

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D2143774	(X3) Date Survey Completed 01/06/2020
Name of Provider or Supplier Pain Care Of Oregon, Llc	Street Address, City, State 3555 Lear Way, Medford, OR	
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 interview with the testing personnel, technical supervisor and laboratory director and proficiency testing (PT) record review, the laboratory director or designee and testing personnel failed to sign the attestation statement page provided by American Proficiency Institute (API), the proficiency testing provider. Findings include: 1. The attestation statement page were not signed by the testing personnel and laboratory director or designee for the following testing events. a) 2nd event 2019 Hematology. b) 2nd and 3rd event 2019 Comprehensive Chemistry. c) 2nd and 3rd event 2019 Immunoassay. 2. The Laboratory Director, Technical Supervisor, Testing Personnel and the Chief Operation Officer concurred with these findings 01/06/20 @ 17:00 PM.</p>
D2094	<p>ROUTINE CHEMISTRY CFR(s): 493.841(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons</p>

other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:

Based on interview with the testing personnel, technical supervisor and laboratory director and proficiency testing (PT) record review, the laboratory director or designee and testing personnel failed to document corrective action for unacceptable analyte. Findings include: 1. Review of The American Proficiency Institute (API) second event 2019 for Comprehensive Chemistry revealed one of the five sodium analytes had an unacceptable score. There was no corrective action documented for the unacceptable score. 2. The Laboratory Director, Technical Supervisor, Testing Personnel and the Chief Operation Officer concurred with these findings 01/06/20 @ 17:00 PM.

D2128

HEMATOLOGY

CFR(s): 493.851(e)

(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:

Based on interview with the testing personnel, technical supervisor and laboratory director and proficiency testing (PT) record review, the laboratory director or designee and testing personnel failed to document corrective action for unacceptable analyte. Findings include: 1. Review of The American Proficiency Institute (API) second event 2019 for Hematology revealed one of the five Mean Corpuscular Hemoglobin (MCH) had an unacceptable score. There was no corrective action documented for the unacceptable score. 2. The Laboratory Director, Technical Supervisor, Testing Personnel and the Chief Operation Officer concurred with these findings 01/06/20 @ 17:00 PM

D5403

PROCEDURE MANUAL

CFR(s): 493.1251(b)

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:

Base on review of calibration records and laboratory's procedure manual and interview with the staff , the laboratory failed to perform calibration of the Sysmex XP 300 Hematology Analyzer. Findings include: 1. The hematology procedure manual stated that calibrations for the Sysmex XP 300 Hematology Analyzer will be perform every six months. 2. Review of calibration records revealed that the last calibration for the Sysmex XP 300 Hematology Analyzer was performed 02/21/2019. 3. The Laboratory Director, Technical Supervisor ,Testing Personnel and the Chief Operation Officer concurred with these findings 01/06/20 @ 17:00 PM.

D5407

PROCEDURE MANUAL

CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedure manuals and interview with the staff the Laboratory Director(LD) did not sign and date the procedure manuals used in the laboratory. Findings include: 1. The Procedure Manuals were not signed and dated by the Laboratory Director for the following Procedures. a) Hematology Quality Control Procedure. b) Tosoh Quality Control Procedure. c) Critical Laboratory Values Procedure. 2. The Laboratory Director, Technical Supervisor ,Testing Personnel and the Chief Operation Officer concurred with these findings 01/06/20 @ 17:00 PM.

D5439

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or

replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
Based on review of calibration records and interview with the staff the laboratory failed to perform calibration verification every six months for the Tosoh AIA 900 Chemistry Analyzer. Findings include: 1. Calibration verification every six months were not performed for the following analytes that had less than 3 calibrators. These analytes were Ferritin , Prolactin, Follicle Stimulating Hormone, and Prostate Specific Antigen. The last calibration verification were performed 02/19/2019. 2. The Laboratory Director, Technical Supervisor ,Testing Personnel and the Chief Operation Officer concurred with these findings 01/06/20 @ 17:00 PM.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
Based on interview with staff and review of laboratory's policy and procedures, personnel records, competency records, method validation records, and calibration records, the laboratory director (LD) did not fulfill her responsibilities to provide overall management and direction of the laboratory. Refer to D6079, D6092, D6103, D6106 and D6107.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on review of personnel records and interview with staff, the laboratory director failed to delegate the duties of the General Supervisor or delegate the responsibilities to personnel meeting the qualifications. Findings include. 1. Review of personnel records revealed there was no delegation of a General Supervisor for the laboratory. 2.

	<p>The Laboratory Director, Technical Supervisor ,Testing Personnel and the Chief Operation Officer concurred with these findings 01/06/20 @ 17:00 PM.</p>
<p>D6092</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv)</p> <p>The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.</p> <p>This STANDARD is not met as evidenced by: Based on interview with the testing personnel, technical supervisor and laboratory director and proficiency testing (PT) record review, the laboratory director or designee and testing personnel failed to document corrective action for unacceptable analyte. Findings include: 1. Review of The American Proficiency Institute (API) second event 2019 for Comprehensive Chemistry revealed one of the five sodium analytes had an unacceptable score. There was no corrective action documented for the unacceptable score. 2. Review of The American Proficiency Institute (API) second event 2019 for Hematology revealed one of the five Mean Corpuscular Hemoglobin (MCH) had an unacceptable score. There was no corrective action documented for the unacceptable score. 3. The Laboratory Director, Technical Supervisor ,Testing Personnel and the Chief Operation Officer concurred with these findings 01/06/20 @ 17:00 PM.</p>
<p>D6103</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.</p> <p>This STANDARD is not met as evidenced by: Based on interview with the staff and review of laboratory policies and procedures and competency records the laboratory director failed to ensure that testing personnel were competent to perform testing in all specialties and subspecialties. Findings include: 1. There was no procedure for assessing competency for Testing Personnel. 2. Competency record documents revealed that Testing Personnel were assessed competency for the whole general laboratory process and not for each test system or specialty or subspecialty. 3. The Laboratory Director, Technical Supervisor ,Testing Personnel and the Chief Operation Officer concurred with these findings 01/06/20 @ 17:00 PM.</p>
<p>D6106</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p>

	<p>This STANDARD is not met as evidenced by: Based on interview with the staff and review of the laboratory's procedure manuals, the laboratory director (LD) failed to ensure all procedure manuals available to staff were approved. Findings include: 1. One out of three procedure manuals for the Sysmex XP 300 Hematology test system was not signed and approved by the LD. This procedure was the Hematology Quality Control Procedure. 2. Two out of twenty six procedure manuals for the Tosoh AIA 900 was not signed and approved by the LD. These procedures were the Tosoh Chemistry Quality Control and the Critical Laboratory Values Procedures. 3. The Laboratory Director, Technical Supervisor , Testing Personnel and the Chief Operation Officer concurred with these findings 01/06 /20 @ 17:00 PM.</p>
<p>D6107</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)</p> <p>The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records and laboratory's policies and procedures and interview with the staff , the laboratory director (LD) failed specify in writing or sign off on the delegation of duties and responsibilities of the clinical consultant (CC), general supervisor (GS) and the testing personnel (TP). Findings include: 1. The Clinical Consultant delegation of duties and responsibilities was not signed by the LD. 2. There was no written delegation of duties and responsibilities for a General Supervisor. 3. There was no written delegation of duties and responsibilities for each testing personnel. 4. The Laboratory Director, Technical Supervisor ,Testing Personnel and the Chief Operation Officer concurred with these findings 01/06/20 @ 17:00 PM.</p>
<p>D6108</p>	<p>LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447</p> <p>The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on interview with staff and review of laboratory's policy and procedures, personnel records, competency records, method validation records, and calibration records, the technical supervisor (TS) did not fulfill his responsibilities to provide technical supervision of the laboratory. Refer to D6115 and D6120.</p>
<p>D6115</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2)</p>

The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:

Based on review of validation and installation records and interview with the staff the Technical Supervisor(TS) failed to review and verify the precision and accuracy of the test system. Findings include: 1. Review of the Sysmex XP 300 Hematology Analyzer installation and validation records was reviewed 2/21/2019 by a Testing personnel not qualified to be a TS. 2. The Laboratory Director, Technical Supervisor ,Testing Personnel and the Chief Operation Officer concurred with these findings 01/06/20 @ 17:00 PM.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Base on review of competency records and interview with the staff the Technical Supervisor (TS) failed to assess and document the competency of the testing personnel. Findings include. 1. One out of two testing personnel (TP) had a 6 month and annual competency evaluations dated 06/07/2019 and 12/04/2019 respectively, however, the competency evaluation did not clearly specify what specialty or subspecialty or test system he was evaluated on. 2. The Laboratory Director, Technical Supervisor ,Testing Personnel and the Chief Operation Officer concurred with these findings 01/06/20 @ 17:00 PM.