

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D1087951	(X3) Date Survey Completed 11/17/2020
Name of Provider or Supplier Omega Interventional Pain Pllc	Street Address, City, State 3838 S 700 E #300a, Salt Lake City, UT	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing records review, lack of documentation, and interview with staff, the laboratory failed to ensure testing personnel sign the proficiency testing attestation statement to affirm proficiency testing was performed in the same manner as patient testing for 9 of 9 testing events reviewed from November 2018 to November 2020. Findings include: 1. Proficiency testing records review lacked the testing personnel's signature attesting they performed proficiency testing in the same manner as they performed patient testing for Immunoassay and gas chromatography /Mass Spectrometry testing for American Proficiency Institute 1st and 2nd events of 2019 and 2020 and the College of American Pathology DMPM A,B, and C of 2019 and events A and B of 2020. 2. In an interview with staff on 11/17/2020 at approximately 1:30 P.M. staff confirmed one staff member typed in the names of all testing personnel performing testing when entering proficiency test results.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p>

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on quality control records review, procedure manual review, and interview with staff, the laboratory failed to ensure quality control (QC) procedures included an approved procedure to alter the quality control mean for tests that exhibited a trend in QC performance for one of eleven test days reviewed (06/08/2020). The laboratory performed approximately 35 drug analyses per patient tested for Gas Chromatography and tandem Mass Spectrometry testing. Findings include: 1. Quality control record review included documentation the laboratory testing staff altered the quality control mean on 06/08/2020 to account for a trend in quality control results for a test run completed on 06/10/2020. 2. In an interview with staff on 11/17/2020 at approximately 1:35 P.M. staff confirmed they did not have an approved procedure to change quality control mean values to ensure trends were evaluated and root caused were verified prior to altering each test's mean.