

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0289356	(X3) Date Survey Completed 07/19/2024
Name of Provider or Supplier Adventhealth Lab	Street Address, City, State 13100 Fort King Rd, Dade City, FL	
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 announced CLIA validation survey was conducted at Adventhealth Lab on 07/15/2024-07/17/2024. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and records review, the laboratory failed to follow the manufacturer's instructions and the laboratory's stated performance specifications for Urine Fentanyl from 08/28/2023 to 07/15/2024. Findings Included: During a tour of the laboratory on 7/15/2024 at 2:00 PM an opened bottle of Fentanyl lot #22010106 with expiration date of 2024-04-30 Calibration reagent was observed in reagent refrigerator. Technical Supervisor E (TS #E) and Technical Supervisor C (TS#C) confirmed on 07/15/2024 at 2:25 PM the Fentanyl Calibration reagent lot #22010106 expired on 2024-04-30 had been used to perform Calibration for Fentanyl testing on 06/12/2024 with expired reagent. Review of the manufacturer's instructions for Fentanyl testing stated Calibration was to be performed every 30 days. Review of the laboratory Fentanyl Procedure approved by the Lab Director 08/15/2023 Calibration was to be performed every 30 days and that the Calibration stability was the stated expiration. Review of Calibration log from 08/28/2023 to 07/15/2024 documented Calibration was performed 8/28/2023, 09/29/23 (32 days later), 11/15/2023 (47 days later), 12/16/2023 (31 days later), 12/23/2023 (7 days later), 01/22/2024 (30 days later), 03/19/2024 (57 days later), 04/05/2024 (17 days later), 6/12/2024 (68 days later), and 07/15/2024 (33 days later). TS #E and TS # C both confirmed on 07/15</p>

/2024 at 4:30 PM patient Fentanyl testing had not been performed following the manufacture's instruction and laboratory's procedure for performance specifications regarding the frequency of Calibration and the stability of Calibration reagent.