Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0017525	05/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lexington Medical Center	250 Hospital Drive, Lexington, NC	

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
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on interview with the laboratory director 5/15/18 and review of the laboratory's histology procedures 5/15/18 and 5/16/18, the laboratory director failed to ensure that an approved procedure manual was available for all aspects of the testing process. During interview 5/15/18 at approximately 2:00 p.m., the laboratory director acknowledged that the procedure manual is outdated. She stated she has initiated re-writing the manual and has completed some procedures. She stated these newly-written policies and procedures were placed in the front of the procedure manual, but she has not signed off on them. She stated she has not completed the manual revision because of her daily duties as the laboratory director and the laboratory's only on-site pathologist. She stated she has also been responsible for training the cytotechnologist to perform grossing and training one of the phlebotomist to perform other histology duties such as specimen accessioning, staining, and shipping. Review of the histology procedure manual revealed a coversheet in the front of the manual was used to document review by the laboratory director. The last entry, dated 10/21/16, stated "Manual in process of revision due to limited Histology now". The following procedures were in the front of the manual but were not attached and had not been signed and dated by the laboratory director to indicate approval: "Specimen Receipt, Identification, and Rejection" "Specimen and Cassette Labeling" "Specimen Retention and Discard" "Health and Safety" "Add-On Special Procedures" "Slide Send Outs" "Non-Pathologist Grossers" "Surgical Pathology Ordering and Accessioning" "NCBH Pathology Processes".