Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2182047	06/04/2024
Name of Provider or Supplier	**Street Address, City, State**	
Brio Clinical Inc	1910 S Archibald Ave, Ste U, Ontario, 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**
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on surveyors' review of laboratory's proficiency testing (PT) results from the American Proficiency Institute (API) and interviews with the technical supervisor (TS) and laboratory manager (LM) on June 4, 2024, at approximately 1:30 p. m., the laboratory failed to attain at least 80% score in the proficiency testing program for the virology molecular diagnostic test, immunology and routine chemistry. The findings include: 1. The laboratory participated in the API PT testing program for the subspecialty of Immunology. A. The API reported the following results for the following events: second event of 2021 (Q2-2021), first event of 2022 (Q1-2022), third event of 2022 (Q3-2022) and third event of 2023 (Q3-2023) for anti-HIV analyte

	resulting in an unsuccessful participation. Therefore, the accuracy of the patients' test results rendered by the laboratory during that time cannot be assured. Event Score Q2-2021 60% Q1-2022 0% Q3-2022 0% Q3-2023 60% B. The API reported for Syphilis Serology for first and third events of 2022: 0% score. C. The API reported for RA/RF for first and third events of 2022: 0% score. D. The API reported for Hepatitis surface antigen (HBsAg) and Hepatitis B core antibody (anti-HBc) for first and third events of 2022: 0% score. E. The API reported for Total Bilirubin and Uric Acid for second and third event of 2022: 0% score. 2. The TC and LM affirmed on June 4, 2024, at approximately 1:30 p.m. that the laboratory failed to achieve satisfactory performance for all analytes mentioned in statement #1. 3. Based on the laboratory's testing declaration form signed by the laboratory director on June 4, 2024, the laboratory performed and reported approximately 57,351 diagnostic tests, including virology molecular diagnostic, immunology, and routine chemistry.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) test result records, interviews with the technical supervisor (TS) and laboratory manager (LM), and review of thirty (30) randomly chosen patients records; it was determined that the laboratory failed to attain at least 80% of acceptable score in routine chemistry for the following analytes: Chloride, Creatinine, Glucose, Iron, LDH, Magnesium, Potassium, Sodium, Total Protein, Triglyceride and BUN tests for the third event of 2022 (Q3-2022). The findings include: 1. Based on review of PT records for Q3-2022, API reported an unsatisfactory score as follow: a. 0% = Chloride, Creatinine, Glucose, Magnesium, Sodium, Total Protein, Triglyceride and BUN b. 60% = Iron, LDH and Potassium 2. At the day of the survey (June 4, 2024), the submitted laboratory testing declaration stated that the laboratory analyzed and reported approximately 27,000 routine chemistry tests including Chloride, Creatinine, Glucose, Iron, LDH, Magnesium, Potassium, Sodium, Total Protein, Triglyceride and BUN tests during the time the laboratory had unsatisfactory proficiency testing results. 4. The TS and LM affirmed on June 4, 2024, at approximately 1:30 p.m. that the laboratory received the above unsatisfactory proficiency testing scores.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of policies and procedures for coagulation, thirty (30) randomly chosen patients reports, and interview with the technical supervisor (TS), laboratory manager (LM), and testing personnel (TPs); it was determined that for the current prothrombin time (PT) reagent lot number in-use the laboratory failed to follow

	manufacturer's instructions for the calculation for International Normalized Ratio (INR). The findings included: 1. The laboratory performed PT on the Coagulation Instrumentation Laboratory equipment CS-2500. No documentation was found in neither the system or paperwork for the calculation of the INR. 2. On the day of the survey 6/4/2024 at approximately 3:00 p.m. TS, LM, and TP affirmed that laboratory failed to verify the accuracy of the INR calculation. 3. Based on the laboratory's annual testing declaration submitted on 6/4/2024, the laboratory analyzed and reported approximately 7,200 hematology test results including coagulation.
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 the lack of a complete laboratory verification of performance specifications for chemistry, coagulation, and microbiology and interviews with the technical supervisor (TS), testing personnel (TP) and laboratory manager (LM) on June 4, 2024, the laboratory failed to demonstrate an established performance specifications documentation comparable to those established by the manufacturer. The findings included: 1. Based on review of documentation for verification procedure for chemistry, coagulation, and microbiology, it was found that it was incomplete. Performance specifications for accuracy and precision for the Attelica instrument in chemistry, CS-2500 for coagulation and MALDI-TOF for microbiology were not performed. 2. The TS, TP and LM affirmed at the time of the survey on June 4, 2024, at approximately 11:45 a. m. that the testing and documentation for verification provided at the time of the survey were performed by the manufacturer. 3. Based on the estimated tests volumes reported on June 4, 2024; the laboratory performed and reported approximately 36,600 tests annually for chemistry, coagulation, and microbiology.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's quality control records and

