

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D2031046	<b>(X3) Date Survey Completed</b>  07/15/2024
<b>Name of Provider or Supplier</b>  Lebauer Healthcare	<b>Street Address, City, State</b>  520 North Elam Avenue, Greensboro, 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>D6127</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records and interview with TP (testing personnel) #1 on 7/15/24, the TS (technical supervisor) failed to perform and document semiannual competency for 1 of 3 TP (TP #3) during the first year of testing. Review of personnel records revealed TP #3 (hired April 2023) did not have a semiannual competency evaluation during the first year of patient testing. TP #1 had documented an initial competency evaluation for TP #3 in May 2023 after the completion of training, but there was no documentation of a semiannual competency evaluation by the TS (laboratory director). During interview at approximately 11:45 a.m., TP #1 confirmed that TP #3 did not have a semiannual competency evaluation.</p>
<b>D6128</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records and interview with TP #1 on 7/15/24, the TS</p>

failed to perform and document annual competency evaluations for for 2 of 3 TP (TP #1, TP #2) during 2021, 2022, and 2023. Findings: 1. Review of personnel records for TP #1 revealed competency evaluations for 2021, 2022, and 2023 were performed by other testing personnel, not by the TS (laboratory director). 2. Review of personnel records for TP #2 revealed the 2021 competency evaluation was performed by another testing personnel, not by the TS (laboratory director). There was no 2022 competency evaluation available for review. The 2023 competency evaluation was for TP #2's supervisory duties at a sister laboratory and did not include testing personnel duties at this location. It was signed by the laboratory director at the sister laboratory. During interview at approximately 11:45 a.m., TP #1 confirmed that competency evaluations were performed by testing personnel, not by the TS (laboratory director).