Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0920849	05/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Mobile Ob/Gyn Pc	6701 Airport Blvd Ste B-321, Mobile, 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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) (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 a review of the American Proficiency Institute (API) Proficiency Testing (PT) records, and interviews with the Technical Consultant (TC) (also the Testing Personnel 1), the laboratory failed to test PT samples in the same manner as patient samples were tested. The surveyor noted 14 of the 21 PT events were tested in duplicate from 2023-2025. The findings include: 1. A review of the 2023-2025 API PT records revealed the laboratory tested all five of the Routine Chemistry and Hematology PT samples on two different days for the following events: A) 2023 Chemistry Core (Routine Chemistry), First, Second and Third Events B) 2024 Chemistry Core (Routine Chemistry), First, Second and Third Events C) 2025 Chemistry Core (Routine Chemistry), First Event D) 2023 Hematology First, Second and Third Events B) 2024 Hematology First, Second and Third Events C) 2025 Hematology First Event 2. At 10:00 AM on 05-14-2025, the surveyor reviewed the findings and asked how many times patient samples were tested. The TC stated the laboratory has a policy to rerun patient samples with critical results. However, critical patient values were rechecked immediately, not on a different day as the laboratory had retested the PT samples.

D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (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 Procedure (P&P) Manual and interview with the Technical Consultant (TC) (also the Testing Personnel 1), the laboratory failed to provide an updated Complete Blood Count (CBC) procedure after testing began on the Beckman Coulter (BC) DxH 500 analyzer. The surveyor noted no documentation of the new procedure from the start date on 08-09-2024 to the date of the current survey on 05-14-2025. The findings include: 1. A review of the P&P Manual revealed no updated written procedure for CBC testing performed on the BC DxH 500 Hematology analyzer after testing was discontinued on the previous BC AcT Diff analyzer. 2. A further review of the P&P Manual revealed a testing procedure for the BC AcT Diff was still on file but the title, AcT Diff had been crossed out, and DxH 500 was written over it. 3. During the exit conference on 5-14-2025 at 3:00 PM with the TC and Administrator, the TC confirmed the above findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observations during the laboratory tour, a review of the Beckman Coulter (BC) DxH 500 Series Control package insert, and an interview with the Technical Consultant (TC) (also the Testing Personnel 1), the laboratory failed to write the new expiration dates on the CBC QC vials upon opening. The surveyor noted three of three levels of QC currently in use with open dates of "5/12". The findings include: 1. During the laboratory tour on 05-14-2025 at approximately 8:05 AM the surveyor observed the three levels of CBC QC in use were labeled with the date, "5-12", however the testing personnel had not recorded the new expiration date on the vials upon opening. 2. A review of the BC DxH 500 Series Control package insert revealed QC was stable for "16 open vial days". 3. During the exit conference with the TC and Administrator on 05-14-2025 at 3:00 PM, the TC confirmed the above findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by:

	Based on direct observation during the laboratory tour and interviews with the Technical Consultant (TC) (also the Testing Personnel 1) and Testing Personnel 2 (TP2), the laboratory had utilized expired Total Protein reagents for 15 patient tests from 05-12-2025 to the date of the current survey on 05-14-2025. The findings include: 1. During the laboratory tour with the TC and TP2 on 05-14-2025 at approximately 8:24 AM, the surveyor asked if there were any room temperature Chemistry reagents in use. The TC opened the storage area with the Total Protein reagent, Lot F4720, with an Expiration Date of 10-31-2024. 2. In an interview at approximately 8:26 AM on 05-14-2025, the TC and TP2 stated they had not noticed the Total Protein Reagent had expired until the surveyor discovered it on the day of the survey; the laboratory currently did not have any unexpired reagent for patient testing. 3. At approximately 12:42 PM on 05-14-2025, the TC stated the testing history of the analyzer revealed the laboratory started using the expired Total Protein reagent on 05-12-2025, had 92 tests remaining on 05-14-2025, and 15 patient tests performed. The laboratory ordered new Total Protein reagent and stopped testing until the new reagent arrives. 4. During the exit conference with the TC and Administrator on 05-14-2025 at 3:00 PM, the above findings were reviewed and confirmed with the TC.
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 a review of the validation records for the Beckman Coulter (BC) DxH 500 Hematology analyzer, the BC Operation Qualification Checklist, and an interview with Technical Consultant (TC) (also the Testing Personnel 1), 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 08-09-2024 to the date of the current survey, 05-14-2025. The findings include: 1. A review of Hematology analyzer records revealed no documentation of the LD's review and approval (indicated by signature and date) of the BC DxH 500 validation studies, which included the following: A) Repeatability B) Carryover C) Calibration D) Linearity 2. During the exit conference with the TC and Administrator on 05-14-2025 at 3:00 PM, TC confirmed the above findings.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on reviews of personnel records, Beckman Coulter (BC) DxH 500 installation validation studies and an interview with the Technical Consultant (TC) (also the Testing Personnel 1), the Laboratory Director (LD) failed to clearly specify which duties and responsibilities were delegated to the TC. The surveyor noted there was no document written for the Delegation of Authority (DoA) from the date of the last

	survey, 12-22-2022 to the date of the current survey, 05-14-2025. The findings include: 1. A review of personnel records revealed there was no written DoA document for the TC from the LD. 2. A review of the BC DxH 500 install validation studies revealed the R&D DxH 500 Series Linearity Report was signed by the TC 08-09-2024. Per CLIA regulation the LD cannot delegate the responsibility for signing new and revised procedures. 3. During an interview with the TC on 05-14-2025 at approximately 11:00 AM, the TC stated the laboratory had the DoA document and will provide it for review. 4. At the exit conference with the TC and Administrator on 05-15-2025 at 3:00 PM, the surveyor was unable to review the DoA because the TC cannot find the document.