Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0665255	(X3) Date Survey Completed 10/04/2018
Name of Provider or Supplier Mizell Memorial Hospital/Respiratory Care Dept	**Street Address, City, State** 702 Main Street, Opp, 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
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 installation and validation documentation for the IL GEM 3500 Arterial Blood Gas analyzer and an interview with Testing Personnel #1 (also the Respiratory Therapy Supervisor), the surveyor determined the Laboratory Director failed to document review and approval of the initial validation procedures as verifying the manufacturer's performance specifications for the analyzer, before patient testing began. The findings include: 1. A review of the installation documentation for the IL GEM 3500 Arterial Blood Gas analyzer revealed no review and approval by the Laboratory Director (as indicated by a signature and date) on the initial verification procedures performed on 1/11/2017. The documentation included only the signature of the Respiratory Therapy Supervisor, dated 1/17/2017. 2. During an interview and review of these records on 10/4/2018 at 12:18 PM, the Supervisor stated the Director may have looked at the validation records, however he did not sign his approval. The surveyor then asked when patient testing began on the new analyzer, and the Supervisor answered it was probably the day the validation was finished (1/11/2017). Thus the above findings were confirmed. SURVEYOR:Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor