Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2105504	05/17/2022
Name of Provider or Supplier	**Street Address, City, State**	
Bio Tox Laboratory Llc	4619 Allen Road, Allen Park, 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
D0000	The Department of Licensing and Regulatory Affairs has evaluated this facility during an announced recertification survey and determined that it is not in compliance with CLIA regulations (42 CFR Part 93, effective April 24, 2003) and Immediate Jeopardy was identified. The following Conditions were not met: 493.1100 Condition: Facility administration 493.1250 Condition: Analytic systems 493.1441 Condition: Laboratories performing high complexity testing; laboratory director 493.1459 Condition: Laboratories performing high complexity testing; general supervisor
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: . Based on record review and interview with the Technical Supervisor (TS), the laboratory failed to report all positive SARS-CoV-2 test results every day of patient testing for 22 (to February 2022) of 24 months reviewed. Findings include: 1. The surveyor observed the laboratory's Atila Biosicences analyzer and high complexity molecular iAMP COVID-19 Detection test system on 5/17/22 at 9:00 am. 2. A review of the laboratory's records on 5/17/22 revealed an email from the local health department requesting the laboratory not report negative results. 3. The surveyor requested documentation indicating all positive SARS-CoV-2 patient test results were

	reported to the local health department on 5/17/22 at 1:35 pm and they were not made available. 4. An interview on 5/17/22 at 1:36 pm with the TS revealed the laboratory only had fax transmissions of positive SARS-CoV-2 dating to March 2022 and confirmed the laboratory did not have record that of all positive SARS-CoV-2 patient test results were sent to the local health department.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to retain quality control and patient test records for 15 (May 2020 to August 2021) of 24 months reviewed. Findings include: 1. The surveyor requested documentation of quality control and patient test records from May 2020 on 5/17/22 at 10:51 am and it was not made available. 2. A review of the laboratory's test run documentation on 5/17/22 revealed a lack of documentation prior to 3/10/21. 3. An interview with TP1 on 5/17/22 at 10:51 am revealed the laboratory did not have documentation of quality control and patient test records prior to 3/10/22 and was intermittently unable to retain data from all testing dates until August 2021 due to power outages and flooding. The laboratory had not backed up its data to ensure retention.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Supervisor (TS), the laboratory failed to have a request for patient testing from an authorized person for 8 (Patients 63511, 23743, 27825, 34488, 13536, 13535, 13627, and 13007) of 77 patient test requests reviewed. Findings include: 1. A review of patient test requests revealed a lack of an authorized person for the following patients: a. Patient 13007, tested for SARS-CoV-2 on 3/10/22. b Patient 13627, tested for SARS-CoV-2 on 3/17/22. c. Patient 13535, tested for SARS-CoV-2 on 3/17/22. d. Patient 13536, tested for SARS-CoV-2 on 3/17/22. 2. An interview on 5/17/22 at 11:37 am with the TS confirmed the patients listed above did not have an authorized person on the test request and revealed the laboratory's process for patients seeking testing without a test request from an authorized person is to have the patient's health provider's name added to the form without receiving requests for patient testing from those health providers. 3. A review of patient test requests revealed the following patients with an authorized person's name written on the test request were not received from an authorized person: a. Patient 34488, tested for SARS-CoV-2 on 11/4/21. b. Patient 27825, tested for SARS-CoV-2 on 9/9/21. c. Patient 23743, tested for SARS-CoV-2 on 7/15/21. d. Patient 63511, tested for SARS-CoV-2 on 5/7/22.

