Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	30D2179715	08/31/2022
Name of Provider or Supplier	**Street Address, City, State**	
Integrative Healthcare Center, The	155 Main Dunstable Rd, Ste 200, Nashua, NH	

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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory's established written policies and procedures for specimen storage and preservation failed to meet manufacturer's requirements. Findings include: 1) Review on 8/31/2022 of the laboratory's procedure manual (version date 10/16/2020) revealed on page 47 of 175 the specimen collection and storage requirements for 6-Acetylmorphine (6-AM), Amphetamine, Benzodiazapine, Buprenorphine, Cocaine, Ecstasy, EDDP, Fentanyl, Opiates, Oxycodone, THC, and Creatinine. Specimen and storage requirements for all analytes were: Room Temperature (RT) storage up to 7 days, Refrigerated (2-8 degrees Celsius) up to 30 days, and frozen thereafter. 2) Review on 8/31/2022 of the package inserts for the toxicology and specimen integrity analytes (listed above) revealed the following storage requirements did not match the laboratory's procedure manual: 6-AM, EDDP, and Fentanyl must be tested immediately or stored refrigerated up to 7 days and frozen thereafter; Buprenorphine must be stored at RT and/or refrigerated for 5 days and frozen thereafter; Oxycodone can be stored at RT and/or refrigerated for 7 days and must be frozen thereafter; Creatinine must be tested immediately or stored refrigerated 1-2 days and frozen thereafter. 3) Interview with Staff C (Technical Consultant) on 8/31/2022 at 9:45 a.m. confirmed the above findings. 4) Review on 8/31/2022 of patient results revealed 73 patients had been tested and reported on 8/29/2022 for the toxicology and routine chemistry tests listed

	above. Further review revealed 68 of 73 patients tested had specimen collection dates of 8/26/2022, and 1 of 73 of these patients had a collection date of 8/24/2022. Test results were reported for 6-AM, EDDP, Fentanyl, and Creatinine for the 69 of 73 patients with collection dates 8/26/2022 and 8/24/2022. 5) Interview on 8/31/2022 at 11:30 a.m. with Staff A (testing personnel) confirmed the above findings and revealed the laboratory did not have a mechanism for monitoring specimen collection dates and ensuring specimen storage requirements had been met prior to and after performing testing. Further interview revealed the practice of performing testing Mondays on samples collected the week prior occurred routinely in 2021 and 2022. 6) The laboratory performs 24,800 6-AM, EDDP, Fentanyl, and Creatinine tests annually.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory (lab) failed to make available to the lab's clients, the lab's policies and procedures pertaining to specimen collection, handling and referral to the laboratory. Findings include: 1) Review on 8/31 /2022 of the lab's procedure titled "Urine Drug Screen Collection" revealed instruction for the collection and handling of urine specimens collected onsite. Policies and procedures for off-site clients collecting urine specimens and referring them to the lab was not available. 2) Interview 8/31/2022 at 11:40 a.m. with Staff B (testing personnel) revealed the laboratory did not have policies and procedures as outlined in 493.1242(a) for clients collecting specimens and referring them to the lab.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish and follow written policies to monitor, assess and correct problems identified with storage and acceptability of specimens used for Toxicology and Routine Chemistry testing in 2021 and 2022. Findings include: 1) The laboratory failed to establish and follow policies and procedures outlining specimen storage requirements followed manufacturer's instructions and failed to reject specimens when manufacturer's instructions for specimen storage requirements are not followed. Refer to D5311.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's

	instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to record temperatures for the refrigerator used to store patient specimens in 2022. Findings include: 1) Observation in the laboratory on 8/31/2022 at 9:40 a.m. revealed a small refrigerator located below the counter. The refrigerator had 1 patient specimen stored inside (collected 8/30/22 at 9:15 a.m.). There was no thermometer in this refrigerator. 2) Interview with Staff A (testing personnel) on 8/31/2022 at 9:40 a.m. confirmed this refrigerator was used to store specimens and revealed the laboratory did not monitor the temperature of this specimen refrigerator. Staff A believed the specimen refrigerator had been in use for a few months.