

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2156467	<b>(X3) Date Survey Completed</b>  08/07/2020
<b>Name of Provider or Supplier</b>  Orlando Physician Network Inc	<b>Street Address, City, State</b>  27637 Us Hwy 27, Leesburg, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<p>An initial survey was conducted on 8/7/20. Florida Heart and Vascular Multispecialty Group PA clinical laboratory was found not in compliance with 42 CFR 493, requirements for clinical laboratories. Based on the survey findings an Immediate Jeopardy situation was identified. The laboratory was notified of the Immediate Jeopardy at 5:20 PM on 8/7/20. The laboratory was unable to provide documentation of the validations of the Abbott i-Stat instrument received by the laboratory on 1/3/20. The laboratory was unable to provide documentation of the calibration of the Abbott i-Stat instrument received by the laboratory on 1/3/20 at least once every 6 months. The laboratory failed to perform quality controls at least daily for patient specimens tested on the Abbott i-Stat instrument from 12/6/19 to 12/20/19 and 1/5/20 to 2/6/20.</p> <p>(D5400) The following Conditions were not met: D5200 - 493.1230 General Laboratory Systems D5400 - 493.1250 Analytic Systems D6000 - 493.1403 Moderate Complexity Laboratory Director D6063 - 493.1421 Testing Personnel Qualifications</p>
<b>D5200</b>	<p><b>GENERAL LABORATORY SYSTEMS</b> CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to monitor and evaluate the overall quality of the general laboratory system and correct identified problems. Findings: Cross Reference D5209: Based on a review of the procedure manual and interview, the laboratory procedure manual failed to establish a procedure to assess the training and competency of 1 of 1 technical consultant and 2 out of 2 testing</p>

	<p>personnel. Cross Reference D5217: Based on record review and interview, the laboratory failed to verify the accuracy of BNP (Brain Natriuretic Peptide) and Troponin at least twice annually in 2020. Cross Reference D5291: Based on a review of the procedure manual and interview, the laboratory failed to establish a quality assessment (QA) procedure for monitoring, assessing and correcting identified problems.</p>
<p><b>D5209</b></p>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the procedure manual and interview, the laboratory procedure manual failed to establish a procedure to assess the training and competency of 1 out of 1 technical consultant and 2 out of 2 testing personnel, (A, B). Findings: Review of the laboratory's procedure manual, signed by the Laboratory Director on 10/1/19, showed that there was no procedure on training and competency. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 8/7/20, the laboratory had an estimated annual test volume of 78 tests per year. The laboratory performed the following tests on the i-Stat: BNP (Brain Natriuretic Peptide) and Troponin. During an interview on 8/7/20 at 4:23 PM, the Laboratory Consultant stated there was no procedure on training and competency</p>
<p><b>D5217</b></p>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to verify the accuracy of BNP (Brain Natriuretic Peptide) and Troponin at least twice annually in 2020. Findings: Review of the American Proficiency Institute (API) proficiency testing (PT) binder showed that there was no record of PT performed on BNP and Troponin. Review of the "Relaymed - Patient Test Report" patient testing for BNP and Troponin started on 12/6/19. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, signed and dated by the Laboratory Director on 8/7/20, the laboratory had an estimated annual test volume of 78 test per year. During an interview on 8/7/20 at 2:30 PM, the Laboratory Consultant stated that the laboratory did not perform any PT for BNP and Troponin.</p>
<p><b>D5291</b></p>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231</p>

through 493.1236.

This STANDARD is not met as evidenced by:

Based on a review of the procedure manual and interview, the laboratory failed to establish a quality assessment (QA) procedure for monitoring, assessing and correcting identified problems. Findings: Review of the laboratory's procedure manual, signed by the Laboratory Director on 10/1/19, showed that there was no procedure on QA. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 8/7/20, the laboratory had an estimated annual test volume of 78 test per year. The laboratory performed the following tests on the i-Stat: BNP (Brain Natriuretic Peptide) and Troponin. During an interview on 8/7/20 at 4:23 PM, the Laboratory Consultant stated there was no procedure on QA.

**D5400**

**ANALYTIC SYSTEMS**

CFR(s): 493.1250

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 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on record review and interview, the laboratory failed to monitor and evaluate the overall quality of the analytic system and correct identified problems. Findings: Cross Reference D5403: Based on record review and interview, the laboratory's written procedure manual was incomplete. Cross Reference D5421: Based on record review and interview, the laboratory was unable to provide documentation of the validations of the Abbott i-Stat instrument received by the laboratory on 1/3/20. Cross Reference D5439: Based on record review and interview, the laboratory was unable to provide documentation of the calibration of the Abbott i-Stat instrument received by the laboratory on 1/3/20 at least once every 6 months. Cross Reference D5447: Based on record review and interview, the laboratory failed to perform quality controls at least daily for patient specimens tested on the Abbott i-Stat instrument from 12/6/19 to 12/20/19 and 1/5/20 to 2/6/20. Cross Reference D5781: Based on record review and interview, the laboratory failed to document corrective action when the refrigerator temperature was out of range on 16 out of 23 days from July 9, 2020 to August 7, 2020.

