

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D1081850	<b>(X3) Date Survey Completed</b>  03/04/2025
<b>Name of Provider or Supplier</b>  Premier Health Center	<b>Street Address, City, State</b>  409 Wake Chapel Road, Fuquay Varina, NC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control (QC) reagent package insert, surveyor observation and interviews with testing personnel (TP) #1 and chief quality officer 03/04/25, the laboratory failed to ensure QC reagents for drug screen testing were not used when they had exceeded their expiration date. Approximately 144 patients were tested from 02/07/25 until 03/04/25 when expired QC was in use. Findings: Review of QC reagent package insert for Carolina Liquid Chemistries Corp UDT Multi-Control revealed "STORAGE AND STABILITY...Store at 2-8 C. Unopened vials are stable until expiration date on label. Once opened, vials of controls are stable for 30 days when stored tightly capped at 2-8 C.". At approximately 12:45 p.m. surveyor observed 4 bottles of Carolina Liquid Chemistries UDT Multi-Control on a shelf in the door of the laboratory refrigerator; Lot #B2411, open date of 01/08/25. 1. 1X CNTL A Level 1 2. 1X CNTL A Level 2 3. 1X CNTL B Level 1 4. 1X CNTL B Level 2 Interview with TP #1 at approximately 12:45 p.m. confirmed the date of 01/08/25 written on the 4 bottles of QC reagent was the date the reagents were opened. They also stated they were unaware the QC reagents expired in 30 days once opened. At approximately 1:15 p.m. the chief quality officer stated approximately 144 patients were tested when QC reagent had exceeded the expiration date.</p>
<b>D6125</b>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v)</p> <p>(b)(8)(v) Assessment of test performance through testing previously analyzed</p>

specimens, internal blind testing samples or external proficiency testing samples; and

This STANDARD is not met as evidenced by:

Based on review of laboratory procedure, 2024 "Competency Assessment - Toxicology Data Analysis and Data Review" testing personnel (TP) competency records and interview with chief quality officer 03/04/25, TS #2 failed to document the assessment of the test performance of 7 of 7 data analysis and data review TP reviewed at time of survey. Findings: Review of laboratory procedure "SYSTEM LEVEL PROCEDURE: Competency" revealed "5.3...Competency testing includes the following six areas of assessment: 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and...". Review of 2024 "Competency Assessment - Toxicology Data Analysis and Data Review" TP competency records revealed a checklist, with 7 tasks. The "tasks" are given a "N" - Does not meet standard and/or expectation; "Y" - Meets standard and/or expectation; or n/a - Not applicable. Review of 8 of 8 TP Task #7 - Blinded Sample Assessment - Data Review revealed a "Y". The assessment failed to include documentation of the results obtained by TP and a comparison of the results obtained from the "Blinded Sample". The assessment also fails to include the expectation or standard that is to be met to determine test performance. Interview with chief quality officer at approximately 11:00 a.m. confirmed the competency assessment records failed to include documentation of the results obtained by TP and the comparison of the results obtained from the blind sample. She also confirmed the assessment records fail to include the expectation or standard that is to be met to determine test performance.