 of 2) failure to attain scores of at least 80% of acceptable responses for Blood Cell Identification in Q2 and Q3 2020 Hematology PT events, and interview with the testing personnel and the laboratory director, it was determined that the laboratory failed to successfully participate in a PT program approved by CMS for Hematology in which the laboratory is certified under CLIA regulations. The findings included: The laboratory failed to achieve satisfactory performance for the Blood Cell Identification in two out of two consecutive testing Q2 and Q3</p>

	<p>Hematology PT 2020 events in the specialty of Hematology constituting unsuccessful PT performance. (See D2130)</p>
D2020	<p>BACTERIOLOGY CFR(s): 493.823(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on review with the laboratory's American Proficiency Institute (API) proficiency testing (PT) for a specialty of Bacteriology from Q3 2018 thru Q3 2020 PT events, and interview with the laboratory testing personnel (TP), it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent for Bacteriology testing event is unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory performed Bacteriology testing including but is not limited to <i>C. trachomatis</i> and <i>N. gonorrhoeae</i>. b. The laboratory enrolled with API PT program in order to be following CLIA's "Evaluation of proficiency testing performance" 42 CFR part 493.1236. c. The laboratory attained a score of 0 % for <i>C. trachomatis</i> and <i>N. gonorrhoeae</i> Q2 2020 API Bacteriology PT event, which was unsatisfactory analyte performance for the testing event. d. The laboratory performed <i>C. trachomatis</i> and <i>N. gonorrhoeae</i> in approximately 110 patient samples monthly. e. The TP affirmed (1/25/2021 @ 11:35 am) that the laboratory attained a score of 60 % for <i>C. trachomatis</i> and <i>N. gonorrhoeae</i> in Q2 2020 API Bacteriology PT event, which was unsatisfactory analyte performance for the testing event.</p>
D2098	<p>ENDOCRINOLOGY CFR(s): 493.843(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review with the laboratory's American Proficiency Institute (API) proficiency testing (PT) for endocrinology from Q3 2018 thru Q3 2020 PT events, and interview with the laboratory testing personnel (TP), it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in a subspecialty of Endocrinology testing event is unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory performed Endocrinology testing including but is not limited to Thyroxine. b. The laboratory enrolled with API PT program in order to be following CLIA's "Evaluation of proficiency testing performance" 42 CFR part 493.1236. c. The laboratory attained a score of 60 % for Thyroxin in Q1 2019 API PT event, which was unsatisfactory analyte performance for the testing event. d. The laboratory performed Thyroxin in approximately 1913 patient samples monthly. e. The TP affirmed (1/25/2021 @ 11:35 am) that the laboratory attained a score of 60 % for Thyroxin in Q1 2019 API PT event, which was unsatisfactory analyte performance for the testing event.</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p>

Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review with the laboratory's American Proficiency Institute (API) proficiency testing (PT) for the specialty of Hematology from Q3 2018 thru Q3 2020 PT events, and interview with the laboratory testing personnel (TP), it was determined that the laboratory failed to achieve satisfactory performance for Blood Cell Identification (BCI) in two consecutive Q2 and Q3 PT 2020 testing events, was unsuccessful performance. The findings included: a. The laboratory performed Hematology testing including but is not limited to Blood Cell Identification (BCI). b. The laboratory enrolled with API PT program in order to be in compliance with CLIA "Evaluation of proficiency testing performance" 42 CFR part 493.1236. c. The laboratory attained scores of 40 % and 60 % for BCI in Q2 2020 and Q3 2020, respectively for API Hematology PT events, which was unsuccessful performance. d. The failures of BCI PT results are shown as follows: Q2 2020 (40 %) PT event, FAIL Sample # Result Target BCI-07 Lymph Plasmacytoid, Lymphocyte normal BCI-09 Neutrophil band (stab), Neutrophil segmented BCI-10 Schistocyte, Sickle Cell (drepanocyte) Q3 2020 (60%) PT event, FAIL Sample # Result Target BCI-12 Neutrophil band (stab), Neutrophil segmented BCI-13 Neutrophil with toxic gran, Neutrophil band (stab) e. The TP affirmed (1/25/2021 @ 11:35 am) that the laboratory attained scores of 40 % and 60 % for BCI in Q2 2020 and Q3 2020, respectively for Hematology API PT events, in two consecutive events was unsuccessful performance.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on review with the laboratory's American Proficiency Institute (API) proficiency testing (PT) from Q3 2018 thru Q3 2020 PT events, and interview with the laboratory testing personnel (TP), it was determined that the laboratory director failed to ensure that the proficiency testing samples were tested as required under Subpart H of 42 CFR part 493. The findings included: a. The laboratory enrolled with API PT program for the testing systems including but are not limited to Bacteriology, Endocrinology, and Hematology, in order to be following CLIA "Evaluation of proficiency testing performance" 42 CFR part 493.1236. b. The laboratory failed to attain an overall testing event score of at least 80 percent for Bacteriology PT testing event is unsatisfactory performance, see D-2020. c. The laboratory failed to attain a score of at least 80 percent of acceptable responses for Endocrinology PT testing event is unsatisfactory analyte performance, see D-2098

D6076

LABORATORY DIRECTOR

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on review with the laboratory's American Proficiency Institute (API) proficiency testing (PT) from Q3 2018 thru Q3 2020 events, and interview with the laboratory testing personnel (TP), it was determined that the laboratory director failed to provide and fulfill the overall management and direction. The findings included: a. The laboratory performed the high complexity testing including but is not limited to Hematology with Blood Cell Identification (BCI). b. The laboratory enrolled with API PT program for the specialty of Hematology and failed to meet the compliance with CLIA "Evaluation of proficiency testing performance" 42 CFR part 493.1236. c. The laboratory attained scores of 40 % and 60 % for BCI in Q2 2020 and Q3 2020, respectively, for the same analyte in two consecutive events, was unsuccessful performance, see D-2130 See D-2016 and D-6089

D6089

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:

Based on review with the laboratory's American Proficiency Institute (API) proficiency testing (PT) from Q3 2018 thru Q3 2020 events, and interview with the laboratory testing personnel (TP), it was determined that the laboratory director failed to ensure the proficiency testing samples were tested as required under subpart H of 42 CFR part 493. The findings included: a. The laboratory performed Hematology testing including but is not limited to Blood Cell Identification (BCI), which is a high complexity testing. b. The laboratory attained scores of 40 % and 60 % for BCI in Q2 2020 and Q3 2020, respectively for Hematology API PT events, which was unsuccessful performance, see D-2130.