Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2063148	06/18/2019
Name of Provider or Supplier	**Street Address, City, State**	
Biogenica Laboratories Llc	241 Molnar Dr Unit A1, Elmwood Park, NJ	

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
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on surveyor observation of the area where Molecular testing was performed and interview with the Technical Consultant (TC), the laboratory failed to have a unidirectional workflow for specimen preparation, reagent preparation, product detection and amplification from August 2017 to the date of the survey. The TC confirmed on 6/18/19 at 10:00 am the laboratory did not have a unidirectional work flow.
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 on surveyor review of Performance Specification (PS) data and interview with the Technical Consultant (TC), the laboratory failed to retain PS work records for the AB Sciex Triple Quad 4500 MD used to perform confirmatory Drug Testing from April 2017 to the date of survey. The TC confirmed on 6/18/19 at 10:15 am that PS analyzer work records were not retained.

D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to evaluate results when they received Not Graded score in Chemistry - Miscellaneous with American Proficiency Institute in the 1st event of 2018 and 2019. The findings include: 1. There was no evaluation documented when the laboratory received "Not Graded" for Opiate sample UDS-02 in 1-2018 and UDS -01 in 2019. 2. There was no documented evidence the laboratory evaluated the failures. 3. This deficiency was cited on the previous survey 7 /7/17. 4. The Plan Of Corrections stated "All proficiency results will be reviewed and signed by director, as well as have corrective action put in place and filed with all CAP documents for responses that are unacceptable" but was not followed. 5. The TP#1 confirmed on 6/18/19 at 10:00 am that the laboratory did not perform and document an evaluation of unacceptable PT results.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR), Procedure Manual (PM) and interview with the Technical Consultant (TC), the laboratory failed to follow the section XVI. Reporting procedure found on page 32 of the PM when reporting Urine Drug Confirmatory tests from April 2017 to the date of survey. The finding includes: 1. Cutoffs values from the PM differed on the FR as below: a. Methamphetamine: PM cutoff: 50 FR cutoff: 200 b. 3,4-Methylenedioxymethamphetamine (MDMA): PM cutoff: 50 FR cutoff:100 c. 3,4-Methylenedioxyamphetamine (MDA) PM cutoff: 50 FR cutoff: 100 d. 3,4-Methylenedioxy-N-ethylamphetamine (MDEA); PM cutoff: 50 FR cutoff: 100 e. Amphetamine; PM cutoff: 50 FR cutoff: 100 2. The TC confirmed on 6/18/19 at 11:00 am that the laboratory did not follow the PM.
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: a. Based on surveyor review of the Procedure Manual (PM) and interview with the Technical Consultant (TC), the laboratory failed to have a procedure to verify new lots of reagents and prepared mobile phases before it was put in use for Urine Toxicology tests from March 2017 to the date of the survey. The TC confirmed on 6 /18/19 at 2:10 pm that laboratory did not have the above procedure. b. Based on surveyor review of the PM and interview with the TC, the laboratory failed to have all applicable procedures for Molecular Tests performed on the Illumina from August 2017 to the date of the survey. The findings include: 1. The laboratory did not have a procedure for: a. Carryover and cross contamination. b. Prevention of contamination, specimen alteration or loss. c. Prevention of contamination while aliquoting. d. Corrective action for failed quality control e. The selection and evaluation of referral laboratory. f. The review of Next Gen Sequencing (NGS) results with confirmatory tests. g. Security parameters h. Records and audit trail maintenance on NGS data base. i. Methods/Reagents used for depletion of host or unwanted nucleic acids j. Criteria for corrective action. k. Process used for classification, interpretation and reporting sequences. l. The course of action to be taken if the test system becomes inoperable. 2. The TC confirmed on 6/18/19 at 2:50 pm that the PM did not have all applicable procedures.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on lack of Performance Specification (PS) records and interview with the Testing Personnel (TP), the laboratory failed to ensure that PS procedures were performed for pH, Creatinine, and Specific Gravity tests performed on AU480 analyzer from August 2017 to the date of survey. The finding includes: 1. There was no documented evidence Accuracy, Precision, and Reference Range validation were performed. 2. This was previously cited on the last survey 7/7/17. 3. The Plan Of Corrections stated "Performance specification documents and validation of accuracy precision and reportable ranges will be printed and signed for all Specimen validity testing" but was not followed. 4. The TP #3 listed on the CMS form 209 confirmed on 6/18/19 at 11:15 am that PS were not performed.

