

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2083457	(X3) Date Survey Completed 12/19/2019
Name of Provider or Supplier Crossroads Treatment Center Of Greensboro, Pc	Street Address, City, State 2706 North Church Street, 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
D6115	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2)</p> <p>The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.</p> <p>This STANDARD is not met as evidenced by: Based on review of LCMS (liquid chromatography/mass spectrometry) instrument validation records, review of patient test report and telephone interview with TS (technical supervisor) #2 on 12/19/19, the TS failed to ensure performance characteristics were accurately validated for the Shimadzu LCMS analyzer. Findings: Review of validation records for the Shimadzu LCMS analyzer revealed the analyte Naloxone was validated for a cut-off level of 15 nanograms per milliliter (ng/mL) for the determination of a positive or negative result. Review of patient test report, # CTG2249M, revealed the laboratory cutoff for Naloxone was reported out as either negative or positive with a 75 ng/mL cut-off level. During telephone interview at approximately 10:50 a.m., TS #2 confirmed the cutoff for Naloxone should be 15 ng/mL and was incorrectly set as 75 ng/mL. She stated it would be rare that any patients tested by the facility would ever test positive for Naloxone, as it is not commonly seen in their patient population.</p>