Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0857452	10/20/2020
Name of Provider or Supplier	**Street Address, City, State**	
Alabama Pediatrics	2815 Independence Drive, Birmingham, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the 2018 - 2020 American Proficiency Institute (API) proficiency testing records and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory director and/or testing personnel failed to sign attestation statements for three of nine proficiency testing events reviewed by the surveyor. The findings include: 1. A review of the API proficiency testing records revealed the Laboratory Director failed to sign attestation statements for the following events: Immunology (Mycoplasma) Event #1, 2019; and Microbiology Event #2, 2019. The testing personnel failed to sign the following attestation statements: Immunology (Mycoplasma) Event #1, 2019; Chemistry Event #3, 2018; and Microbiology Event #2, 2019. 2. In an interview on 10/20/2020 at 4:25 PM, TP #1 confirmed the missing signatures of the laboratory director and/or the testing personnel on the above mentioned testing events.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible,

	traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of the 2019 -2020 calibration records for the Medonic Hematology analyzer for Complete Blood Count (CBC) testing, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to perform the calibration at least every six months, between August 2019 and August 2020, and according to the manufacturer's guidelines. This affected one of four possible opportunities to perform the calibration. The findings include: 1. A review of the Medonic Users' Manual revealed the manufacturer recommended the calibration be performed at least every six months. 2. A review of the calibration records for the Medonic revealed the laboratory performed calibrations on 3/01/2019, 8/30/2019 and not again until 8/22/2020, exceeding the six month time frame, recommended by the manufacturer. 3. During an interview on 10/20/2020 at 4:25 PM, TP #1 stated she was not able to find a calibration record for the Medonic for February of 2020, and added she was not aware what happened to the report. When the surveyor asked with what frequency the Medonic should be calibrated, TP #1 stated the laboratory usually calibrated the instrument at least every six months. .
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of Individualized Quality Control Plans (IQCPs) for Mycoplasma, total-Bilirubin (performed on a serum sample on the Piccolo) and throat and urine cultures (Microbiology), a review of quality control records, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to ensure the IQCPs included Quality Assessment (QA) Plans. Additionally, each year from 2018 - 2020, the laboratory started with a new IQCP for each test, neither including a QA plan. This affected 3 of 3 IQCPs developed by the laboratory. The findings include: 1. A review of the IQCP plans for Mycoplasma (discontinued at the beginning of 2020), total-Bilirubin and media for throat and urine cultures, revealed the plans included risk assessments and quality control plans, but no evident quality assessment plans. 2. In an interview on 10/20/2020 at 2:30 PM, the surveyor asked TP #1 to review and explain the plans, as well as indicate the QA plan, a requirement for a complete IQCP. The QA plan should consist of the laboratory's written policies and procedures for monitoring the effectiveness of the IQCPs. TP #1 stated all the plans were done in the same manner, and the last survey (2/07/2018) was the first time one was done and reviewed. 3. During a second interview regarding the IQCPs, on 10/20/2020 at 3:00

	PM, the surveyor asked why there was an IQCP for each test for each year, 2018, 2019 and 2020. The surveyor asked if the plans were established each year. TP #1 stated she was not aware she did not need to establish a plan each year, but confirmed that she did for each year, since the last survey in 2018. The surveyor inquired of the testing frequency of the quality control for total-Bilirubin. TP #1 stated the IQCP indicated the external quality control should be run at least every thirty days. 4. A review of the total-Bilirubin control testing record revealed no quality control testing between July 24, 2019 and September 10, 2019 and between November 25, 2019 and January 27, 2020. During the interview on 10/20/2020 at 3:00 PM, TP #1 reviewed the quality control records and confirmed the laboratory had missed performing the quality control testing at least every thirty days, according to the direction of the QCP (Quality Control Plan). The surveyor explained if the laboratory had established a QA plan to monitor the effectiveness of the IQCP implementation, there would be no need to develop a plan each year; but to revise portions needing revision, based on effective monitoring.