D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . Based on record review and interviews, the laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to perform quarterly and annual maintenance for its Air Science Purair-Flow biosafety cabinet used in SARS-CoV-2 sample preparation as required by the manufacturer. Refer to D5431. 2. The laboratory failed to ensure results of control materials were within acceptable limits before reporting patient SARS-CoV-2 test results. Refer to D5481. 3. The laboratory failed to follow established policies to monitor and correct problems in analytic systems for its SARS-CoV-2 testing. Refer to D5791.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Supervisor (TS), the laboratory failed to perform quarterly and annual maintenance for its Air Science Purair-Flow biosafety cabinet used in SARS-CoV-2 sample preparation as required by the manufacturer for 2 (May 2020 to May 2022) of 2 years reviewed. Findings include: 1. A review of the laboratory's "AIR SCIENCE PURAIR-FLOW Series Laminar Flow Cabinets" user and service manual revealed a section titled "5.1 Maintenance Schedule" stating, "Quarterly 1. Replace pre-filters" and "Annually 1. Have the cabinet recertified by a qualified certification technician." 2. A review of the laboratory's maintenance documentation on 5/17/22 for the biosafety cabinet revealed a lack of documentation of quarterly and annual maintenance or recertification performed. 3. An interview on 5/17/22 at 10:18 am with the TS confirmed the laboratory had not had the biosafety cabinet recertified. 4. An interview on 5/17/22 at 10:31 am with the TS confirmed the laboratory had not performed and documented quarterly maintenance for the biosafety cabinet.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Supervisor (TS), the laboratory failed to ensure results of control materials were within acceptable limits before reporting patient SARS-CoV-2 test results for 7 (3/10/21, 3/17/21, 6/3/21, 7/14 /21, 7/15/21, 7/17/21, and 8/2/21) of 14 testing dates reviewed. Findings include: 1. A review of the laboratory's "iAMP COVID-19 Detection Kit" manufacturer's instructions for use on 5/17/22 revealed a section titled "Interpretation of Test Controls" stating, "Negative Control Template - serves to verify that analyte contamination does not occur during reaction setup and is used once in each instrument run. There should be NO exponential amplification curve shown in any channel (FAM or HEX) for the negative control template, otherwise the test is invalid, and the results cannot be used for diagnosis." and "Positive Control Template - serves as a control for amplification and detection of SARS-CoV-2 RNA specific sequences of the N and ORF1ab genes. It should show exponential curves in both channels (FAM and HEX)." 2. A review of the results of control materials on 5/17/22 revealed controls had not passed for the following test dates: a. On 3/10/21, the negative control had a cycle threshold (Ct) value of 28.09 in the FAM channel and a Ct value of 27.62 in the HEX channel. The run had two patient samples. b. On 3/17/21, the negative control had a Ct value of 19.2 in the FAM channel. The run had 23 patient samples. c. On 6/3/21, the positive control showed no amplification in the FAM channel. The run had 10 patient samples. d. 7/14/21 had two patient runs: i. The first run with one patient sample, the negative control showed a Ct of 37.2 in the HEX channel. The positive control did not show amplification in either the FAM or HEX channels. ii. The second run with two patient samples, the negative control had a Ct of 28.99 in the HEX channel. e. On 7/15/21, the negative control showed a Ct of 28.76 in the HEX channel. The run had three patient samples. f. On 7/17/21, the negative control showed a Ct of 31.12 in the HEX channel. The run had 18 patients. g. 8/2/21 had three patient runs: i. The first run with six patient samples, the negative control had a Ct of 19.79 in the FAM channel. ii. The second run with six patient samples, the negative control had a Ct. of 19.07 in the FAM channel. iii. The third run with 66 patient samples, the negative control showed a Ct value of 47.83 in the HEX channel. 3. A review of 15 patient test reports from the dates listed above revealed the laboratory reported patient test results when the results of control materials did not meet the criteria for acceptability. 4. An interview on 5/17/22 at 1:41 pm with the TS confirmed the laboratory did not have documentation of reruns for the patient test runs listed above and patient test results were reported.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Supervisor (TS), the laboratory failed to follow established policies to monitor and correct problems in analytic systems for its SARS-CoV-2 testing for 7 (3/10/21, 3/17/21, 6/3/21, 7/14/21, 7 /15/21, 7/17/21, and 8/2/21) of 14 testing dates reviewed when quality control did not

	meet acceptability criteria. Findings include: 1. 1. A review of the laboratory's "iAMP COVID-19 Detection Kit" manufacturer's instructions for use on 5/17/22 revealed a section titled "Interpretation of Test Controls" stating, "Negative Control Template - serves to verify that analyte contamination does not occur during reaction setup and is used once in each instrument run. There should be NO exponential amplification curve shown in any channel (FAM or HEX) for the negative control template, otherwise the test is invalid, and the results cannot be used for diagnosis." and "Positive Control Template - serves as a control for amplification and detection of SARS-CoV-2 RNA specific sequences of the N and ORF1ab genes. It should show exponential curves in both channels (FAM and HEX)." 2. A review of the results of control materials on 5/17/22 revealed controls had not passed for the following test dates: a. On 3/10/21, the negative control had a cycle threshold (Ct) value of 28.09 in the FAM channel and a Ct value of 27.62 in the HEX channel. The run had two patient samples. b. On 3/17/21, the negative control had a Ct value of 19.2 in the FAM channel. The run had 23 patient samples. c. On 6/3/21, the positive control showed no amplification in the FAM channel. The run had 10 patient samples. d. 7/14 /21 had two patient runs: i. The first run with one patient sample, the negative control showed a Ct of 37.2 in the HEX channel. The positive control did not show amplification in either the FAM or HEX channels. ii. The second run with two patient samples, the negative control had a Ct of 28.99 in the HEX channel. e. On 7/15/21, the negative control showed a Ct of 28.76 in the HEX channel. The run had three patient samples. f. On 7/17/21, the negative control showed a Ct of 31.12 in the HEX channel. The run had 18 patients. g. 8/2/21 had three patient runs: i. The first run with six patient samples, the negative control had a Ct of 19.79 in the FAM channel. ii. The second run with six patient samples, the negative control had a Ct. of 19.07 in the FAM channel. iii. The third run with 66 patient samples, the negative control showed a Ct value of 47.83 in the HEX channel. 3. A review of the laboratory's "BIOTOX" policy on 5/17/22 revealed a section titled "Responsibility for the Quality Assurance Program" stating, "The Laboratory Director has overall responsibility for the Quality Assurance Program. The Laboratory Director will act to implement the Quality Assurance policies as a part of the all-encompassing Risk Management Program. The Director will evaluate the laboratory's QA needs, write the QA policies, regularly monitor QA indicators, document actions, and communicate QA policies to all employees. The Director and Technologist will write procedures to implement QA policies, monitor and document indicators daily, monthly, or as needed, and maintain an on-going Quality Control program. The Director will review all laboratory proficiency testing results and all quarterly and annual QA indicator monitoring done. The laboratory staff has the ultimate responsibility for performing quality work, reporting accurate and timely results, and identifying, correcting, and reporting problems. 4. The surveyor requested corrective action documentation for the patient testing runs listed above on 5/17/22 at 10:58 am and it was not made available. 5. An interview on 5/17/22 at 1:41 pm with the Technical Supervisor confirmed the laboratory had not documented corrective action for the quality control failures in patient testing runs and patient test results were reported.
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 record review and interview, the Laboratory Director failed to provide the laboratory with overall management and direction. Findings include: 1. The laboratory failed to follow established policies to monitor and correct problems in analytic systems for its SARS-CoV-2 testing. Refer to D6094. 2. The Laboratory Director failed to ensure patient test results were reported only when quality control testing had met manufacturer control acceptability criteria. Refer to D6097. 3. The Laboratory Director failed to ensure General Supervisor #1 was qualified to perform the duties of a General Supervisor. Refer to D6102. 4. The Laboratory Director failed to ensure Testing Personnel #1 was competent to perform the high complexity SARS-CoV-2 testing. Refer to D6103.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: . Based on record review and interviews, the laboratory failed to follow established policies to monitor and correct problems in analytic systems for its SARS-CoV-2 testing. Refer to D5791.
D6097	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: . Based on record review and interviews, the Laboratory Director failed to ensure patient test results were reported only when quality control testing had met manufacturer control acceptability criteria. Refer to D5481.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: . Based on record review and interviews, the Laboratory Director failed to ensure General Supervisor #1 was qualified to perform the duties of a General Supervisor. Refer to D6143.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Supervisor (TS), the Laboratory Director failed to ensure Testing Personnel #1 was competent to perform the high complexity SARS-CoV-2 testing for 9 (April 2021 to January 2022) of 13 months Testing Personnel #1 has been employed as a high complexity testing personnel. Findings include: 1. An interview on 5/17/22 at 9:30 am with the TS revealed Testing Personnel #1 was hired as a testing personnel and general supervisor in April 2021. 2. A review of the laboratory's personnel competency records on 5/17 /22 revealed one competency assessment performed 1/12/22. 3. A review of the laboratory's established "Personnel Competency Assessment Policy" on 5/17/22 revealed a section stating, "All testing personnel must have a competency assessment semi-annually the first year and annually thereafter. This assessment must include the six necessary points for six evaluation." and "Any paperwork used for determining the competency of an employee should be attached to the assessment form." 4. An interview on 5/17/22 at 9:30 am with the TS confirmed competency assessments for Testing Personnel #1 were not performed as required.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: . Based on record review and interview, the General Supervisor did not meet the qualification requirements of 493.1463. Findings include: 1. General Supervisor #1 failed to meet the qualification requirements to serve as a General Supervisor. Refer to D6143.
D6143	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical

technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493. 1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c) (4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c) (5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5) (ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3) (i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:
Based on record review and interview with the Technical Supervisor (TS), General Supervisor #1 failed to meet the qualification requirements to serve as a General Supervisor for 13 months since becoming the General Supervisor in April 2021 Findings include: 1. The surveyor requested educational and experience documentation for General Supervisor #1 listed on the CMS-209 form on 5/17/22 at 9: 34 am and the following was not made available: a. Documentation of at least 2 years of laboratory training or experience, or both, in high complexity testing. 2. A review of the laboratory's "Personnel Requirement" policy on 5/17/22 listed General Supervisor #1 as the General Supervisor for the laboratory. 3. A review of the laboratory's "High Complexity Laboratories" policy on 5/17/22 revealed a section

	titled "General Supervisor" stating, "Qualified as Testing Personnel for high complexity testing AND at least 2 years laboratory training or experience in high complexity testing." 4. An interview on 5/17/22 at 9:34 am with the TS confirmed General Supervisor #1 had no training or experience in high complexity laboratory testing prior to employment at the laboratory in April 2021.