Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D1017083	05/27/2021
Name of Provider or Supplier	**Street Address, City, State**	
Lexington/Richland Alcohol & Drug Abuse Council	2711 Colonial Drive, Columbia, SC	

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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on policy and procedure review, lack of documentation, record review and laboratory personnel interview, it was determined that the laboratory failed to complete the performance specifications (accuracy, precision, reportable range) for the One Step Multi-Drug Screen Test Card with Integrated I-cup test prior to patient testing two of four months reviewed (February 2021 through May 2021). Findings include: 1. Policy and procedure manual review on 05/27/2021 revealed that the laboratory consultant is responsible for verification of the test procedures performed and establishment of the laboratory's test performance charactersistics, including the precision and accuracy of each test and test system. 2. During an onsite complaint investigation on 05/27/2021, documentation of performance specifications evaluations (accuracy, precision, reportable range) for the One Step Multi-Drug Screen Test Card with Integrated I-cup was unavailable for review. 3. Patient record review on 05/27/2021 revealed that 203 patients had testing performed with the One Step Multi-Drug Screen Test Card with Integrated I-cup test two of four months reviewed (February 2021 through May 2021). 4. The laboratory manager confirmed during an onsite interview on 05/27/2021 at 02:00 pm patient testing was being performed during

	February 2021 through March 2021 and that performance specifications evaluations (accuracy, precision, reportable range) for the One Step Multi-Drug Screen Test Card had not been performed or documented.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on One Step Multi-Drug Screen Test Card with Integrated I-cup package insert, lack of documentation, and testing personnel interview, it was determined that the laboratory failed to document at least two levels of acceptable quality control before patient testing for 2 of 4 months reviewed (February 2021 through March 2021). Findings include: 1. Review of One Step Multi-Drug Screen Test Card with Integrated I-cup package insert revealed that external positive and negative controls are recommended as part of the test process prior to patient testing. 2. During an onsite complaint investigation on 05/27/2021, documentation of daily external controls was unavailable for review. 3. The laboratory manager confirmed during an onsite interview on 05/27/2021 at 2:00 pm that the laboratory had been performing and reporting the One Step Multi-Drug Screen Test Card with Integrated I-cup test since February 2021 and had failed to perform and document at least two levels of acceptable external quality control before testing 203 patient specimens for 2 of 4 months reviewed (February 2021 through March 2021).