Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0641549	06/03/2025
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (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 College of American Pathologists (CAP) Proficiency Testing (PT) records, CAP PT Kit Instructions, and an interview with Technical Consultant (TC), the surveyor determined the Laboratory Director (or Designee) failed to sign the Attestation statements for three out of five Microbiology PT events in 2024-2025. The findings include: 1. A review of the 2024-2025 CAP PT records revealed the Laboratory Director (or Designee) did not sign the Attestation statements for the following PT events: A) Viral Markers VM-A 2024 event B) Chlamydia GC HC6-C 2024 event C) Maternal Screenings FP-A 2025 event 2. A further review of the CAP PT Kit Instructions and Result Form Resource revealed the following instructions on page 4; 9. "Attestation Page: The laboratory director or designee and the testing personnel must sign the attestation page included with the kit or print the online result form with attestation page for physical signature". 3. TC confirmed the above findings during the exit conference on 06-03-2025 at 4:00 PM.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based on a review of the College of American Pathologists (CAP) Proficiency Testing (PT) records, and an interview with the Technical Consultant (TC), the laboratory failed to implement a mechanism to verify the accuracy of the Gestational Age US Ultrasound Quant (GAUUQ), a non-regulated analyte. The surveyor noted the PT evaluation failures occurred in two consecutive events for 2024-2025. The findings include: 1. A review of the CAP PT records revealed the GAUUQ PT grade of zero percent for the following events: A) Maternal Screenings FP-C 2024 event B) Maternal Screenings FP-A 2025 event 2. An interview with the TC on 06-03-2025 at approximately 1:43 PM revealed the age information required was not provided during submission. 3. During the exit conference on 06-03-2025 at 4:00 PM, TC confirmed the above findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Based on a review of the Complete Blood Count (CBC) Quality Control (QC) records and an interview with the Technical Consultant (TC), the laboratory had no documentation of a mechanism to monitor for shifts and trends of test performance over time. The surveyor noted 5 of 5 months reviewed in 2025 were missing at the time of the survey. The findings include: 1. A review of the CBC QC records for the Beckman Coulter DxH 520 revealed there was no evidence of Levey Jennings charts or peer group comparison data for January through May of 2025. 2. During the exit conference on 06-03-2025 at 4:00 PM, TC confirmed the above findings.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on reviews of the validation records for the Beckman Coulter (BC) DxH 520 analyzer, the BC Operation Qualification Checklist (OQC), and an interview with Technical Consultant (TC), the Laboratory Director (LD) failed to document and date review and approval of procedures verifying the manufacturer's performance specifications before patient testing began. This was noted from the date of validation on 06-24-2024 to the date of the current survey, 06-03-2025. The findings include: 1. A review of BC DxH 520 validation records and BC OQC revealed no documentation of the LD's review and approval (indicated by signature and date) of the BC DxH 520

	validation studies, which included the following: A) Repeatability (Precision) B) Carryover C) Linearity D) Hematology Method Comparison E) Calibration 2. During the exit conference on 06-03-2025 at 4:00 PM, the TC confirmed the above findings.