Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1078844	11/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Phamatech, Inc	15175 Innovation Dr, San Diego, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by:
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 the number and severity of the deficiencies cited herein, the Condition: Analytic Systems was not met. The laboratory failed to establish a written procedure manual that included the preparation of quality control materials (see D5403), ensure that quality control material used to monitor patient testing was not used when it had exceeded the expiration date (see D5417), maintain documentation to indicate that the laboratory had performed instrument maintenance as defined by the manufacturer with at least the frequency specified by the manufacturer (see D5429), establish statistical parameters for unassayed quality control materials over time through concurrent testing of quality control materials having previously determined statistical parameters (see D5469), ensure that test results of quality control materials met the

	laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results (see D5481), have a system that twice a year evaluated and defined the relationship between test results using different instruments (see D5775), and establish comprehensive written procedures to monitor assess, and when indicated, correction problems identified in the analytic systems (see D5791).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by:
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by:
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: 1. Based on laboratory personnel interviews and toxicology instrument maintenance record review on November 27, 2018, the laboratory failed to maintain documentation to indicate that the laboratory had performed maintenance as defined by the manufacturer with at least the frequency specified by the manufacturer for the

	Olympus AU5800. Findings included: a. For its toxicology patient screening tests, the laboratory used the Olympus AU2700 as its primary toxicology testing instrument, and used the Olympus AU5800 in the event the Olympus AU2700 became inoperable. b. The laboratory maintained no documentation to indicate that the laboratory had performed maintenance as defined by the manufacturer with at least the frequency specified by the manufacturer for the Olympus AU5800. c. According to laboratory personnel, the laboratory screened approximately 100 patient toxicology specimens weekly. 2. Based on laboratory personnel interviews and toxicology instrument maintenance record review on November 27, 2018, the laboratory failed to maintain documentation to indicate that the laboratory had performed maintenance as defined by the manufacturer with at least the frequency specified by the manufacturer for the Olympus AU2700. Findings included: a. For its toxicology patient screening tests, the laboratory used the Olympus AU2700 as its primary toxicology testing instrument. b. Laboratory records indicated that the manufacturer required daily maintenance was performed on the Olympus AU2700 by laboratory personnel on May 25, 2018, May 28, 2018, May 29, 2018, May 30, 2018, and May 31, 2018. However, closer scrutiny of the laboratory's Olympus AU2700 daily maintenance records revealed an inconsistency that put into question whether daily maintenance on the Olympus AU2700 had been performed on those dates. That is, the laboratory's Olympus AU2700 daily maintenance record for May 25, 2018, May 28, 2018, May 29, 2018, May 30, 2018, and May 31, 2018 indicated that daily maintenance was performed by an individual in which laboratory attendance records showed was on "holiday" or "vacation" status on those dates, and had not been working in the laboratory. c. Information recorded on the laboratory's Olympus AU2700 daily maintenance log for May 2018 could not be authenticated. The document appeared to have been falsified to give the appearance the laboratory complied with this requirement. d. According to laboratory personnel, the laboratory screened approximately 100 patient toxicology specimens weekly. 3. Based on laboratory personnel interviews and toxicology instrument maintenance record review on November 27, 2018, the laboratory failed to maintain documentation to indicate that the laboratory had performed maintenance as defined by the manufacturer with at least the frequency specified by the manufacturer for the Olympus AU2700. Findings included: a. For its toxicology patient screening tests, the laboratory used the Olympus AU2700 as its primary toxicology testing instrument. b. Although laboratory records indicated that weekly, monthly, and quarterly manufacturer required maintenance had been performed on the Olympus AU2700, it is unknown whether these maintenance activities were performed timely because laboratory records included no dates when the weekly, monthly, and quarterly manufacturer required maintenance had been performed. c. According to laboratory personnel, the laboratory screened approximately 100 patient toxicology specimens weekly.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be

