Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2199881	09/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Alabama Men's Clinic	1 Independence Plaza, Suite 130, Birmingham, 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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the Procedure Manual for the FastPack System and an interview with Testing Personnel #2, the Laboratory Director failed to document approval of the Procedure Manual before patient testing started March 8, 2021. The findings include: 1. A review of the Procedure Manual for FastPack System revealed no indication of review by evidence of signature. 2. During an interview on 09/23/2021 at 11:45 AM, Testing Personnel #2 confirmed the Laboratory Director had not signed the Procedure Manual for the FastPack System for this location.
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 validation records for the FastPack for Testosterone and Prostate-Specific Antigen (PSA) and an interview with Testing Personnel (TP) #2, the

	surveyor determined the Laboratory Director failed to ensure the validation was reviewed and approved before patient testing started. This was noted for one of one new instruments installed (patient testing started on March 8, 2021). The findings include: 1. A review of the validation records for the FastPack for Testosterone and PSA revealed the validation was performed March 4, 2021; there was no documentation of the Laboratory Director's review and approval. 2. During an interview on 09/23/2021 at 11:10 AM, TP #2 confirmed patient testing started in March of 2021 and the Laboratory Director did not sign the validation as indication of review and approval.