

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2012529	(X3) Date Survey Completed 03/28/2018
Name of Provider or Supplier Wfbh Cfem--Greensboro	Street Address, City, State 3903 North Elm Street, 2nd Floor, Greensboro, 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	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment plan, review of 2016, 2017, and 2018 quality assessment records, and interview with the laboratory director 3/28 /18, the laboratory director failed to ensure that the laboratory's quality assessment program was established and maintained to assure the quality of services. Findings: 1. Review of the laboratory's quality assessment plan revealed it was originally written for the laboratory's sister facility and had not been updated to reflect activities performed at this location. During interview at approximately 1:15 p.m., the laboratory director confirmed that the plan included quality assessment activities not applicable at this location. He stated the sister facility is larger and performs more testing. 2. The quality assessment plan states "QUALITY ASSURANCE INDICATORS: POLICIES 1. Pre-analytical Monitors ... i. Personnel Assessment ... Competency assessment may utilize proficiency testing, QC documentation, blind testing, direct observation, or written test. ... Problems noted during the assessment of personnel, such as unsatisfactory performance appraisal or competency assessment, or failure to remain current in training and/or certification requirements will be documented and a plan of correction implemented. ..." The plan also includes criteria for acceptable interpersonnel quality control (competency) performance. Review of 2016, 2017, and 2018 quality assessment records revealed the 2016 "INTERPERSONNEL QUALITY CONTROL" evaluation was performed in April 2016, and the 2018 evaluation was performed in March 2018. Records for the 2017 "INTERPERSONNEL QUALITY CONTROL" evaluation were not available for review during the survey. There was no documentation of corrective action for the</p>

missed evaluation. During interview at approximately 1:20 p.m., the laboratory director confirmed that the interpersonnel quality control evaluation was not performed during 2017.