Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2192364	(X3) Date Survey Completed 11/15/2022
Name of Provider or Supplier Vitality Pain Management Llc Evansville	**Street Address, City, State** 7145 East Virginia Street, Suite 5000a, Evansville, IN	
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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory failed to label two of nine reagent vessels (cuvettes) containing reagents (Buprenorphine and Benzodiazepine) with correct expiration dates and lot numbers used in one of one analyzer (Indiko Plus SN: 864000090635) testing in the specialty of Routine Chemistry and subspecialty of Toxicology. Findings include: 1. On 11/15/2022 at 11:25am, during a tour of the laboratory, SP-2 (testing personnel) was observed using the analyzer: Indiko Plus (SN: 864000090635) for toxicology testing. The analyzer contained two reagent vessels (cuvettes) that were labeled as expired. 2. On 11/15/2022 at 11:29am, Sp-2 (testing personnel) stated the reagent vessels (cuvettes) are reused. SP-2 (testing personnel) acknowledged the reagent vessels (cuvettes) are disposable. 3. On 11/15 /2022 at 11:41am, an opened box of disposable reagent vessels 20ml (cuvettes) was observed in the refrigerator labeled R: 7-9-21 on the box. 4. On 11/25/2022 at 2:30 pm, SP-2 provided boxes of reagents that were currently in use on the Indiko Plus and stored in the refrigerator to indicate the reagents were not expired as labeled on the cuvettes: a) CEDIA Buprenorphine Assay Lot: 74307875, expiration date 6/30/2023. b) DRI benzodiazepine Assay Lot: 74638941, expiration date 8/31/2023. 5. On 11/15 /2022 at 2:38pm, during a second tour of the laboratory, SP-2 (testing personnel) was observed using two cuvettes labeled as expired for reagents Buprenorphine (Bup, Lot # 73926878) with "EXP date 3/3/22" and Benzodiazepine (Lot: 74370994) with "EXP

	date 10-31-22" written on the reagent vessels (cuvettes). These reagent vessels were in use in the Analyzer: Indiko Plus (SN: 864000090635) for toxicology testing. 6. Annual Test Volume for subspecialty for Routine Chemistry is 22,370.