Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0920849	09/12/2018
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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of installation and validation documentation for the BD Max analyzer, and an interview with Technical Consultant (TC) #1, the surveyor determined the laboratory failed to ensure data generated during the initial installation procedures was analyzed and summarized to prove verification of the manufacturer's performance specifications before patient testing began. The findings include: 1. A review of the documentation of the installation procedures for the BD Max analyzer (which uses a CT/GC/TV panel for the qualitative detection of DNA from Chlamydia, Neisseria gonorrhea, and Trichomonas) revealed more than 50 pages of instrument results from quality controls (QC) and patients. Some of the print-outs had hand-written notes, however, there was no documentation of an overall analysis of the data to prove the precision and accuracy of the tests as stated in the manufacturer's performance specifications. 2. During an interview on 9/12/2018 at 11:45 AM, TC #1 was asked when patient testing on the BD Max using the CT/GC/TV panel began. TC #1 checked her records and stated 11/8/2017. When asked about her validation process for the panel, TC #1 explained the lab had run QC for 30 days and performed a comparison of patient results with the BD Affirm and their reference laboratory. Afterwards, she and the Laboratory Director had reviewed the results. When asked if she had summarized their findings, with analysis of the precision and accuracy for

	each of the organisms to prove verification of the manufacturer's performance specifications, TC #1 confirmed she had not done this. Thus the above noted findings were confirmed. .
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of the installation and validation records for the BD Max analyzer, and an interview with Technical Consultant (TC) #1, the surveyor determined the Laboratory Director failed to document his review and approval (as indicated by his signature and date) of the initial procedures verifying the manufacturer's performance specifications before patient testing began. The findings include: 1. A review of the documentation of the installation procedures for the BD Max analyzer (which uses a CT/GC/TV panel for the qualitative detection of DNA from Chlamydia, Neisseria gonorrhea, and Trichomonas) revealed more than 50 pages of instrument results from quality controls (QC) and patients. Some of the print-outs had hand-written notes, however, there was no documentation of an overall analysis of the data to prove the precision and accuracy of the tests, as stated in the manufacturer's performance specifications, or evidence of the Laboratory Director's review and approval of the procedures. 2. During an interview on 9/12/2018 at 11:45 AM, TC #1 stated patient testing on the BD Max using the CT/GC/TV panel began on 11/8/2017. TC #1 further explained she and the Laboratory Director had reviewed the results generated during the validation study, and the Laboratory Director had approved the instrument for use for patient testing. When asked if the Laboratory Director had signed and dated his review and approval, TC #1 confirmed he had not. Thus the above noted findings were confirmed. SURVEYOR: Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor