

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0641594	(X3) Date Survey Completed 01/06/2022
Name of Provider or Supplier Summerford Health And Rehab	Street Address, City, State 4087 Highway 31 Sw, Falkville, 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	<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 a lack of validation records for the Alere C. Diff (Clostridium difficile) Quik Chek Complete kit, and an interview with the Technical Consultant and the Testing Personnel, the laboratory failed to ensure the manufacturer's performance specifications for accuracy and precision were verified, and the Laboratory Director's review and approval was documented before patient testing began. This affected one of one new moderate-complexity tests. The findings include: 1. During the entrance tour on 1/6/2022 at approximately 9:30 AM, the Technical Consultant stated the laboratory was performing a new test, C. diff using the Alere C. Diff Quik Chek Complete kit. A review of the package insert revealed this is a moderate-complexity test used for the detection of the antigen and toxins A and B produced by Clostridium difficile. 2. During an interview on 1/6/2022 at 10:20 AM, the surveyor requested the records validating the manufacturer's performance specifications for accuracy and precision with the Laboratory Director's review and approval. The Technical Consultant explained the laboratory failed to perform the validation because he thought the kit was a waived test. The surveyor then asked when patient testing began; the Testing Personnel stated "7/11/2019". .</p>
D5449	CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of quality control (QC) records for the Alere C. Diff (Clostridium difficile) Quik Chek Complete kit and an interview with the Technical Consultant and the Testing Personnel, the laboratory failed to perform external QC each day of patient testing in 2019-2021, in the absence of an IQCP (Individualized Quality Control Plan). The findings include: 1. A review of QC records for the Alere C. Diff Quik Chek Complete kit (a moderate-complexity test used for the detection of the antigen and toxins A and B produced by Clostridium difficile) revealed positive and negative QC was performed approximately once a month. 2. During an interview on 1/6/2022 at 1:15 PM, the surveyor asked how often QC was performed; the Testing Personnel stated she performed QC once a month, as per the manufacturer's instructions, if she has a patient. The surveyor then asked if she performed patient testing on other days when external QC was not run; the Testing personnel answered "Yes". 3. As the interview continued at approximately 1:20 PM On 1/6/2022, the surveyor explained whenever the manufacturer's requirements were less stringent than the CLIA requirement of positive/negative QC each day of patient testing, the laboratory had the option of developing and implementing an IQCP. The Technical Consultant confirmed the laboratory had not implemented an IQCP because had thought the kit was a waived test. (Refer to D5421.) The surveyor then asked when patient testing began; the Testing Personnel stated "7/11/2019". SURVEYOR IS #32558 Licensure and Certification Surveyor