

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2181769	(X3) Date Survey Completed 11/03/2023
Name of Provider or Supplier Softcell L-Form Laboratories Llc	Street Address, City, State 453 South 600 East #154, St George, UT	
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
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory record review and interview with the technical supervisor (TS), the laboratory failed to ensure the twice a year evaluation of two Kingfisher Flex Systems, two Ion Chef Instruments, and two Ion GeneStudio S5 Plus Systems that compared the relationship between instruments in 2022 and 2023. The laboratory performed approximately 8,000 molecular tests per year. Findings Include: 1. Laboratory record review failed to produce instrument to instrument comparison for the two KingFisher Flex Systems, two Ion Chef Instruments, and two Ion GeneStudio S5 Plus Systems twice a year in 2022 and 2023. 2. In an interview conducted on 11/03 /2023, at 11:20 AM, the TS confirmed the laboratory has not performed an evaluation that defines the relationship between two KingFisher Flex Systems, two Ion Chef Instruments, and two Ion GeneStudio S5 Plus Systems.</p>