Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D1017083	01/31/2018
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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: During an onsite recertification survey on 01/31/2018, based on lack of documentation and testing personnel interview, the laboratory failed to establish and follow quality assessment policies and procedures to monitor, assess, and correct problems identified with general laboratory systems of urine drug screen analysis testing for 2 of 2 years reviewed (2016 and 2017). Findings include: 1. There was no documented established quality assessment plan to address patient confidentialty, specimen identification and integrity, complaint investigations, communications, personnel competency, or proficiency testing performance available for review on the day of the survey for the years 2016 and 2017. 2. Testing personnel confirmed during an onsite interview on 01/31/2018 at 1:30pm that the laboratory did not have established protocols to evaluate general testing quality of urine drug screen analysis in the laboratory.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step

	performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: During an onsite recertification survey on 01/31/2018, based on lack of documentation, and testing personnel interview, the laboratory failed to define the description of the course of action to take if a test system becomes inoperable for the toxicology system of the laboratory. Findings include: 1. Written procedures regarding the step-by-step description of the course of action to take if a test system becomes inoperable for the urine drug screen test systems were unavailable for review on the day of the survey. 2. Testing personnel confirmed during an onsite interview on 01/31/2018 at 1:30pm that the laboratory had failed to ensure that written procedures regarding the description of the course of action to take if a test system becomes inoperable for the reviewed areas were available.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: During an onsite recertification survey on 01/31/2018, based on lack of documentation and testing personnel interview, the laboratory director failed to specify, in writing, the responsibilities and duties of each consultant and each laboratory personnel, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing. Findings include: 1. Documentation of the responsibilities and duties of each consultant and each laboratory personnel along with which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results was unavailable for review on the day of the survey. 2. Testing personnel and the laboratory director confirmed during an onsite interview on 01/31

	/2018 at 01:30pm that the laboratory director failed to specify, in writing, the responsibilities and duties of each consultant and each laboratory personnel, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: During an onsite recertification survey on 01/31/2018, based on records review (CMS 209), absence of competency evaluation documentation and testing personnel interview, it was determined that the laboratory director/technical consultant failed to document initial competency evaluation prior to patient testing for 1 of 2 testing personnel (employees number 1 through 15 of CMS 209) performing hematology and chemistry testing for 1 of 2 years reviewed (2017). Findings include: 1. The laboratory listed two testing personnel for moderate testing on the CMS 209. 2. On the day of the survey, an initial competency evaluation prior to patient testing for the year 2017 for employee number 3 of the CMS 209 was not available for review. 3. During an onsite interview on 01/31/2018 at 1:30 pm, testing personnel confirmed that the director/technical consultant failed to document initial competency evaluation for 1 of 2 testing personnel.