Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D2102939	11/29/2022
Name of Provider or Supplier	**Street Address, City, State**	
Brio Primary Care	2 Bella Grove Drive, Greenville, SC	

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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on procedure manual review, proficiency testing record review, and testing personnel interview the laboratory failed to test proficiency testing samples in the same manner as patient specimens for 5 of 7 proficiency testing events reviewed from 2020 through 2022 (2020, Event 3, 2021, Events 2 and 3 and 2022, Events 1 and 2). Findings include: 1. The laboratory procedure manual stated that all CBCs with the following critical values should be verified by repeat analysis: a. Hemoglobin (Hgb) less than 7.0 g/dL or greater than 20.0 g/dL b. Hematocrit (Hct) less than 21.0% or greater than 64.0% 2. Review of proficiency testing records revealed the following CBC proficiency results which were reported with no repeat analysis documented: a. 2020, Event 3; specimen Hsy-14; Hgb- 6.4g/dL b. 2021, Event 2; specimen Hsy-08; Hgb- 6.6 g/dL c. 2021, Event 3; specimen Hsy-11; Hgb- 6.5 g/dL d. 2022, Event 1; specimen Hsy-02; Hgb 6.1 g/dL e. 2022, Event 2; specimen Hsy-06; Hgb 6.0 g/dL 3. Testing personnel confirmed during an onsite interview on 11/29/2022 at 3:49pm that the laboratory failed to test the reviewed proficiency testing samples in the same manner as patient specimens.
D5401	PROCEDURE MANUAL

	CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on laboratory procedure manual review, direct observation, and confirmation by the laboratory testing personnel, the laboratory failed to follow their written procedures for patient specimen labeling for 3 of 3 observed specimens. Findings include: 1. The laboratory procedure manual stated that all patient specimens would be labeled with the following information prior to testing; a. Initials of phlebotomist performing collection b. Date and time of collection. 2. During a laboratory walkthrough on 11/29/2022 at 03:33 pm, three patient specimens were observed on the testing rack. The specimens were not labeled with the date or time of collection. 3. Testing personnel confirmed during an onsite interview on 11/29/2022 at 03:49pm, that the laboratory had failed to follow their written procedures for labeling patient specimens prior to testing.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on the Tosoh AIA 900 operators guide, laboratory room humidity record review, and testing personnel interview, it was determined that the laboratory failed to maintain acceptable room humidity levels for a total of 12 days between September 2022 through October 2022. Findings include: 1. Review of the Tosoh AIA 900 operators guide revealed that with each test run, the testing environment humidity should be verified to be between 40 and 80 percent. 2. Review of the laboratory's room humidity records revealed humidity levels were recorded as less than 40% for the following 12 days between September 2022 through October 2022. a. September 2022- 09/27/2022, 09/28/2022, 09/29/2022, 09/30/2022 b. October 2022- 10/05/2022, 10/06/2022, 10/14/2022, 10/18/2022, 10/19/2022, 10/20/2022, 10/21/2022, 10/24 /2022 There was no corrective action for the out of range humidity levels available for review on the day of the survey. 3. Testing personnel confirmed during an onsite interview on 11/29/2022 at 3:49 pm that the documented room humidity levels were outside of the acceptable ranges.