

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D2266902	(X3) Date Survey Completed 07/01/2024
Name of Provider or Supplier Keystone Substance Abuse Services	Street Address, City, State 1668 Herlong Court, Rock Hill, 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
D0000	An onsite announced CLIA initial certification survey was conducted by the South Carolina Department of Public Health's (SC DPH) Bureau of Healthcare Systems and Services on July 1, 2024, at Keystone Substance Abuse Service's clinical laboratory. The laboratory was found to be out of compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview, the laboratory failed to establish and follow an ongoing process for quality assessment of the laboratory. Findings included: 1. No Quality Assessment plan or procedure available at the time of survey. 2. Interview on July 1, 2024 in the laboratory at 11:30am with the laboratory director (LD), the findings were confirmed.</p>
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p>

	<p>This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview, the laboratory failed to review the effectiveness of quality assessments required. Findings included: 1. No documentation of quality assessment activities was available at the time of survey. 2. In an interview on July 1, 2024 in the laboratory at 11:30 am with the LD, the findings were confirmed.</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview, the laboratory failed to provide a written procedure manual for testing performed. Findings included: 1. No written procedure manual was available at the time of survey. 2. In an interview on July 1, 2024 in the laboratory at 11:30 am with the LD, the findings were confirmed.</p>
<p>D5407</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview, laboratory procedures were not available for review or to be signed off by the laboratory director before use. Findings included: 1. The Siemens Viva-ProE manufacture's Quick Reference Guide was being used as the procedure manual for the toxicology testing. 2. No written procedure manual, to include quality control, quality assessment, proficiency testing, or personnel competency was available at the time of survey. No laboratory director review or signature was available. 3. In an interview on July 1, 2024 in the laboratory at 11:30 am with the LD, the findings were confirmed.</p>
<p>D5413</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p>

This STANDARD is not met as evidenced by:
Based on direct observation and lack of documentation, the laboratory failed to monitor the temperature and humidity of the laboratory environment. Findings included: 1. In a tour of the laboratory on July 1, 2024 at 12:00pm, the surveyor observed that there was no thermometer in the laboratory. 2. No documentation of room temperature or humidity was available for 3 out of 3 years reviewed. 3. In a review of records for 21 out of 21 months revealed lack of documentation for corrective action taken when refrigerator/freezer temperatures were outside their acceptable range. 4. In an interview on July 1, 2024 in the laboratory at 12:00 pm with the LD, the findings were confirmed.

D6010

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(2)

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)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed.

This STANDARD is not met as evidenced by:
Based on direct observation and lack of documentation, the laboratory director failed to ensure the environmental conditions of the laboratory. Findings included: 1. In a tour of the laboratory on July 1, 2024 at 12:00 pm with the LD, the surveyor observed that there was no thermometer present in the laboratory. 2. No documentation was available at the time of the survey of room temperature or humidity being monitored in the laboratory for 21 out of 21 months reviewed. 3. In an interview on July 1, 2024 in the laboratory at 11:30 am with the LD, the findings were confirmed.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:
Based on lack of documentation and staff interview, the laboratory director failed to provide an approved procedure manual for testing performed in the laboratory. Findings included: 1. No written procedure manual was available at the time of survey. 2. In an interview on July 1, 2024 in the laboratory at 12:00 pm with the LD, the findings were confirmed.