Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2040304	07/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Md Tox Laboratory	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
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based review of the laboratory's records, and interview with the laboratory testing personnel, it was determined that the laboratory failed to retain records including validation of new procedures, calibrations and or calibration verification of test system performance specifications. The findings included: a. The laboratory implemented the new procedures to perform ABO type and Rh (D) type. b. The laboratory claimed that the laboratory had performed and validated the new procedures for ABO type and Rh (D) type. c. At the time of the survey (7/24/2018), there were no ABO type and Rh (D) type validation records available. d. At the time of the survey (7/24/2018), there were no 2017 calibration verification records for Olympus AU 400 chemistry instruments available either.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on observation of the laboratory temperature records and interview with the laboratory personnel, it was determined that the laboratory failed to follow written

	policies and procedures to assess employee and, if applicable, consultant competency. The findings included: a. The laboratory used many digital thermometers for the purpose of storage of the laboratory supplies and reagents. b. Observe and interview with the laboratory personnel about how are the features of the digital thermometers work. c. The digital thermometers display three numbers/information to indicate that the current temperature, "Min" and "Max" in the past, some time ago, plus other mode to set the acceptable ranges. d. The laboratory monitor temperature person and other laboratory personnel did not present well that they were competent in monitoring or understand the temperature monitoring. e. An inconsistent acceptable temperature range was set for the freezer # 1005 to between -15 oC and -30 oC on the chart, but on the freezer door was set at -15 oC to -25oC. f. The digital thermometer for freezer # 1005 reading at the time of the survey (7/24/2018 @ 11 am) had indicated the "Min" at -28 oC while the "Max" at 24, which were out of the acceptable range of -15 oC to -25 oC. g. The digital thermometer for freezer # 1001 reading at the time of the survey (7/24/2018 @ 11 am) had indicated the "Max" at 5, which was out of the acceptable range of -15 oC to -25 oC. h. The digital thermometer for refrigerator # 1004 reading at the time of the survey (7/24/2018 @ 11 am) had indicated the "Min" at 1 oC while the "Max" at 24, which were out of the acceptable range of 2 oC to 8 oC.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and interview with the laboratory testing personnel, it was determined that the laboratory failed to follow the manufacturer's calibration verification (CV) instructions and to perform CV for its chemistry instruments. The findings included: a. The laboratory performed routine chemistry using Olympus AU 400 instrument, the test system provided less than three (3) calibrators for the most of the enzyme test procedures. b. The laboratory must perform and document calibration verification (CV) following the manufacturer's CV instructions, at least once every 6 month and including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to

	verify the reportable range of the test results for the test system. c. At the time of survey (7/24/2018 @ 13:15), no CV records available for 2017.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of the laboratory records, interview with the laboratory testing personnel, it was determined that the laboratory failed to perform and document all test result comparison activities twice a year to evaluate and define the relationship between test results using the different methodologies, or instruments. The findings included; a . The laboratory used Pentra Excel 80 to perform CBC (complete blood cell counts) including but are not limited to WBC (white blood cell) and automated WBC cell differentials. b. The laboratory also provided and reported with manual WBC cell differentials when the automated cell differentials meet the laboratory established specific criteria to verify for the accuracy of automated results. c. The laboratory failed to document twice annually all test result comparison activities.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory reports, and interview with the testing personnel, it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. The findings included: a. Sample randomly 5 patient test results reports, including its requisition form, quality control records for the tests ordered and performed on the dates to support and verify the accuracy of the testing systems and the accuracy for the patient test reports (Patient Test Result Reports Quality Assessment). b. One health provider has authorized and ordered for its patient, ID #1046 for the following tests: CBC, TSH (3rd IS); T4, Free; T3, Free; PSA, total (Hybrietech); and Magnesium. c. The blood was collected on 07/16/2017 10:34 AM and a final reported was generated on 7/17/2018 5:53 PM. d the laboratory requisition accession# 82164 for that patient #1046 was provided along with its final report on 7/24/2018 for the surveyor to quality assess the laboratory operation, which still showed "pending" to all the tests ordered mentioned above item (b). e. The laboratory personnel could not explain why the laboratory requisition still showed "pending" to all the tests ordered, but the final report has been generated and released to the health provider.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's records, and interview with the laboratory personnel, it was determined that the laboratory director failed to be 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. The findings included: See D-5209, D-6013, D-6021, and D-6045,
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the laboratory records, interview with the laboratory testing personnel, it was determined that the laboratory director failed to ensure that verification procedures used were adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. The findings included: See D-5439
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by:

	Based on review of the laboratory records, interview with the laboratory testing personnel, it was determined that the laboratory director failed to ensure that quality assessment programs were established and maintained to assure the quality of laboratory services provided. See D-5439, D-5775, and D-5891
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on review of the laboratory records, interview with the laboratory testing personnel, it was determined that the laboratory director failed to delegate the technical consultant to provide and identify training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed. The findings included: See D-5209