**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 record review and interview, the laboratory's written procedure manual was incomplete. Findings: Review of the laboratory's procedure manual, signed by the Laboratory Director on 10/1/19, showed the procedure manual did not include a procedure on specimen collection, specimen labeling, specimen processing, the criteria for acceptability and rejection of patient specimens, normal values, quality control, and proficiency testing. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 8/7/20, the laboratory had an estimated annual test volume of 78 test per year. The laboratory performed the following tests on the i-Stat: BNP (Brain Natriuretic Peptide) and Troponin. During an interview on 8/7/20 at 4:23 PM, the Laboratory Consultant stated there was no procedure on the above mentioned.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**

CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory was unable to provide documentation of the validations of the Abbott i-Stat instrument received by the laboratory on 1/3/20. Findings: Review of the laboratory's quality control documentation showed the laboratory did not have documentation available at the time of the survey for the validations on the Abbott i-Stat instrument (serial number 408178), that was received by the laboratory on 1/3/20 to replace the laboratory's i-Stat instrument (serial number 407839) that was not working. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, signed and dated by the Laboratory Director on 8/7/20, the laboratory had an estimated annual test volume of 78 test per year. The laboratory performed the following tests on the i-Stat: BNP (Brain Natriuretic Peptide) and Troponin. During an interview on 8/7/2020 at 11:30 AM, the Executive Manager stated the old i-Stat (serial number 407839) failed on 12/20/19 and they received a new i-Stat. During an interview on 8/7/2020 at 1:20 PM, Testing Personnel B stated they received the new i-Stat on 1/3/20. During an interview on 8/7/2020 at 4:50 PM, the Laboratory

Consultant stated she was unable to get a copy of the validation from the manufacturer on the new i-Stat.

**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 record review and interview, the laboratory was unable to provide documentation of the calibration of the Abbott i-Stat instrument received by the laboratory on 1/3/20 at least once every 6 months. Findings: Review of the laboratory's quality control documentation showed the laboratory did not have documentation available at the time of survey for the calibration on the Abbott i-Stat instrument (serial number 408178) received by the laboratory on 1/3/20. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, signed and dated by the Laboratory Director on 8/7/20, the laboratory had an estimated annual test volume of 78 test per year. The laboratory performed the following tests on the i-Stat: BNP (Brain Natriuretic Peptide) and Troponin. During an interview on 8/7/2020 at 11:30 AM, the Laboratory Consultant stated calibration on the i-Stat was not performed.

**D5447**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(3)(i)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to perform quality

controls at least daily for patient specimens tested on the Abbott i-Stat instrument from 12/6/19 to 12/20/19 and 1/5/20 to 2/6/20. Findings: Review of the "Relaymed - Patient Test Report" patient testing for BNP (Brain Natriuretic Peptide) and Troponin showed that patient test results were reported on 12/6/19 to 12/18/19, and 1/5/20 to 2/6/20. The laboratory used the i-Stat instrument serial number 407839 from 12/6/19 to 12/18/19. No documentation of daily controls were available for review from the i-Stat instrument serial number 407839. The laboratory used the i-Stat instrument serial number 408178 starting 1/4/20. The list of daily controls printed from the i-Stat instrument serial number 408178 on 8/7/20 showed there were not any controls run on the instrument from 1/5/20 to 7/1/20. No patients testing was performed from 2/7/20 to 7/10/20. The following are dates patient testing was performed with no documentation of daily controls available for review: 12/6/19 - 1 test 12/11/19 - 4 tests 12/16/19 - 2 tests 12/17/19 - 1 test 12/18/19 - 2 tests 1/5/20 - 4 tests 1/6/20 - 1 test 1/11/20 - 2 tests 1/14/20 - 3 tests 1/18/20 - 4 tests 1/28/20 - 3 tests 1/29/20 - 2 tests 2/1/20 - 1 test 2/4/20 - 1 test 2/6/20 - 3 tests According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, signed and dated by the Laboratory Director on 8/7/20, the laboratory had an estimated annual test volume of 78 tests per year. During an interview on 8/7/2020 at 11:20 AM, the Laboratory Consultant stated that daily controls were not performed.

