

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2126670	(X3) Date Survey Completed 06/09/2022
Name of Provider or Supplier Allcells, Llc	Street Address, City, State 1250 Hancock St, Quincy, 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 AllCells, LLC 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 personnel competency record review and interview with the Technical Consultant (TC) and Quality Manager on 6/09/2022, the 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 asked for the personnel competency records for review. The review revealed that semiannual competency evaluations were not performed and documented for seven (7) out of the nine (9) new testing persons (TP) in their first year of performing moderate complexity testing. The TC and Quality Manager confirmed in an interview on 6/09/2022 at 2:05 PM that the TC failed to perform and document semiannual competency evaluations for seven (7) TP's in their first year of performing moderate complexity testing. The laboratory performs 12,000 CBC's annually.</p>