

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2176360	(X3) Date Survey Completed 03/30/2021
Name of Provider or Supplier Solid Diagnostics, Inc	Street Address, City, State 281 Cambridge St, Burlington, 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	An initial CLIA certification survey was conducted for Solid Diagnostics, Inc. laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate 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 General Supervisor (GS), the Technical Consultant (TC) failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tested patient specimens as evidenced by the following: The surveyor reviewed the personnel competency records for calendar year 2020 on 3/30/2021. The review revealed that semiannual competency evaluations were not performed and documented for one (1) out of the three (3) testing persons (TP) for calendar year 2020. The GS confirmed in an interview on 3/30/2021 at 10:40 A.M. that the TC failed to perform and document semiannual competency evaluations for one of the three TP's. .</p>