

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2126670	(X3) Date Survey Completed 10/23/2019
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. .
D2005	<p>ENROLLMENT CFR(s): 493.801(a)(4)</p> <p>Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview the laboratory failed to authorize the proficiency testing (PT) program to release all data to Health and Human Services (HHS) as evidenced by the following: A review of the CMS CLIA Application and Summary report revealed no proficiency testing results for Hematology testing. A review of PT records for second and third events in 2018 and calendar year 2019 revealed that the laboratory's CLIA number was not listed on the American Association of Bioanalysts (AAB) PT reports. The technical consultant confirmed through interview at 10:30 AM on 10/23/19 that the AAB PT reports did not contain the laboratory's CLIA number therefore Hematology PT results were not released to HHS.</p>