Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2038664	(X3) Date Survey Completed 11/19/2019
Name of Provider or Supplier East Carolina School Of Dental Medicine	**Street Address, City, State** 1851 Macgregor Downs Road, Greenville, 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
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual, review of laboratory records and interview with laboratory director (LD) 11/19/19, the LD failed to ensure the establishment of quality assessment (QA) programs for the pre-analytical and post-analytical laboratory services provided. Findings: Review of laboratory procedure manual revealed the laboratory did have an analytical QA policy established for the review of laboratory test results. There was no documentation of QA policies or procedures for the pre-analytical, and post-analytical assessment of the laboratory services provided. For example: The laboratory had no QA for pre-analytical assessment. For example: patient identification, or the quality of the slides sent back from the processing laboratory. The laboratory had no QA for post-analytical assessment. For example: the tracking of laboratory specimens sent out for processing, to include whether the specimens sent out for processing were received, if the slides were returned and processed, if a test report was generated and whether the test report was reviewed by the ordering practioner. Interview with LD at approximately 11:30 a.m. confirmed the laboratory had not established pre-analytical and post-analytical QA policies or procedures.