| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 29D2258284 | 07/07/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Brio Clinical Inc | 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 |
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| **D0000** | This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on July 7, 2026. The findings and conclusions of any investigation by the Division of Healthcare Purchasing and Compliance 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. |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records for the second test event in 2024, two test events in 2025 and the first event in 2026 Chemistry-Miscellaneous test events, and an interview with the laboratory supervisor, the laboratory failed to verify the accuracy of the plasma ammonia (NH3) test for one of one 2024 PT reviewed. Findings include: 1. A review of the American Proficiency Institute (API) Proficiency Testing (PT) Chemistry-Miscellaneous records for the 2024 test event two revealed that the laboratory failed to verify the accuracy of the plasma ammonia test for the one of one 2024 test event reviewed. The laboratory obtained a score of 67% on the 2024 Chemistry-Miscellaneous test event two for ammonia. Only two events are included each year in the enrollment for the Chemistry-Miscellaneous proficiency testing program. 2. There were no records of alternative testing done to verify the accuracy of ammonia after the failure of event 2 in 2024. 3. The findings were confirmed during an interview with the laboratory supervisor conducted on July 7, 2026 at approximately 11:00 AM. According to the submitted CMS-116 form, the laboratory performs 52,500 chemistry tests annually. |

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| **D5291** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the director approved proficiency testing procedure, a review of the 2024 American Proficiency Institute (API) Proficiency Testing (PT) Chemistry-Miscellaneous test event two, and an interview with the laboratory supervisor the laboratory failed to ensure that the proficiency testing procedure was adequate to ensure that verification of accuracy was performed and documented two of two times annually for those tests that are enrolled in only two test events per year. Findings include: 1. A review of the director approved proficiency testing procedure showed that there were no instructions for an alternative verification of accuracy in the event of a failure for those tests in which only two test events per year are obtained from the external proficiency testing company. 2. A review of the American Proficiency Institute (API) Proficiency Testing (PT) Chemistry-Miscellaneous records for October 2024 revealed that the laboratory failed to verify the accuracy of the ammonia test two of two times during 2024. The laboratory obtained a score of 67% on the 2024 Chemistry-Miscellaneous test event two for ammonia. 3. There was no record of alternative testing done to verify the accuracy of ammonia after the failure of event 2 in 2024. 4. The findings were confirmed during an interview with the laboratory supervisor conducted on July 7, 2026 at approximately 11:00 AM. According to the submitted CMS-116 form, the laboratory performs 52,500 chemistry tests annually. |
| **D5807** | TEST REPORT<br>CFR(s): 493.1291(d)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a random patient audit of seven patients tested between the dates of November 20, 2024 and April 2, 2026, and an interview with the laboratory supervisor, the laboratory failed to ensure that the Estimated Glomerular Filtration Rate (EGFR) was calculated using the race neutral equation for four of five patient records that included the EGFR result on the report. Findings include: 1. A random patient audit of seven patients tested between the dates of November 20, 2024 and April 2, 2026 revealed that four of five patient reports that included the Estimated Glomerular Filtration Rate (EGFR) patient values on the report were not calculated using the race neutral equation. The dates of the the reports reviewed were February 17, 2025, July 7, 2025, October 28, 2025 and April 3, 2026. 2. The finding was confirmed during an interview with the laboratory supervisor conducted on July 7, 2026 at approximately 9:45 AM. According to the provided CMS-116 form, the laboratory performs 52,500 chemistry tests annually. |
| **D5891** | POSTANALYTIC SYSTEMS QUALITY ASSESSMENT |

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| | CFR(s): 493.1299(a)<br><br>(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 postanalytic systems specified in 493.1291.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the director approved laboratory procedures, and an interview with the laboratory supervisor, the laboratory failed to establish a policy and procedure to periodically test 11 of 11 calculated results performed by the either the Atellica Data Manager (ADM) or the laboratory information system (LIS), a procedure to verify the results sent via interfaced systems, and patient specific data for the LIS and there was no documentation of periodic checks of the ADM or the LIS system. Findings include: 1. There was no established policy and procedure to test the Atellica Data Manager (ADM) to ensure that the two of two calculated results were accurate and reliable. The results calculated by the ADM were the Estimated Glomerular Filtration Rate (EGFR) and the Free Testosterone (FTES) 2. There was no established policy and procedure to test the Laboratory Information System (LIS) to ensure that the nine of nine calculated results were accurate and reliable. The results calculated by the LIS were the Urine Protein/Creatinine ratio, Urine Albumin /Creatinine ratio, Very Low Density Lipoprotein (VLDL) Cholesterol, Cholesterol /High Density Lipoprotein (HDL) ratio, Blood Urea Nitrogen (BUN)/Creatinine ratio, Anion Gap, Total Globulin, Albumin/Globulin ratio, Indirect Bilirubin. 3. There was no established policy and procedure to test the results sent via interface to the laboratory information system (LIS) from the Sysmex hematology and coagulation instruments and from the Siemens chemistry instruments to ensure that the patient specific data was accurate and reliable. 3. There was no documentation of the Atellica Data Manager (ADM) and laboratory information system (LIS) testing to ensure that results that were calculated, the results sent via interface, and the patient specific data was accurate and reliable. 4. The findings were confirmed during an interview conducted on July 7, 2026 at approximately 2:30 PM. According to the provided CMS-116 form, the laboratory performs 400,000 chemistry tests, 100 diagnostic immunology tests and 5200 hematology tests annually. |