D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specifications (PS) and interview with the Technical Consultant (TC), the laboratory failed to have complete PS for Urine and Oral Fluid Drug tests performed on the AbSciex Triple Quad 4500 MD from April 2017 to the day of the survey. The findings include: 1. A review of the PS reveled the laboratory did not establish performance characteristics as follows: a. A lack of stability study revealed the laboratory did not evaluate sample stability. b. There was no validation performed to establish the expiration date of reagents and working solutions. d. The validation of the hydrolysis control did not include validation of: i. Optimal Enzyme Concentration ii. Temperature of the Heat Block iii. Time on the Heat Block e. The laboratory failed to have acceptable criteria for PS from clinical scientific literature. f. There was no source available for cut off points. g. There was no criteria to review chromatography. h. There was no criteria for manual integration of peaks. i. Verification of manufacturers instructions for Specimen Collection, handling and rejection were not performed. j. The laboratory did not state how carryover was prevented k. Method comparison studies were not evaluated. l. There was no documentation to show interference/matrix effect studies were performed. 2. The TC confirmed on 6/18/19 at 2:20 pm that the LD did not ensure that all PS were established.
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 surveyor review of the Quality Control (QC) procedure and interview with the Technical Consultant (TC), the laboratory failed to ensure that QC procedure for urine toxicology tests performed on the AB Sciex 4500 MD was established with acceptable criteria prior to patient testing from April 2017 to the date of survey. The finding includes: 1. A review of the PS procedures revealed the laboratory acceptance criteria for "Quality Control can be outside of 20%" but based on Clinical Scientific Literature the acceptance criteria for toxicology QC must be 20%. 2. The TC confirmed on 6/18/19 at 1:15 pm that PS were not performed on the drugs listed above.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records, Procedure Manual (PM) and interview with the Technical Consultant (TC), the Laboratory Director (LD), failed to perform Corrective Action (CA) when the laboratory used PS that were outside the established parameters to perform Urine Toxicology tests on the Ab Sciex Triple Quad 4500 MD from April 2017 to the date of survey. The findings include: 1. The laboratory used PS which exceeded linearity as follows: a. Methadone (EEDP): Linearity was established at 39.468 but Limit of Quantification (LOQ) used was 25. b. Impiramine: Linearity was established at 12.060 but LOQ used was 10. c. Lorazepam: Linearity was established at 17.428 but LOQ used was 10. d. 3,4-Methylenedioxyamphetamine (MDA): Linearity was established at 27.63 but LOQ used was 25. e. Meprobamate: Linearity was established at 33.63 but LOQ used was 25. f. Morphine: Linearity was established at 44.462 but LOQ used was 25. g. Trimipramine: Linearity was established at 66.828 but LOQ used was 50. 2. The laboratory used Reference Ranges for cutoff values which did not pass accuracy as follows: a. Methylenedioxypyrovalerone (MDPV): Accuracy was established at 2.0 but LOQ used was 2.5. b. Lorazepam: Accuracy was established at 20 but LOQ used was 10. 3. The TC confirmed on 6/18/19 at 2:30 pm that CA was not taken on PS outside established parameters.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the

	condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Technical Consultant (TC), the laboratory failed to report Urine Drug confirmation test results accurately from April 2017 to the date of survey. The finding includes: 1. The laboratory performed non Food and Drug Administration cleared tests and there was no statement stating the test had not been cleared or approved by the U.S. Food and Drug Administration" on the FR. 2. The TC confirmed on 6/18/19 at 11:45 am that Urine Drug confirmation tests were not reported accurately.
D6074	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5) Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Technical Consultant (TC), the testing personnel failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the AB Sciex Triple Quad 4500 MD and AB Applied Biosystem MD Sciex analyzer from April 2107 to the date of the survey. The TC confirmed on 6/18 /19 at 1:45 pm that there was no documented review of trends and shifts.
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 surveyor review of the laboratory Procedure Manual and interview with the Technical Consultant (TC), the Laboratory Director failed to ensure a Quality Assurance (QA) program was established to assure quality of laboratory services provided from 7/7/17 to the date of the survey. The TC confirmed on 6/18/19 at 1:45 pm that a QA program was not established.