

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D2217410	<b>(X3) Date Survey Completed</b> 03/07/2023
<b>Name of Provider or Supplier</b> Banj Clinical Laboratory	<b>Street Address, City, State</b> 3624 Mlk Jr Blvd, Lynwood, CA	
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>D2021</b>	<p><b>BACTERIOLOGY</b> CFR(s): 493.823(b)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) records from API, and interview with the laboratory technical consultant on March 7, 2023, at 11:50 am, the laboratory failed to participate in the 3rd PT event of 2022. The findings include: 1. The laboratory participated in the API PT testing program in 2022 for its CT/GC test. However, the laboratory did not participate in the 3rd PT event. The technical consultant said that the laboratory lost the PT sample, probably was stolen. Therefore, the accuracy of the reported results during the 3rd PT event cannot be assured and may harmed patients. 2. The laboratory technical consultant on March 7, 2023, at 11: 50 am, affirmed that the laboratory did not participate in the PT testing for the 3rd event of 2022 and received a "0" score. 3. The laboratory's testing declaration form, signed by the laboratory director on 3/6/2023 stated that the laboratory performs approximately 7,200 tests, annually.</p>
<b>D5300</b>	<p><b>PREANALYTIC SYSTEMS</b> CFR(s): 493.1240</p>

Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on Surveyor review of laboratory's policy & procedure, patients' test records, and interview with the laboratory technical consultant and testing person on March 7, 2023, at 11:30 am, it was determined that the laboratory did not meet the requirement under 493.1241, 493.1242 and 493.1249 to fulfil the preanalytic systems condition. The laboratory's failure to meet the condition may have potential to harm and affect patient care. The findings include: 1. The laboratory failed to have a written or electronic request for patient testing from an authorized person, see D5301. 2. The laboratory failed to follow specimen rejection policy and procedure, see D5311. 3. The laboratory failed to perform preanalytic systems quality assessment, see D5391. 3. The laboratory's testing declaration form, signed by the laboratory director on 3/6/2023 stated that the laboratory performs approximately 7,200 tests, annually.

**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 Surveyor review of laboratory's patients test records, and interview with the laboratory technical consultant and testing person on March 7, 2023, at 11:30 am, the laboratory failed to have test request from an authorized person. The findings include: 1. The laboratory performed CT/GC molecular tests on urine samples with the GeneExpert instrument. It received the samples without any test request from an authorized person. The technical consultant informed that the lab received samples from their own clinic located at a different location. However, no test request documents were available. Therefore, it cannot be assured that an authorized person is requesting the test. 2. The laboratory technical consultant on March 7, 2023, at 11:30 am, affirmed that the laboratory did not have any test request documents. 3. The laboratory's testing declaration form, signed by the laboratory director on 3/6/2023 stated that the laboratory performs approximately 7,200 tests, annually.

**D5311**

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL  
CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:  
Based on Surveyor review of laboratory's policy & procedure, and interview with the laboratory technical consultant and testing person on March 7, 2023, at 11:20 am, the laboratory failed to follow specimen rejection policy. The findings include: 1. The laboratory received urine sample for CT/GC test and rejected the sample. The testing person said that he rejected the sample due to low volume. However, it did not keep any documentation of the rejected sample and the corrective action taken. Therefore, patient care may have been affected negatively. 2. The laboratory technical consultant and testing person on March 7, 2023, at 11:20 am, affirmed that the laboratory did not document the rejected sample. 3. The laboratory's testing declaration form, signed by the laboratory director on 3/6/2023 stated that the laboratory performs approximately 7,200 tests, annually.

**D5391**

**PREANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:  
Based on Surveyor review of laboratory's policy & procedure, patients' test records, and interview with the laboratory technical consultant and testing person on March 7, 2023, at 11:40 am, the laboratory failed to establish and follow written policies and procedure to assess quality of its preanalytical systems. The findings include: 1. The laboratory did not have a system in place to identify problems in the preanalytical system such as test request and sample rejection. When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. This correction process involves identification and resolution of the problem, and development of policies that will prevent recurrence. Therefore, the quality of the service provided by the laboratory may be impaired and may have affected patient care adversely. 2. The laboratory technical consultant on March 7, 2023, at 11:40 am, affirmed that the laboratory did not establish and follow preanalytic systems quality assessment policy and procedure. 3. The laboratory's testing declaration form, signed by the laboratory director on 3/6/2023 stated that the laboratory performs approximately 7,200 tests, annually.

