Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 29D2258284	**(X3) Date Survey Completed** 08/22/2024
Name of Provider or Supplier Brio Clinical Inc	**Street Address, City, State** 4528 W Craig Rd, Ste 110, N Las Vegas, NV	
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**
D0000	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on August 22, 2024. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the laboratory 2023 and 2024 American Proficiency Institute (API) Proficiency Testing (PT) records, and an interview with the technical consultant and the laboratory manager, the laboratory failed to ensure that the analysts performing the testing signed the attestations. Findings include: 1. A review of the 2023 API PT Hematology/Coagulation test event three records revealed that the testing personnel who performed the testing for the event did not sign the attestation. 2. A review of the 2024 API PT Immunology/Immunohematology test event one records revealed that the testing personnel who performed the testing for the event did not sign the attestation. 3. The findings were confirmed during an interview with the technical consultant and the laboratory manager conducted on August 23, 2024 at approximately 2:30 PM. The laboratory performs approximately 1,000 hematology tests and 1,300 diagnostic immunology tests annually.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)

	The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of the laboratory 2023 and 2024 American Proficiency Institute (API) Proficiency Testing (PT) records, and an interview with the technical consultant and the laboratory manager, the laboratory failed to ensure that the results that were not graded by the proficiency testing agency were evaluated and documented. Findings include: 1. A review of the 2023 API PT Immunology/Immunohematology test event one revealed that there was no documentation of evaluation for the ungraded results for the Herpes Simplex Virus (HSV) 1/2. 2. A review of the 2023 API PT Hematology/Coagulation test event two revealed that that there was no documentation of evaluation for the ungraded results for the educational blood cell identification samples. 3. A review of the 2023 API PT Hematology/Coagulation test event three revealed that there was no documentation of evaluation for the ungraded results for the educational blood cell identification samples. The laboratory reported a result of 2% for "Lymphocyte, reactive." The expected result stated to see the data summary. The data summary was not available at the time of the survey to evaluate consensus with other laboratories. The laboratory reported a result of 2% for "Neutrophil, seg or band." The expected result was listed as 12-38%. For sample ECI-15, the laboratory reported a result of "Plasma cell." The expected result stated, "See commentary." The commentary was not available at the time of the survey to evaluate the reported result. 4. A review of the 2023 API PT Immunology/Immunohematology test event three revealed that there was no documentation of evaluation for the ungraded result for the C-Reactive Protein (CRP) sample CRP-05. 5. The findings were confirmed during an interview with the technical consultant and the laboratory manager conducted on August 23, 2024 at approximately 2:45 PM. The laboratory performs approximately 1,300 diagnostic immunology tests and 1,000 hematology tests annually.
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 a review of the manufacturer's package insert, observation of the Sysmex CS-2500 programming for the INR calculation, and an interview with the Technical Consultant and the Laboratory Manager, the laboratory failed to ensure that the ISI was updated in the instrument when the current lot number of Dade Innovin reagent was placed in use for the Prothrombin Time (Protime) test. Findings include: 1. A review of the Dade Innovin package insert revealed that the ISI value for lot number 564603 for use on the Sysmex CS-2500 coagulation instrument was 1.08. 2. Observation of the current programming in the Sysmex CS-2500 analyzer revealed

	that the ISI in the instrument was 1.03. 3. The findings were confirmed during an interview with the General Supervisor numbers one and two conducted on August 22, 2024 at approximately 2:15 PM. The laboratory performs approximately 1,000 hematology tests annually.