	interviews with the technical supervisor (TS) and testing personnel (TP); it was determined that the laboratory failed to perform control procedures using the number and frequency specified by the manufacturer to support control procedures for all microbiology media used in the laboratory. Findings included: 1. The laboratory used various culture media to test patient samples. For example, blood agar, MacConkey, chocolate agar, etc. 2. At the time of the laboratory tour on 6/4/2024 at approximately 5:00 p.m., the TP failed to present documentation for quality control for all media used in the microbiology section. 3. The TS and TP affirmed that the laboratory had not used QC organisms to check the culture media capability to support growth as recommended by the manufacturer. 4. Based on the laboratory testing declaration submitted at the time of the survey, the laboratory cultured and reported approximately 2,400 bacteriology tests annually.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the lack of quality control (QC) documentation, observation of culture media used in the bacteriology section and interview with the technical supervisor (TS) and testing personnel (TP); it was determined that the laboratory failed to perform QC testing on all culture media. The findings included: 1. The laboratory did not check of sterility, ability to support growth, physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer of all the media used for cultures. 2. The laboratory must document all control procedures performed. 3. Based on the laboratory's annual declaration submitted at the time of the survey (June 4, 2024), the laboratory analyzed and reported 2,400 bacteriology cultures which results cannot be assured. 4. The TS and TP confirmed on June 4, 2024, at approximately 5:00 p.m. that the laboratory failed to perform and document; check of sterility, ability to support growth, physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer of all the media used for cultures.
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 the deficiencies found during an onsite survey on June 4, 2024, and the severity of the cited deficiencies, it was determined that the laboratory director failed to provide overall management and direction on the preanalytical, analytical and post-

	analytical phases of laboratory testing. Findings include: 1. The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. See D6082. 2. The laboratory director must ensure that performance specifications for verification (accuracy and precision) for test and instruments used for clinical diagnosis are performed by the laboratory personnel. See D6086. 3. The laboratory director must ensure that testing personnel perform quality control for all media used in bacteriology and properly document for INR calculations for prothrombin time. See D6087.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on the surveyors' tour of the laboratory, review of the laboratory's records, review of thirty randomly selected patient test results, and interviews with the laboratory's technical supervisor and testing personnel on June 4, 2024; it was determined that the laboratory director is cited herein due to failure to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of the laboratory testing were monitored. See D2087, D5411, D5421, D5445 and D5477.
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 the surveyors' review of the laboratory's policies & procedures, performance specifications verification records, and interviews with the laboratory's technical supervisor, laboratory manager and testing personnel on June 4, 2024; the laboratory director failed to perform verification of accuracy and precision performance characteristic for instruments in chemistry, coagulation, and microbiology. Findings include See D5421.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on interviews with the technical supervisor, laboratory manager, and testing

	personnel, review of microbiology quality control, INR calculations documentation, and policies and procedures records on June 4, 2024; the laboratory director failed to ensure that laboratory personnel are properly trained and competent when performing the test methods as required for accurate and reliable results. See D5411, D5445, and D5477.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on surveyors' review of laboratory's policy and procedure, verification records, and interviews with the laboratory technical supervisor, laboratory manager and testing personnel on June 4, 2024, the laboratory technical is herein cited for failure of having a complete performance specification established for Atellica for chemistry, CS-2500 for coagulation and MALDI-TOF for microbiology testing and documentation for INR performance. See D5411 and D5421.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on the findings and deficiency cited, the Technical Supervisor is herein cited for deficient practice in establishing a quality control program appropriate for bacteriology assays requiring culture of the specimen. See D5445.