

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2118858	(X3) Date Survey Completed 10/07/2021
Name of Provider or Supplier Interventional Pain Management Center	Street Address, City, State 3800 E Johnson, Suite E, Jonesboro, AR	
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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Through a review of package instruction for Roche Coaguchek, laboratory patient logs, patient medical records, lack of documentation, as well as interviews with staff, it was determined the laboratory failed to follow manufacturer's instructions when performing the Coaguchek test system for evaluating Prothrombin Test (PT) and International Normalized Ratio (INR). The laboratory performed seventy-four PT /INR tests. Survey Findings Follow: A. A review of Roche Coaguchek package insert revealed the purpose of the test system "The purpose of Coaguchek test system is intended for use by professional healthcare providers for quantitative Prothrombin Time (PT) Testing for monitoring Warfarin therapy." B. A review of laboratory patient logs from March 2020-September 2021 revealed patient #100651, patient #020153, patient #061563, patient #071130, patient #071967, patient #071641, patient #040545, patient #011661, patient #071164 and patient #101848 had PT/INR test performed on the Roche Coaguchek. C. A review of medical records for the patients listed above revealed these patients had the PT/INR test performed on the Roche Coaguchek but were not on Warfarin Therapy. D. In an interview with the Clinic Manager on 10/7/2021 at 11:30, she confirmed the patients were not on Warfarin therapy and the "PT/INR was performed on these patients as part of their Sedation Protocol and that each patient receives a CBC, BMP, PT/INR before their surgical procedure."</p>