Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2278195	10/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
Compass Recovery, Llc	65d Elm Street, Hatfield, 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	An initial CLIA recertification survey was conducted for the Compass Recovery, LLC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Please refer to Conditions of Participation for Clinical Laboratories 42 CFR Part 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 all appropriate validation studies prior to reporting out patient test results as evidenced by the following: Thermo Fisher Indiko Plus: a) A review of validation studies for the Thermo Fisher Indiko Plus chemistry analyzer revealed that there was no documentation of day to day precision studies being performed. b) The laboratory director confirmed in an interview on 10/17/23 at 11:36 AM that day to day precision studies had not been performed on the tests performed on the analyzer prior to testing and reporting out patient test results. The laboratory performs approximately 320,200 routine chemistry, urinalysis and toxicology tests annually. .
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2)

	The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on observation, the laboratory director failed to provide a safe environment in which employees are protected from chemical and biological hazards as evidenced by the following: a) On the day of the survey in the presence of the laboratory consultant, it was observed that there was no permanently mounted eyewash which would provide fifteen minutes of continuously flowing water near the laboratory area. b) The laboratory consultant confirmed in an interview on 10/17/23 at 10:53 AM that there was no permanently mounted eyewash available in the laboratory area.