

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2086253	(X3) Date Survey Completed 07/12/2023
Name of Provider or Supplier Unc Reach Enhanced Primary Care	Street Address, City, State 401 E Whitaker Mill Rd, Raleigh, 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
D5413	<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> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer package insert, absence of records, interview with the technical consultant (TC #2) 7/12/2023 and email received 7/13/2023 from TC #1, the laboratory failed to monitor and document the room temperature of its Primary Care laboratory since testing began in August 2021, a period of approximately 24 months. Findings: Review of the package insert for the MedTox Profile-V MedTox Scan instrument revealed "Section 6....Reagents and Materials Provided/Storage Conditions...The kit, in its original packaging, should be stored at 2-25 degrees Celsius until the expiration date on the label.". Review of records for documentation of room temperature monitoring of the Primary Care laboratory revealed no documentation. Interview with TC #2 at approximately 1:10 p.m. 7/12/2023 confirmed there was no documentation of room temperatures in the Primary Care laboratory. Email received by TC #1 at approximately 2:16 p.m. 7/13/2023 confirmed the room temperature of the Primary Care laboratory was not monitored or documented since testing began in August of 2021.</p>
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p>

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, review of quality control (QC) records for the MedTox Profile-V MedTox Scan instruments and interview with TC #2 7/12/2023, the laboratory failed to ensure QC was acceptable one of four weeks in June 2023 for the instrument located in the Crisis Assessment laboratory. And failed to ensure QC was acceptable one of four weeks in June 2023 for the instrument located in the Primary Care laboratory. Findings: Review of laboratory's policy "Point of Care Ambulatory Quality Control Program...D. Quality Control Review for Acceptability" revealed "Quality control results will be reviewed for acceptability before reporting patient results....". Review of QC records revealed the following dates in which QC was unacceptable: 1. 6/19/23, the Crisis Assessment laboratory failed to attain an acceptable negative buprenorphine QC result prior to patient testing. 2. 6/26/23, the Primary Care laboratory failed to attain an acceptable positive buprenorphine QC result prior to patient testing. Interview with TC #2 at approximately 11:30 a.m. confirmed the laboratory failed to obtain acceptable QC results prior to patient testing on 6/19/23 and 6/26/23.