Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0987260	04/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Birmingham Internal Medicine Associates	70 Plaza Drive, Pell City, AL	

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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on a review of the test menu with the Laboratory Manager, record reviews and interviews, the surveyor determined the laboratory failed to report SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronovirus 2) test results for negative Coronovirus Disease 2019 (COVID-19), performed using Abbott ID NOW COVID - rapid antigen testing. The laboratory begin testing for COVID-19 on 11/02/2020 and performed 2230 tests from date of implementation. The laboratory failed to report 1727 negative results for SARS-CoV-2 for the COVID-19 antigen test results to the Alabama Department of Public Health (ADPH); although positive results were reported to the Report Card for (ADPH). Findings include: 1. During the tour of the laboratory at 9:30 AM on April 21, 2021, the laboratory manager stated the laboratory used the rapid antigen testing by Abbott ID Now to perform COVID testing. From the start date of this testing, 11/02/2020, to April 21, 2021, the laboratory staff performed and resulted 2230 total tests, with 1727 of these tests being negative, which were not reported to the State Health Department. These totals were received via fax on 4/28 /2021. 2. At 10:29 AM on April 21, 2021, the Laboratory Manager (LM) stated another employee said the laboratory was not required to report the negative test

	results, only the positives. The surveyor discussed with the LM the separate mechanism, than the REPORT CARD, to ensure all negative test results are reported. During the exit interview, at 4:56 - 5:30 PM, the office staff confirmed the negative COVID results were not reported, and confirmed only positive results were submitted to ADPH via the REPORT CARD. The surveyor discussed the requirement to report positive and negative COVID test results. Note: The Report Card has the following statement "If you are a Laboratorian, reporting on behalf of a laboratory, blood bank, or plasma center, the REPORT Card is not the mechanism you should use to report a patient that has a reportable disease or health condition."
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of the Chemistry calibration verification records (a lack of documentation for 2018 and 2019) and interviews with Testing Personnel (TP) #1, who is also the Laboratory Manager, and the Quality Assurance Manager, the surveyor determined the laboratory failed to perform calibration verifications for Hemoglobin A1c (Hgb A1c), tested on the Tosoh G8, in 2018 and 2019; and failed to perform calibration verifications for analytes tested on the Beckman Coulter AU 680, at least every 6 months, between June, 2018 and June of 2019. This is a repeat deficiency. The findings include: 1. The laboratory failed to provide documentation the staff performed calibration verifications for Hgb A1c, performed on the Tosoh G8, for 2018 and 2019. A routine calibration for this analyte requires only two calibrators, hence, a calibration verification should be performed at least every six months. 2. The laboratory failed to provide documentation the staff performed a calibration verification for Chemistry analytes tested on the AU 680, at a six-months interval between June 25, 2018 and June 3, 2019. The analytes are routinely calibrated using one or two calibrators. 3. In an interview on April 21, 2021 at 3:00 PM, the surveyor requested the calibration verifications for the AU 680 from the laboratory manager and the Tosoh for 2018 and 2019. The laboratory manager believed the records may have been stored in an offsite ware-house. The surveyor discussed the missing records

	with the Laboratory Manager and Quality Assurance Manager, again during the exit interview at 4:56 - 5:30 PM. The records were not provided during the survey, and the surveyor requested the laboratory staff send the records to the State Agency by noon on Friday, April 23, 2021. The records were not received. The cover-sheet of the fax indicated the laboratory staff did not find the calibration records for the Tosoh for 2018 and 2019, and nothing was indicated for the AU 680.