

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2060724	(X3) Date Survey Completed 10/01/2025
Name of Provider or Supplier Sbh Diagnostics Inc	Street Address, City, State 4 Strathmore Rd, Natick, MA	
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
D0000	A CLIA recertification survey was conducted for the SBH Diagnostics Inc. laboratory on 10/01/2025 pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D6127	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>(b)(9) 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 record review and interview with the Technical Supervisor (TS) on 10/01/2025, the TS failed to evaluate and document the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tested patient specimens as evidenced by the following: The surveyor asked to review the personnel competency records. The review revealed that a semiannual competency evaluation was not performed and documented for the one new Testing Person (TP) performing high complexity testing. The TS confirmed in an interview on 10/01/2025 at 11:55 AM that the TS failed to perform and document a semiannual competency evaluation for the one new TP in the first year of performing high complexity testing. The laboratory performs 70 Routine Chemistry tests annually.</p>