**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 Surveyor review of laboratory's test validation records and interview with the laboratory technical consultant and testing person on March 7, 2023, at 12:00 pm, it was determined that the laboratory did not meet the requirement under 493.1253 to

fulfil the analytic systems condition. The laboratory's failure to meet the condition may have potential to harm and affect patient care negatively. The findings include: 1. The laboratory failed to verify the CT/GC test performance specifications, see D5421. 2. The laboratory's testing declaration form, signed by the laboratory director on 3/6/2023 stated that the laboratory performs approximately 7,200 tests, annually.

**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 Surveyor review of laboratory's test verification records and interview with the laboratory technical consultant and testing person on March 7, 2023, at 12:00 pm, the laboratory failed to verify the CT/GC test performance specifications. The findings include: 1. The laboratory performed CT/GC molecular tests on urine samples with the GeneExpert instrument. This is an FDA approved test so; the laboratory must verify the accuracy and precision before reporting any patient's result. Therefore, the validity of the test results rendered by the laboratory cannot be assured and might have harmed patients. 2. The laboratory technical consultant on March 7, 2023, at 12:00 pm, affirmed that the laboratory did not have any test verification documents. 3. The laboratory's testing declaration form, signed by the laboratory director on 3/6/2023 stated that the laboratory performs approximately 7,200 tests, annually.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:  
Based on Surveyor review of laboratory's policy & procedure, test verification records, proficiency testing results and patient test records and interview with the laboratory technical consultant and testing person on March 7, 2023, at 12:00 pm, and the severity and the number of deficiencies found and cited herein, it was determined that the laboratory director failed to provide effective direction over the operation of the laboratory, hence the Condition: Laboratories performing high complexity testing; laboratory director was not met. The laboratory director's failure to provide direction over the laboratory operation has a consequence of potential erroneous test result reporting and patient harm. The findings include: 1. The laboratory director failed to assure compliance with the applicable regulations. (See D6004) 2. The laboratory director failed to ensure that the test verification was performed accordingly. (See D6013) 3. The laboratory director failed to ensure that the proficiency testing samples

are tested as required. (See D6016) 4. The laboratory director failed to ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided. (See D6021)

**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 Surveyor review of laboratory's policy & procedure, test records and interview with the laboratory technical consultant and testing person on March 7, 2023, at 12:00 pm, the laboratory director failed to assure laboratory's compliance with the applicable regulations and potentially harmed patients. The findings include: See D2021, D5300 and D5400.

**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 Surveyor review of laboratory's CT/GC test verification records and interview with the laboratory technical consultant and testing person on March 7, 2023, at 12:00 pm, the laboratory director failed to ensure that the CT/GC test verification was performed before reporting patients results. The findings include: See D5421.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(i)

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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

	<p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing records, and interview with the laboratory technical consultant on March 7, 2023, at 11:50 am, the laboratory director failed to ensure that the proficiency testing samples were tested accordingly. The findings include: See D2021.</p>
<p><b>D6021</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy &amp; procedure, patient testing records, and interview with the laboratory technical consultant and testing person on March 7, 2023, at 11:40 am, the laboratory director failed to ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided. The findings include: See D5391.</p>
<p><b>D6040</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(2)</p> <p>The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's test verification records and interview with the laboratory technical consultant on March 7, 2023, at 12:00 pm, the laboratory technical consultant failed to verify the accuracy and precision of the CT/GC test. The findings include: The laboratory performed CT/GC molecular tests on urine samples with the GeneExpert instrument. This is an FDA approved test so; the laboratory must verify the accuracy and precision before reporting any patient's result. Therefore, the validity of the test results rendered by the laboratory cannot be assured and might have harmed patients. See D5421</p>