	established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on laboratory personnel interview and toxicology quality control record review on November 27, 2018, the laboratory failed to establish statistical parameters for unassayed toxicology positive quality control materials over time through concurrent testing of quality control materials having previously determined statistical parameters. Findings included: a. At the time on this survey (November 27, 2018), in order to monitor its patient toxicology screening and confirmation tests, the laboratory was using the following unassayed positive quality control materials: 1.) ETOH screening positive quality control material: labeled as lot number 11072018, expiration date December 31, 2018. 2.) Multi-Drug screening positive quality control material: labeled as lot number 11142018, expiration date January 25, 2019. 3.) Mepro screening positive quality control material: labeled as lot number 10102018, expiration date December 31, 2018. 4.) Barbiturates confirmation low positive quality control material: labeled as lot number 68460, expiration date December 31, 2020. b. These unassayed toxicology positive quality control materials were made by the laboratory. c. The laboratory maintained no documentation to indicate that the laboratory had established statistical parameters for these unassayed toxicology positive quality control materials over time through concurrent testing of the control materials having previously determined statistical parameters. d. According to laboratory personnel, the laboratory screened approximately 100 patient toxicology specimens weekly, and performed approximately 800 various patient toxicology confirmation tests weekly.
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 laboratory personnel interviews and toxicology confirmation testing record review on November 27, 2018, the laboratory failed to ensure that test results of quality control materials met the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. Findings included: a. In its toxicology section, the laboratory performed patient toxicology confirmation tests using gas chromatography - mass spectrometry (GCMS) methodology. In each patient toxicology confirmation test run, the laboratory included two levels of positive quality control materials and one negative quality control materials to monitoring its patient testing. b. For the each of the following toxicology confirmation test runs, although the laboratory included quality control materials in each run, laboratory documentation failed to include any information (e.g., lot number, expiration date, etc.) that referenced the quality control materials used so that it could be determined whether the quality control material test results met the laboratory's and/or manufacturer's test system criteria for acceptability. All patient specimen test results obtained from these test runs were reported by the laboratory. 1.) For the laboratory's patient benzodiazepines confirmation test run dated November 14,

2018 (batch number 190334), laboratory documentation failed to include any reference information for the two positive and one negative quality control materials used to determine whether quality control material test results met the laboratory's and /or manufacturer's test system criteria for acceptability. At least four patient specimens (laboratory accession numbers 10024258, 10024206, 10024148, and 10024348) were tested and reported from this benzodiazepines confirmation test run. 2.) For the laboratory's patient barbiturates confirmation test run dated November 14, 2018 (batch number 190335), laboratory documentation failed to include any reference information for the two positive and one negative quality control materials used to determine whether quality control material test results met the laboratory's and /or manufacturer's test system criteria for acceptability. At least three patient specimens (laboratory accession numbers 10023866, 10024208, and 10024360) were tested and reported from this barbiturates confirmation test run. 3.) For the laboratory's patient benzoylecgonine confirmation test run dated November 14, 2018 (batch number 190337), laboratory documentation failed to include any reference information for the two positive and one negative quality control materials used to determine whether quality control material test results met the laboratory's and/or manufacturer's test system criteria for acceptability. At least one patient specimen (laboratory accession number 10023986) was tested and reported from this benzoylecgonine confirmation test run. 4.) For the laboratory's patient tetrahydrocannabinol confirmation test run dated November 14, 2018 (batch number 190342), laboratory documentation failed to include any reference information for the two positive and one negative quality control materials used to determine whether quality control material test results met the laboratory's and/or manufacturer's test system criteria for acceptability. At least six patient specimens (laboratory accession numbers 10023874, 10024159, 10024179, 10023929, 10023951, and 10023952) were tested and reported from this tetrahydrocannabinol confirmation test run. 5.) For the laboratory's patient amphetamines confirmation test run dated November 15, 2018 (batch number 190403), laboratory documentation failed to include any reference information for the two positive and one negative quality control materials used to determine whether quality control material test results met the laboratory's and/or manufacturer's test system criteria for acceptability. At least one patient specimen (laboratory accession number 10026755) was tested and reported from this amphetamines confirmation test run. 6.) For the laboratory's patient barbiturates confirmation test run dated November 15, 2018 (batch number 190406), laboratory documentation failed to include any reference information for the two positive and one negative quality control materials used to determine whether quality control material test results met the laboratory's and/or manufacturer's test system criteria for acceptability. At least one patient specimen (laboratory accession number 10026760) was tested and reported from this barbiturates confirmation test run. 7.) For the laboratory's patient barbiturates confirmation test run dated November 15, 2018 (batch number 190407), laboratory documentation failed to include any reference information for the two positive and one negative quality control materials used to determine whether quality control material test results met the laboratory's and/or manufacturer's test system criteria for acceptability. At least one patient specimen (laboratory accession number 10026580) was tested and reported from this barbiturates confirmation test run. 8.) For the laboratory's patient tetrahydrocannabinol confirmation test run dated November 15, 2018 (batch number 190408), laboratory documentation failed to include any reference information for the two positive and one negative quality control materials used to determine whether quality control material test results met the laboratory's and/or manufacturer's test system criteria for acceptability. At least nine patient specimens (laboratory accession numbers 10026594, 100213648, 10026551, 10026580, 10015697, 10015496,

