Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D2258284	09/29/2023
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
D0000	This Statement of Deficiencies was generated as a result of the CLIA proficiency testing desk review conducted off-site for your laboratory on 9/29/2023. 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.
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 desk review of federal database CASPER Report 0155D and American Proficiency Institute (API) proficiency testing (PT) evaluation forms on 9/29/2023,

	the laboratory failed to maintain successful participation with the American Proficiency Institute (API) PT program. Findings include: 1. The laboratory failed to achieve an overall satisfactory proficiency testing event performance for two out of three testing events for the analyte partial thromboplastin time (PTT). 2. The laboratory received a score of 0% in the third testing event of 2022 and a score of 60% in the second testing event of 2023, resulting in unsuccessful proficiency testing performance for the analyte PTT. Refer to D2131.
D2131	HEMATOLOGY CFR(s): 493.851(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on desk review of federal database CASPER Report 0155D and American Proficiency Institute (API) proficiency testing (PT) evaluation forms on 9/29/2023, the laboratory failed to successfully participate in a proficiency testing program. Findings include: 1. The laboratory failed to maintain successful participation with the API PT program shown by the unsuccessful performance for partial thromboplastin time (PTT) in the third testing event of 2022 and second testing event of 2023. 2. CASPER Report 0155D and the API PT evaluation both reported a score of 0% in the third testing event of 2022 and a score of 60% in the second testing event of 2023 for the analyte PTT.
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 desk review of federal database CASPER Report 0155D and American Proficiency Institute (API) proficiency testing (PT) evaluation forms on 9/29/2023, the Condition: Laboratories Performing High Complexity Testing: Laboratory Director was not met. The laboratory director failed to provide overall management and direction in accordance with CFR 493.1445. Findings include: The laboratory director failed to ensure that the laboratory successfully participated in a PT program approved by CMS; as described in 42 CFR subpart I for each specialty, subspecialty and analyte or test in which the laboratory is certified under CLIA. Refer to D6089.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by:

	Based on desk review of federal database CASPER Report 0155D and American Proficiency Institute (API) proficiency testing (PT) evaluation forms on 9/29/2023, the laboratory director failed to ensure that the laboratory successfully participated in a proficiency testing program. Findings include: 1. The laboratory failed to maintain successful participation with the API PT program shown by the unsuccessful performance for partial thromboplastin time (PTT) in the third testing event of 2022 and second testing event of 2023. 2. CASPER Report 0155D and the API PT evaluation both reported a score of 0% in the third testing event of 2022 and a score of 60% in the second testing event of 2023 for the analyte PTT.