

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2078530	(X3) Date Survey Completed 10/10/2019
Name of Provider or Supplier Coastal Southeastern United Care	Street Address, City, State 3640 Express Drive, Shallotte, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2018 and 2019 College of American Pathologists (CAP) proficiency testing (PT) records and interview with general supervisor (GS) 10/10/19, the laboratory failed to ensure attestations were signed as required by the testing personnel (TP) who performed the tests and the laboratory director (LD). Review of 2018 and 2019 CAP PT records revealed TP and LD failed to sign attestations for the following PT events: a. 2018 CAP/American Association of Clinical Chemistry (AACC), Urine Drug Screen (UDS)-B. b. 2018 CAP/AACC, UDS-C. c. 2019 CAP /AACC, UDS-A. d. 2019 CAP/AACC, UDS-B. Interview with GS at approximately 12:00 p.m. confirmed the TP and LD had not signed the attestations for the PT events in which the laboratory participated.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedures and policies, review of 2018 and 2019 staff competency records and interview with GS 10/10/19, the laboratory failed to establish</p>

and follow policies to assess GS competency. Review of laboratory procedures and policies revealed the laboratory failed to establish competency assessment policies for the laboratory responsibilities delegated to the GS. Review of 2018 and 2019 staff competency records revealed no documentation of competency assessments for the GS. Interview with GS at approximately 11:30 a.m. confirmed the laboratory had not established or performed competency assessments for the GS.

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:
Based on review of laboratory procedures, review of laboratory records and TP interview 10/10/19, the laboratory's manuals were not complete and current for the testing performed. Finding: The laboratory procedure manual did not include an instrument calibration procedure to include: a. the frequency that calibrations should be performed; b. the calibration materials to be used; c. the review of the calibration results to determine acceptability; and, d. troubleshooting guidance for calibration failures. Interview with TP at time of survey confirmed the laboratory failed to have an instrument calibration procedure.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:
Based on review of manufacturer's instructions, the absence of documentation and interview with GS 10/10/19, the laboratory failed to follow the manufacturer's instructions to determine the suitability of specimens for testing. Findings: The laboratory uses Thermo Scientific test kits for its urine drug of abuse (DOA) testing.

The test kits used are; a. DRI Opiate Assay; b. DRI Barbiturate Assay; c. DRI Benzodiazepine Assay; d. DRI Cannabinoid Assay; e. DRI Methadone Assay; f. DRI Oxycodone Assay; and , g. DRI Ethyl Glucuronide Assay. The review of each DOA package insert revealed the manufacturer's requirement that each specimen's potential of Hydrogen (pH) be measured to determine its suitability for testing the respective assay. Findings: a. The manufacturer's package inserts for DRI Opiate, DRI Cannabinoid, DRI Barbiturate, DRI Benzodiazepine, DRI Cannabinoid, DRI Methadone, and DRI Oxycodone reads under Specimen Collection and Handling, "... Samples within a pH range of 3 to 11 are suitable for testing with this assay..." b. The manufacturer's package insert for DRI Ethyl Glucuronide reads under Specimen Collection and Handling, "...Samples within a pH range of 4.5 to 11 are suitable for testing with this assay...". During GS interview at 11:30 a.m. it was confirmed that the laboratory was unaware of the manufacturer's requirement that the pH of each specimen be tested to determine its suitability for testing. Because the laboratory was unaware of the manufacture's pH requirement, there were no records of pH data available for review.

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on review of operator's manual for the Thermo-Fisher Indiko Plus chemistry analyzer, review of laboratory records, and interview with GS 10/10/19, the laboratory failed to document corrective action when humidity fell below the required range for the Indiko Plus chemistry analyzer. Review of operator's manual for the Thermo-Fisher Indiko Plus chemistry analyzer revealed operating specifications for humidity to be 40 percent (%) or greater. Review of 2018 and 2019 laboratory humidity records revealed the following days in which humidity was below 40% and no correction action was documented. a. 2018; 1/15, 1/16, 1/17, 1/18, 1/19, 2/1, 3/5, 3/6, 3/8, 3/9, 3/13, 3/14, 3/16, 3/22, 3/23, 3/26, 3/27, 11/29 b. 2019; 1/11, 1/15, 1/16, 1/18, 1/22, 1/23, 1/25, 1/28, 1/29, 1/30, 2/1, 2/5, 2/14, 2/19, 2/20, 2/25, 2/26, 2/27, 3/6, 3/7, 3/18, 3/20, 3/27, 3/28, 4/1. Interview with GS at approximately 12:30 p.m. confirmed the laboratory had not documented corrective action when the humidity was below 40%. The GS presented the surveyor with a letter from Thermo-Fisher, dated March 21, 2016, in which it stated the Indiko Plus chemistry analyzer would operate at humidity specifications as low as 10%. He also confirmed the laboratory had not validated whether the current analyzer in the current facility could operate as required at a humidity level as low as 10%.