Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2181769	04/24/2025
Name of Provider or Supplier	**Street Address, City, State**	
Softcell L-Form Laboratories Llc	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
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: _ Based on review of the laboratory document "Summary Report for TaqMan Genotyping and TaqMan Copy Number Variation Assays on the QuantStudio 5 Platform on 384 Block" and interview with laboratory staff, the laboratory failed to verify analytical specificity to include interfering substances, reference intervals, and any other performance characteristics required for test performance for the Pharmacogenomic profiling/Express PGx Assay. The laboratory tested approximately 1000 patient samples annually. _ Findings include: 1. Review of the document "Summary Report for TaqMan Genotyping and TaqMan Copy Number Variation Assays on the QuantStudio 5 Platform on 384 Block" (validation summary) failed to find establishment of the performance characteristics of interfering substances and reference intervals for the Pharmacogenomic profiling/Express PGx Assay. 2. Review of the validation summary found that it stated that "assay to assay contamination from neighboring wells" could be a potential source of error for the Express PGx Assay. No establishment of performance characteristics for carryover were found in the validation summary. 3. Interview with the general supervisor on 04/24/2025 at

	approximately 3:30 PM it was discussed that several performance characteristics were not established for the Pharmacogenomic profiling/Express PGx Assay.