Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0641594	03/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Summerford Health And Rehab	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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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 2018-2019 API (American Proficiency Institute) Proficiency Testing records and an interview with the Technical Consultant, the laboratory failed to ensure attestation statements for six of seven surveys were signed by both the Laboratory Director (or his designee) and the Testing Personnel (TP). The findings include: 1. A review of the API Hematology Proficiency Testing (PT) records revealed missing signatures on the attestation statements as follows: A) 2018 Hematology and Chemistry-Event #1: No signature of the Laboratory Director (or his designee) B) 2018 Hematology-Event #2: No signature of the Laboratory Director (or his designee) or the TP C) 2018 Hematology-Event #3: No signature of the Laboratory Director (or his designee) D) 2018 Chemistry-Event #3: No signature of the Laboratory Director (or his designee) or the TP E) 2019 Chemistry-Event #1: No signature of the Laboratory Director (or his designee) 2. During an interview and review of the API records on 3/14/2019 at approximately 10:45 AM, the Technical Consultant reviewed and confirmed the above noted findings. .
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2)

	Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on reviews of the Beckman Coulter AcT diff 2 Hematology analyzer calibration records, and an interview with the Testing Personnel (TP), the surveyor determined the laboratory failed to perform and/or retain documentation for one of two 2018 calibrations, as per laboratory policy. The findings include: 1. A review of the Beckman Coulter AcT diff 2 Hematology analyzer calibration records revealed the following: A) 8/21/2017: Documentation of a valid calibration performed during the period when the previous testing personnel trained the current testing personnel B) February 2018 Hematology records: The manufacturer's assay sheet for the Coulter S-CAL calibrator (Lot number 4735) was in the calibration section, however no other records were available. C) 7/26/2018: Documentation of a valid calibration performed by the current testing personnel 2. During an interview and review of the records on 3/14/2019 at 11:15 AM, the current TP stated she had performed the calibration in February 2018, however she had been unable to locate any of the records except the S-CAL assay sheet. When asked about the required calibration frequency, the TP confirmed the Hematology analyzer should be calibrated every six months, and documentation retained for two years. .
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of personnel listed on Form CMS-209, a review of the personnel files, and an interview with the Technical Consultant, the surveyor determined the Technical Consultant failed to ensure one of one new testing personnel had documentation of an annual competency evaluation in 2018. The findings include: 1. A review of Form CMS-209 revealed one testing personnel (TP #1) who performed Chemistry and Hematology testing five days a week. 2. As the survey continued, the surveyor reviewed the file for TP #1 which included her educational documentation and two competency evaluations performed by the Technical Consultant dated 1/10/2018 and 1/9/2019. A closer review of the 1/10/2018 form revealed this evaluation occurred approximately four months after TP #1's training. 3. During an interview on 3/14/2019 at 10:05 AM, the surveyor explained new testing personnel were required to have two competency evaluations during their first year of performing moderate-complexity patient testing. The 1/10/2018 assessment could be considered the semi-annual evaluation, however there was no record of a second review of TP #1's competency in 2018. The surveyor then asked the Technical Consultant if he had performed a second (annual) competency evaluation for TP #1 in 2018. The Consultant stated he had not; thus the above noted findings were confirmed. .

D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on a review of personnel listed on Form CMS-209, a review of the personnel files, and an interview with the Technical Consultant and the Testing Personnel (TP #1), the surveyor determined the laboratory failed to ensure one of one new testing personnel had documentation of training for moderate complexity testing completed before performing patient testing. The findings include: 1. A review of Form CMS-209 revealed one testing personnel (TP #1) who performed Chemistry and Hematology testing five days a week. [The form also listed TP #2, who had retired in August 2017, and had not worked since that date. TP #2 was deleted from Form-209.] 2. As the survey continued, the surveyor reviewed the file for TP #1 which included her educational documentation and two competency evaluations dated 1/10/2018 and 1 /9/2019. There was no information specifying when employment began, or any documentation of training for TP #1. 3. During an interview on 3/14/2019 at 10:00 AM, the surveyor asked TP #1 when she began working in the laboratory. TP #1 stated 8/17/2017. When asked about her training, TP #1 explained TP #2 had trained her and observed her work for two weeks, and then TP #2 had retired. The surveyor then asked if the training had been documented; the Technical Consultant and TP #1 stated they had not realized this was required, and they did not have these records. Thus the above noted findings were confirmed. SURVEYOR ID#32558 Licensure and Certification Surveyor