

| | | |
|--|---|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 34D2078530 | (X3) Date Survey Completed 04/25/2023 |
| 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 |
|---------------------------|---|
| D5439 | <p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of 2021, 2022 and 2023 Potential of Hydrogen (PH) calibration and quality control (QC) records and interview with general supervisor (GS) 4/25/23, the laboratory failed to perform calibration verifications using minimum, mid-point and maximum values at least every 6 months for the PH testing performed for approximately 28 months.. Findings: Review of laboratory procedure "pH Detect" revealed "...CALIBRATION: The laboratory uses</p> |

both pH 3.0 and pH 11.0 calibrators to generate the calibration curve. Calibration frequency: at least every 7 days". Review of 2021, 2022, and 2023 PH calibration and QC records revealed the laboratory performed 2 point calibrations at least every 7 days and performed 4 levels of QC once a day. Interview with GS at approximately 10:30 a.m. confirmed the laboratory performed 2 point calibrations using calibration reagents with a pH 3.0 and pH 11.0.