Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2011968	04/07/2021
Name of Provider or Supplier	**Street Address, City, State**	
Savida Health Pc	12 Dallaire Ave, Chicopee, 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 Savida Health, PC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform complete validation studies for twelve (12) of twelve (12) unmodified, FDA-cleared, or approved newly implemented test systems, prior to reporting out patient testing results as evidenced by the following: Within run precision: a) A review of validation studies for the Routine Chemistry and Toxicology analytes performed on the Beckman DxC 700 AU chemistry analyzer. revealed that the laboratory failed to include within run precision studies as part of the validation for twelve (12) of the moderate complexity test analytes being performed (creatinine, urinary pH, urine specific gravity, amphetamine, benzodiazepine, buprenorphine, cannabinoid, cocaine metabolite, ethanol, methadone, opiates, and oxycodone). b) The technical supervisor confirmed in an interview on 4/7/21 at 10:33 a.m. that the within run precision studies had not been completed for the 12 moderate complexity analytes. The laboratory performs 1,066,000 Routine Chemistry and Toxicology assays on the analyzer annually. .

D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(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: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to establish performance specifications for one (1) of one (1) newly implemented test systems not subject to FDA clearance as evidenced by the following: Fentanyl Within run precision: a) A review of validation studies for the Routine Chemistry and Toxicology analytes performed on the Beckman DxC 700 AU chemistry analyzer revealed that the laboratory failed to include within run precision studies as part of the validation for one (1) of the high complexity, non FDA categorized, analytes being performed (fentanyl) prior to reporting out patient testing results. b) The technical supervisor confirmed in an interview on 4/7/21 at 10:33 AM that the within run precision studies for fentanyl had not been completed. The laboratory performs 82,000 fentanyl assays annually. Specificity and selectivity: a) A review of validation studies for the Beckman DxC 700 AU revealed that the laboratory failed to address specificity and selectivity as part of the validation for the high complexity, non FDA categorized, fentanyl analyte. b) The technical supervisor confirmed in an interview on 4/7/21 at 10:33 a.m. that specificity and selectivity studies had not been included as part of the validation. The laboratory performs 82, 000 fentanyl assays annually. .