

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D2258284	(X3) Date Survey Completed 07/14/2023
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 generated as a result of the CLIA proficiency testing desk review, conducted off-site for your laboratory on July 14, 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	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the federal database CASPER Report 0155D on July 14, 2023, the laboratory did not successfully participate in a proficiency testing program. The</p>

	<p>American Proficiency Institute (API) proficiency testing (PT) evaluation forms were requested from the laboratory on July 14, 2023. As of August 15, 2023, these forms were not provided. The laboratory's failure to achieve an overall satisfactory proficiency testing event performance for two consecutive testing events for the first and second testing events of 2023 with a score of 20% in the first event of 2023 and a 0% in the second event of 2023 resulted in unsuccessful proficiency testing performance for the analyte amylase. Findings include: The laboratory failed to maintain successful participation with the API PT program shown by the unsuccessful performance for amylase in the first and second testing events of 2023. Refer to D2096.</p>
<p>D2096</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the federal database CASPER Report 0155D on July 14, 2023, the laboratory did not successfully participate in a proficiency testing program. The American Proficiency Institute (API) proficiency testing (PT) evaluation forms were requested from the laboratory on July 14, 2023. As of August 15, 2023, these forms were not provided. Findings include: 1. The laboratory failed to maintain successful participation with the API PT program shown by the unsuccessful performance for amylase in the first and second testing events of 2023. 2. CASPER Report 0155D reported a score of 20% for the first event and 0% for the second testing event of 2022.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on a desk review of federal database CASPER Reports 0153D and 0155D, 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 of this subpart. Findings include: 1. The laboratory director failed to ensure that the laboratory successfully participated in a PT program, approved by CMS; as described in subpart 1 of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. Refer to D6089. 2. The American Proficiency Institute (API) proficiency testing (PT) evaluation forms were requested from the laboratory on July 14, 2023. As of August 15, 2023, these forms were not provided.</p>
<p>D6089</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i)</p>

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 a desk review of the federal database CASPER Report 0155D on July 14, 2023, the laboratory director failed to ensure that proficiency testing samples were tested as required. The American Proficiency Institute (API) proficiency testing (PT) evaluation forms were requested from the laboratory on July 14, 2023. As of August 15, 2023, these forms were not provided. Findings include: 1. The laboratory failed to achieve satisfactory performance for amylase in the first and second proficiency testing events of 2023, resulting in unsuccessful PT performance. 2. CASPER Report 0155D reviewed reported 20% for the first testing event and 0% for the second testing event of 2023 for amylase.