

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D2063148	<b>(X3) Date Survey Completed</b>  07/15/2025
<b>Name of Provider or Supplier</b>  Biogenica Laboratories Llc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5211</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Supervisors (TS), the laboratory failed to evaluate results obtained by the PT provider for Urinary Tract Infection (UTI), Toxicology and Pharmacogenetics (PGX) tests from 1/1/23 to 7/15/25. The findings include: 1. There was no documented evidence coded and ungraded results for the following tests were evaluated by the laboratory: A) UTI: Code 11 for "no appropriate peer group" for all events in 2024 and the 1st event of 2025. B) PGX: Code 26 for "educational challenges" for all events in 2023 and 2024. C) Toxicology: Not graded results for the 2nd event of 2024 and 1st event of 2025. 2. The TS confirmed on 7/15/25 at 1:00 pm, the laboratory did not evaluate coded and ungraded results for PT results obtained from the PT provider.</p>
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Proficiency Testing (PT) records and interview with the Technical Supervisors (TS), the laboratory failed to verify the accuracy and reliability for all analytes for Urinary Tract Infection (UTI),</p>

Wound Pathogen Panel (WPP) and Respiratory Pathogen Panel (RPP) tests performed on the Quantstudio 12 k Flex from 1/1/23 to 7/15/25. The finding includes: 1. Surveyor review of PT records revealed all non-regulated analytes for UTI, WPP and RPP were not included by the PT provider performed in events 2023, 2024 and the 1st event of 2025. 2. The laboratory did not verify the accuracy twice annually on the Quantstudio 12 k Flex analyzer for non-regulated analytes for the following tests: A) WPP: 36 out of 42 analytes were not verified. B) UTI: 3 out of 26 analytes were not verified. C) RPP: 8 out of 28 analytes were not verified. 3. The TS confirmed on 7/15 /25 at 1:10 pm, the laboratory did not verify the accuracy for all non-regulated analytes performed on the Quantstudio 12 k Flex.

**D5291**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual (PM) and interview with the Technical Supervisors (TS), the laboratory failed to establish procedures when the Proficiency Testing (PT) program assigned the laboratory an artificial score of 100% from 1/1/23 to 7/15/25. The finding includes: 1. The laboratory was assigned artificial 100% scores by the PT provider for events performed in 2023, 2024 and the 1st event of 2025 for the specialties of Microbiology, Virology, Mycology, Clinical Cytogenetics and Toxicology. 2. The laboratory lacked a procedure for review of its reported PT results against the PT provider's participant summary results. 3. The TS confirmed on 7/15/25 at 1:35 pm, the laboratory did not establish procedures in the general laboratory systems requirements requirements for review of its reported PT results against the PT provider's participant summary results.

**D5403**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(b)

(b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(14) Description of the course of

action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual (PM) and interview with the Technical Supervisor (TS), the PM lacked all applicable procedures for requirements for patient preparation for urine specimens for Urinary Tract Infection (UTI) tests from 4/30/24 to 7/15/25. The findings include: 1. The PM lacked turn around time (TAT) procedures for urine specimen processing for UTI tests. 2. The PM lacked the storage conditions of urine specimens during transportation to the laboratory. 3. The TS confirmed on 7/15/25 at 1:45 pm, the PM lacked all applicable patient preparation procedures for UTI testing.

**D5423**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**

CFR(s): 493.1253(b)(2)

(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: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(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 Specification (PS) records, Procedure Manual, Culture and Sensitivity Vacutainer Package Insert (CNSVPI), Patient Test Records and interview with the Technical Supervisor, the laboratory failed to ensure that all PS procedures were adequate for the Urinary Tract Infection tests performed on the Quantstudio 12 k flex before reporting patient test results from 5/28/25 to 7/15/25. The findings include: 1. The laboratory received urine specimens in CNS Vacutainer collection kits. The CNSVPI stated the sample stability was 48 hours at room temperature. 2. Patient accession numbers (PAN) 2505134003 and 2505134001 had urine specimens collected on 5/8/25. The laboratory received and tested the samples on 5/13/25. 3. PAN 2505134002 had a urine specimen collected on 5/3/25. The laboratory received and tested the sample on 5/13/25. 4. The laboratory did not perform a stability study for urine samples processed greater than 48 hours after the collection date. 5. The TS confirmed on 7/15/25 at 1:00 pm, the laboratory did not perform a stability study before patient testing.

**D5807**

**TEST REPORT**

CFR(s): 493.1291(d)

(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on the surveyor review of the Test Reports (TR), Procedure Manual (PM) and interview with the Technical Supervisors (TS), the laboratory lacked Reference Intervals (RI) on TR for Urinary Tract Infection (UTI) and Wound Pathogen Panel (WPP) tests from 7/10/25 to 7/15/25. The findings include: 1. UTI and WPP tests did not have RI on 5 out of 5 TR. 2. The TS confirmed on 7/15/25 at 1:45 pm, the laboratory lacked RI on TR.