

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D2147419	(X3) Date Survey Completed 11/05/2018
Name of Provider or Supplier Northwest Medical Diagnostic Laboratory Llc	Street Address, City, State 188 W Northern Lights Blvd, Suite 600, Anchorage, AK	
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	<p>QSO-18-20-CLIA Multiple laboratories may operate at the same physical location (e.g., same building or suite, as applicable) with separate CLIA numbers, as long as each laboratory can demonstrate that it is operating as a separate and distinct entity. In addition, multiple laboratories that operate at the same physical location must meet the following conditions: a) All records (e.g., quality control, procedure manuals, personnel competency) must be kept separate and distinct for each laboratory and must clearly show that each laboratory is operating independently. b) The hours of operation must be specified for each laboratory. c) The hours of operation for each laboratory must be separate and distinct. The times of testing cannot overlap and cannot be simultaneous. Based on surveyor observation, record review and testing person interview, the laboratory did not have separate and distinct documents and records and was performing testing during the same times and at the same location as Interpath Laboratory Anchorage CLIA # 02D2130734. Findings: 1. Two laboratories are operating simultaneously at 188 W Northern Lights Blvd, Suite 600 in Anchorage, AK 99503. 2. The laboratory did not maintain separate temperature and instrument maintenance logs. 3. The testing person's training documents were from other laboratories. 4. The written procedures for Prostate Specific Antigen (PSA), Testosterone, and Thyroid Stimulating Hormone (TSH), were not specific for this laboratory, and included references to an instrument not in use in this laboratory. 6. The laboratory performs approximately 5,000 patient tests annually. 7. The testing person confirmed these findings 11/5/18 at 12:00 pm.</p>
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in</p>

493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on record review and testing person interview, the laboratory did not monitor and evaluate the overall quality of the analytic systems for testing performed by the laboratory. See D5403, D5423, and D5441

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:

Based on review of the laboratory's procedures and testing person interview, the laboratory's procedures did not include test calculations, unacceptable specimen reporting, acceptable elution criteria and accurate step-by-step procedures. Findings: 1. The laboratory is using the Beckman Access 2 Immunoassay Analyzer for Prostate Specific Antigen (PSA), Thyroid Stimulating Hormone (TSH), and Testosterone and the Beckman UA 480 for C-Reactive Protein (CRP). 2. The procedures for CRP, PSA, TSH, and Testosterone do not include the calculation(s) required to convert diluted whole blood results to a serum equivalency. 3. The procedures for CRP, PSA, TSH, and Testosterone do not include how to report unacceptable specimens. 4. The procedures do not include an approved method to determine the adequacy of the patient dried blood spots. a) The procedures state "Observe each specimen to ensure that each specimen has eluted from the filter punches in the surrounding diluent (Usually a properly re-hydrated punch is an off white/light red color). Any specimens containing filter/specimen punches that have dark red areas on the specimen punch should be vortexed at a low speed until the punches are off white/light red to ensure complete specimen re-hydration'. b) There are no analytical criteria on what is an acceptable specimen or elution. 5. The procedures for CRP, PSA and Testosterone do not include specimen stability. 6. The procedures for PSA and Testosterone refer to the Roche Cobas e411 in the Testing Procedure Section, an analyzer not in use at this laboratory. 7. The laboratory performs approximately 5,000 patient tests annually. 8. The testing person confirmed these findings 11/5/18 at 12:00 pm.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on surveyor review of validation documents and testing person interview, the laboratory did not establish the performance specifications for the Beckman AU480 and the Beckman Access chemistry analyzers either for serum or for modified sample types before putting them into use. Findings: 1. There was no initial verification of the C-Reactive Protein (CRP) on the Beckman AU480 analyzer 2. There was no validation of the modified specimen type. The Beckman AU480 chemistry analyzer and CRP reagent are designed to analyze serum for CRP. The laboratory modified the specimen type by: a) using whole-blood spots dried on filter paper and eluted in saline, b) sending dried blood spots through the mail, c) extending the sample stability to 28 days, and d) using a calculation factor to convert the result from the eluate to a serum equivalent. . 3. There was no initial verification of Prostate Specific Antigen (PSA), Thyroid Stimulating Hormone (TSH), and Testosterone on the Beckmann Access analyzer. 4. There was no validation of the modified specimen type for on the Beckman Access analyzer. PSA, Testosterone, and TSH reagents are designed to quantify PSA, Testosterone, and TSH in serum. The laboratory modified the specimen type by: a) using whole-blood spots dried on filter paper and eluted in saline, b) sending dried blood spots through the mail, c) extending the sample stability to 28 days, and d) using a calculation factor to convert the result from the eluate to a serum equivalent. 5. The Testing Person on 11/5/2018 at 12:00 pm confirmed neither the initial verifications nor validations for the modifications were performed at this laboratory prior to testing patient samples. 6. The laboratory performs approximately 5,000 patient tests annually.

D5441

CONTROL PROCEDURES

CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

	<p>This STANDARD is not met as evidenced by: Based on surveyor review of the quality control records and testing person interview, the laboratory did not perform two control materials of different concentrations using the same matrix and sample preparation as patient samples for C-Reactive Protein (CRP), Prostate Specific Antigen (PSA), Thyroid Stimulating Hormone (TSH), and Testosterone. Findings: 1. The laboratory did not use two whole-blood based controls of different concentrations to monitor the entire modified testing process, including the elution of dried whole blood from filter paper into saline and the calculations for converting the initial diluted results back into a serum equivalent. 2. The laboratory performs approximately 5,000 patient tests annually. 3. The testing person confirmed these findings 11/5/18 at 12:00 pm..</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of test validations, procedure manuals, and control records, and lack of records, the laboratory director did not provide overall management and direction for the laboratory. Findings: 1. Failure to ensure tests were verified and modifications were validated prior to testing patients. See D6086 2. Failure to ensure two levels of quality control materials that covered the entire testing process were used. See D6093 3. Failure to ensure written test procedures were complete and accurate. See D6106 Based on the cumulative effective of the above deficiencies, the laboratory director failed to fulfill all the responsibilities of directorship; this constitutes a condition-level deficiency.</p>
<p>D6086</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: Based on review of validation and verification records, the laboratory director failed to ensure that tests were validated as required under subpart K of this part. Finding: The laboratory failed to perform an initial verification and validation of the modifications of whole blood C-Reactive Protein (CRP), Prostate Specific Antigen (PSA), Thyroid Stimulating Hormone (TSH), and Testosterone. See D5423</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p>

This STANDARD is not met as evidenced by:
Based on review of quality control records, the laboratory director failed to ensure that two levels quality control were performed as required under subpart K of this part. Finding: The laboratory failed to perform two levels of a control that covers the whole testing process for C-Reactive Protein (CRP), Prostate Specific Antigen (PSA), Thyroid Stimulating Hormone (TSH), and Testosterone each day of patient testing. See D5441

D6106

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:
Based on review of procedure manuals, the laboratory director did not ensure that complete and accurate procedure manuals were available as required under subpart K of this part. Finding: The procedures for whole blood C-Reactive Protein (CRP), Prostate Specific Antigen (PSA), Thyroid Stimulating Hormone (TSH), and Testosterone were not complete or accurate. See D5403