Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0641549	11/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Uab Ob/Gyn Research And Diagnostic Laboratory	618 20th Street South, Ohb 365, 360, & 537, 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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the Policy and Procedures Manuals and an interview with the Technical Consultant, the surveyor determined the laboratory failed to ensure the new Laboratory Director reviewed, approved, signed and dated the procedures for use by the testing personnel. The findings include: 1. A review of the Policy and Procedure manuals revealed no signature and date by the current Laboratory Director. According to the quality assurance records, the new Laboratory Director assumed his responsibilities on 3/26/2018. [The laboratory also filed a Form CMS-116 with the CLIA State Agency for the Change in Director in March 2018.] There was no evidence the procedures had been reviewed and approved by the new Laboratory Director for use by the testing personnel. 2. During a review of the manuals in an interview on 11/28/2018 at 4:45 PM, the Technical Consultant stated the Laboratory Director had signed a letter delegating this responsibility to the "Assistant Laboratory Director" (the Clinical Consultant on Form CMS-116). The surveyor explained this responsibility must be performed by the Laboratory Director and cannot be delegated. Thus, the above noted findings were confirmed. . .
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 reviews of the environmental logs and the Beckman Coulter Access 2 Operator's Manual, and an interview with the Technical Consultant, the laboratory failed to monitor and document room humidity in Room 365, where the Beckman Access 2 analyzer was operated; the laboratory further failed to determine whether analyzers and tests in two other rooms also had environmental operating requirements. The findings include: 1. During the initial tour on 11/28/2018 at 9:00 AM with the Technical Consultant, the surveyor observed the Access 2 Immunoassay Chemistry analyzer was located in Room 365. The laboratory also ran other tests and analyzers in Rooms 360 and 537. 2. A review of the logs revealed only the room temperature for Room 365 was documented. 3. During an interview on 11/28/2018 at 5:00 PM, the Technical Consultant was asked if Humidity was monitored in Room 365 where the Beckman Access 2 analyzer was operated; the Technical Consultant answered, "No, we don't monitor room humidity". 4. As the interview continued, the surveyor and Technical Consultant reviewed the Environment Requirements in the Beckman Coulter Access 2 Operator's Manual on page 2-6 which included the following: "... Humidity: Operational 20% (percent) to 80% Exposure 10-80%...". 5. The surveyor then asked if the laboratory had reviewed the manufacturer's environmental requirements for analyzers and tests in use in Rooms 360 and 537, and whether room temperature and humidity required monitoring to ensure the laboratory was operating within the required parameters. The Technical Consultant stated she was not sure whether room temperature and humidity were being monitored in Rooms 360 and 537 or whether it was required. Thus, the above noted findings were confirmed. .
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 the installation and quality control (QC) records for the Illumigene analyzer (for the detection of Group B streptococcus) and an interview with the Technical Consultant, the surveyor determined the laboratory failed to implement a valid IQCP (Individualized Quality Control Plan) which included an QC plan and Quality Assessment Plan before patient testing began on 10/4/2017. The findings include: 1. A review of the records for the illumipro-10 Illumigene analyzer (for the detection of Group B Strep) revealed the instrument was validated 9/6 thru 10 /3/2017. The previous Laboratory Director had reviewed the data and approved the analyzer for use for patient specimens on 10/4/17. 2. A review of the QC and patient

	worksheets revealed positive and negative QC was performed monthly and with new lot numbers of reagent cartridges. However patient samples were tested three to five times each week on days when QC was not run. 3. During an interview on 11/28/2018 at 4:30 PM, the Technical Consultant was asked if the laboratory had implemented an IQCP to allow for decreased QC testing frequency. The Technical Consultant stated the validation documentation included an IQCP. The surveyor then reviewed the "Validation IQCP", and determined it was not an "IQCP" as per CLIA regulations; it was actually only the method the manufacturer suggested to validate the analyzer. The surveyor explained an IQCP must include a Risk Assessment, a QC Plan, and a QA Plan. 4. As the interview continued the Technical Consultant provided a Risk Assessment, and stated the laboratory always ran QC monthly and with all new lot numbers of reagent cartridges. When asked if the laboratory had their QC and QA Plans in writing for their IQCP with the approval and signature of the Laboratory Director, the Technical Consultant stated they did not. Thus, the above noted findings were confirmed. SURVEYOR: Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor