

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0304961	<b>(X3) Date Survey Completed</b>  12/02/2021
<b>Name of Provider or Supplier</b>  Wiregrass Medical Center	<b>Street Address, City, State</b>  1200 W Maple Ave, Geneva, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5421</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the installation and validation records for the BioFire Film Array Torch analyzer, and interviews with the Technical Consultant and the Laboratory Manager, the laboratory failed to ensure the manufacturer's performance specifications for accuracy and precision were verified, and the Laboratory Director or Technical Consultant's review and approval was documented before patient testing began. This affected one of one new moderate-complexity instruments in the laboratory. The findings include: 1. A review of the records for the Respiratory Panel 2.1 performed on the BioFire Film Array Torch revealed results from four "pooled samples" run by by two testing personnel on 10/22/2020, and on 10/23/2020. The file contained no documentation of what organisms the pooled samples contained, or the expected results. There was no evidence the raw data had been analyzed and evaluated to confirm the accuracy and precision of the test, as stated in the manufacturer's performance specifications. 2. The validation and installation records also failed to include the Laboratory Director's (or the Technical Consultant's) signature and date indicating review and approval of the new procedures before patient testing began. 3. During an interview on 12/2/2021 at 8:30 AM, the Laboratory Manager had no information on the validation of the BioFire, and stated General Supervisor #2 (the assistant Laboratory Manager) had been responsible for the COVID-19 testing. The</p>

surveyor then asked the Technical Consultant if she had reviewed the BioFire validation procedures; the Technical Consultant stated General Supervisor #2 had never provided any of the documentation for review to ensure the laboratory's results verified the accuracy and precision of the Respiratory Panel 2.1, as stated in the manufacturer's performance specifications. When asked if patient tests were performed on the BioFire, the Laboratory Manager checked the records, and confirmed 24 patient tests had been run, beginning in November 2020. SURVEYOR IS #32558 Licensure and Certification Surveyor