Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2011968	02/08/2019
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. .
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years as evidenced by the following: a) A review of quality control records for calendar year 2017 and 2018 revealed that the lot number and acceptable ranges of past and present quality control material, utilized in Liquid Chromatography-Mass Spectrometry (LC-MS) confirmatory drug testing, was not retained by the laboratory. b) Technical supervisor number 2 confirmed in an interview on 2/8/19 at 10:50 AM that lot numbers and control ranges were not being routinely retained. c) The laboratory performs approximately 753,194 confirmatory drug test utilizing LC-MS annually. .
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions;

	(b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform calibration verifications every six months or, as appropriate, as evidenced by the following: a) A review of quality control records for calendar years 2017 and 2018 was performed. The review revealed that calibration verifications of at least 3 points were not performed once every six months for one (1) of one (1) chemistry analytes requiring calibration verification on the Biolis 24i chemistry analyzer. Six month calibration verifications for urinary creatinine were not available for calendar years 2017 and 2018. b) General supervisor number 1 interviewed on 2/8/19 11:40 AM confirmed that calibration verifications of at least 3 points had not been performed at least once every six months for urinary creatinine. c) The laboratory performs approximately 22,824 urinary creatinines annually. .