	10026680, 10026608, and 10015563) were tested and reported from this tetrahydrocannabinol confirmation test run. 9.) For the laboratory's patient tetrahydrocannabinol confirmation test run dated November 15, 2018 (batch number 190409), laboratory documentation failed to include any reference information for the two positive and one negative quality control materials used to determine whether quality control material test results met the laboratory's and/or manufacturer's test system criteria for acceptability. At least five patient specimens (laboratory accession numbers 10026729, 10026735, 10026743, 10026748, and 10026760) were tested and reported from this tetrahydrocannabinol confirmation test run. 10.) For the laboratory's patient amphetamines confirmation test run dated November 16, 2018 (batch number 190492), laboratory documentation failed to include any reference information for the two positive and one negative quality control materials used to determine whether quality control material test results met the laboratory's and/or manufacturer's test system criteria for acceptability. At least four patient specimens (laboratory accession numbers 10029795, 10029821, 10021403, and 10030677) were tested and reported from this amphetamines confirmation test run. c. Laboratory documentation also indicated that these patient test runs had been reviewed and considered acceptable by laboratory personnel. d. According to laboratory personnel, the laboratory performed reported approximately 800 various patient toxicology confirmation tests weekly.
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 laboratory personnel interview and toxicology instrument record review on November 27, 2018, the laboratory, which performed patient toxicology screening tests using different instruments - the Olympus AU2700 and the Olympus AU5800, failed to have a system that twice a year evaluated and defined the relationship between test results using the different instruments. Findings included: a. For its toxicology patient screening tests, the laboratory used the Olympus AU2700 as its primary toxicology testing instrument, and used the Olympus AU5800 in the event the Olympus AU2700 became inoperable. b. The laboratory maintained no system that twice a year evaluated and defined the relationship between test results using the Olympus AU2700 and Olympus AU5800. c. According to laboratory personnel, the laboratory screened approximately 100 patient toxicology specimens weekly.
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 laboratory personnel interview and molecular testing quality assessment policies and procedures record review on November 26, 2018, the laboratory failed to establish written procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. Findings included: a. In the molecular testing section of the laboratory, on a monthly basis, it was the practice of the laboratory to randomly select patient testing records to ensure that the laboratory's molecular testing analytic systems protocols were being followed and met. b. Although the laboratory maintained documentation of this monthly quality assessment review, the laboratory maintained no written protocols detailing the procedures to be followed to conduct the reviews.
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:
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that 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 laboratory personnel interview and toxicology confirmation testing instrument validation record review on November 27, 2018, the laboratory director failed to ensure that verification procedures used to validate toxicology confirmation testing instruments were adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. Findings included: a. In its toxicology section, the laboratory performed patient toxicology confirmation testing using Shimadzu GCMS-QP2010SE gas chromatography - mass spectrometry (GCMS) instruments. The laboratory used eleven different Shimadzu GCMS-QP2010SE instruments to perform various patient toxicology confirmation tests. b. Although the laboratory maintained documentation to indicate that the laboratory had used its verification procedures to validate the accuracy, precision, and other pertinent performance characteristics of the Shimadzu GCMS-QP2010SE instruments, the laboratory maintained no documentation to indicate that the laboratory director had reviewed and approved these verification documents. c. According to laboratory personnel, the laboratory performed approximately 800 various patient toxicology confirmation tests weekly using the Shimadzu GCMS-QP2010SE instruments.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

	This STANDARD is not met as evidenced by: Based on laboratory personnel interview and molecular testing proficiency testing policies and procedures record review on November 26, 2018, the laboratory director failed to ensure that an approved corrective action plan was available to be followed when any proficiency testing results were found to be unacceptable or unsatisfactory. Findings included: a. To meet the CLIA requirement at 42 C.F.R. 493.1236(c), the molecular testing section of the laboratory enrolled in proficiency testing provided by the College of American Pathologists (CAP). b. In the event the laboratory's CAP proficiency testing results were unacceptable or unsatisfactory, the laboratory maintained no written procedures detailing the corrective actions to be taken to investigate the unacceptable or unsatisfactory proficiency testing results.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 laboratory personnel interviews and quality control record reviews on November 26 and 27, 2018, the laboratory director failed to ensure that quality control programs were established and maintained to assure the quality of laboratory services provided and to identify failure in quality as they occur. Findings included: a. The laboratory failed to meet the Condition: Analytic Systems. See D5400. b. The laboratory failed to establish a written procedure manual that included the preparation of quality control materials. See D5403. c. The laboratory failed to ensure that a quality control material used to monitor patient testing was not used when it had exceeded the expiration date. See D5417. d. The laboratory failed to maintain documentation to indicate that the laboratory had performed instrument maintenance as defined by the manufacturer with at least the frequency specified by the manufacturer. See D5429. e. The laboratory failed to establish statistical parameters for unassayed quality control materials over time through concurrent testing of quality control materials having previously determined statistical parameters. See D5469. f. The laboratory failed to ensure that test results of quality control materials met the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. See D5481. g. The laboratory, which performed the same patient tests using different instruments, failed to have a system that twice a year evaluated and defined the relationship between test results using the different instruments. See D5775. h. The laboratory failed to establish comprehensive written procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. See D5791.
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:
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:
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and toxicology policies and procedures record review on November 27, 2018, the laboratory director failed to ensure that an approved comprehensive procedure manual was available to all personnel responsible for any aspect of the testing process. Findings included: The laboratory failed to establish a written procedure manual that included the preparation of quality control materials. See D5403.