**D5781**

**CORRECTIVE ACTIONS**  
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
Based on record review and interview, the laboratory failed to document corrective actions when the refrigerator temperature was out of range on 16 out of 23 days from July 9, 2020 to August 7, 2020. Findings: Review of the test cartridges for BNP (Brain Natriuretic Peptide) and Troponin showed the storage temperature of 2 to 8 degrees C (Celsius). Review of the "i-Stat System QC (Quality Control) Log: Expiration Date and Storage Conditions" log noted the refrigerated temperature range as 2 to 8 degrees C, 35 to 40 degrees F (Fahrenheit). Review of the temperature log showed the refrigerator temperature was out of range for the following days with no documented corrective action performed: 7/9/2020 - 32 degrees F 7/11/2020 - 28 degrees F 7/13/2020 - 34 degrees F 7/14/2020 - 28 degrees F 7/17/2020 - 34 degrees F 7/20/2020 - 32 degrees F 7/21/2020 - 32 degrees F 7/22/2020 - 32 degrees F 7/23/2020 - 32 degrees F 7/24/2020 - 34 degrees F 7/27/2020 - 34 degrees F 7/28/2020 - 32 degrees F 7/29/2020 - 34 degrees F 8/1/2020 - 34 degrees F 8/2/2020 - 34 degrees F 8/6/2020 - 32 degrees F During an interview on 8/7/20 at 10:30 AM, the Laboratory Consultant stated that temperatures were out of range and there was no documentation of corrective action taken.

**D5805**

**TEST REPORT**

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory's final report failed to list the correct name of the laboratory and did not provide the reference ranges (normal values) for BNP (Brain Natriuretic Peptide) and Troponin for 4 out of 4 (#1-#4) patient test reports reviewed. Findings: Review of the final results and patient notes showed the name of the laboratory where testing was performed was incorrect for 4 out of 4 patients (#1 - #4). Review of the final results and patient notes showed the reference range for BNP and Troponin were not listed. During an interview on 8/7 /2020 at 4:53 PM, the Executive Manager stated the name of the laboratory was wrong and the reference ranges were not listed

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review and interview, the Laboratory Director failed to provide overall management and direction of the laboratory. Findings: Cross Reference D6007: Based on record review and interview, the Laboratory Director failed to ensure testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance, including analytic phases of testing. Cross Reference D6021: Based on record review and interview, the Laboratory Director failed to ensure the quality assurance (QA) program was established to assure the quality of laboratory services provided. Cross Reference D6030: Based on record review and staff interview, the Laboratory Director failed to ensure the procedure manual contained all the required procedures. Cross Reference D6032: Based on review of the procedure manual and interview, the Laboratory Directory failed to specify in writing the responsibilities and duties (job descriptions) of the laboratory director, clinical consultant, technical consultant, and testing personnel.

**D6007**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(1)

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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory

director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

Based on record review and interview, the Laboratory Director failed to ensure that testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance, including analytic and postanalytical phases of testing. Findings: The Laboratory Director failed to ensure the laboratory performed and retained documentation of validations of the Abbott i-Stat instrument received by the laboratory on 1/3/20. (See D5421) The Laboratory Director failed to ensure the laboratory performed and retained documentation of the calibration of the Abbott i-Stat instrument received by the laboratory on 1/3/20 at least once every 6 months. (See D5439) The Laboratory Director failed to ensure the laboratory performed quality controls at least daily for patient specimens tested on the Abbott i-Stat instrument from 12/6/19 to 12/20/19 and 1/5/20 to 2/6/20. (See D5447) The Laboratory Director failed to ensure the laboratory performed and retained documentation of corrective actions when the refrigerator temperature was out of range on 15 out of 23 days between July 9, 2020 to August 6, 2020. (See D5781) The Laboratory Director failed to ensure the laboratory's final report listed the correct name of the laboratory and provided the reference ranges (normal values) for BNP (Brain Natriuretic Peptide) and Troponin for 4 out of 4 (#1 -# 4) patient test reports examined. (See D5805)

**D6021**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on record review and interview, the Laboratory Director failed to ensure the quality assurance (QA) program was established to assure the quality of laboratory services provided. Findings: The Laboratory Director failed to ensure the laboratory established a quality assessment (QA) procedure for monitoring, assessing and correcting identified problems. (See 5291)

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(12)

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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) 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;

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the Laboratory Director failed to ensure the procedure manual contained all the required procedures. Findings: The Laboratory Director failed to ensure the laboratory procedure manual established procedures to assess the training and competency of 1 out of 1 technical consultant and 2 out of 2 (A, B) testing personnel. (See D5209) The Laboratory Director failed to ensure the laboratory's written procedure manual was complete. (See D5403)

**D6032**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(14)

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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and 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 results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of the procedure manual and interview, the Laboratory Director failed to specify in writing the responsibilities and duties (job descriptions) of the laboratory director, clinical consultant, technical consultant, and testing personnel. Findings: Review of the laboratory's procedure manual, signed by the Laboratory Director on 10/1/19, showed there was no job descriptions for the Laboratory Director, Clinical Consultant, Technical Consultant, and Testing Personnel. According to the Laboratory Personnel Report, signed and dated by the Laboratory Director on 8/7/20, there was 1 laboratory director, 1 clinical consultant, 1 technical consultant, and 2 testing personnel. During an interview on 8/7/20 at 4:23 PM, the Laboratory Consultant stated there were no job descriptions.

**D6063**

**LABORATORY TESTING PERSONNEL**

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on record review and interview, the laboratory failed to verify educational qualifications (degrees) of 1 of 2 Testing Personnel for the volume and complexity of tests performed, (B). Findings: Cross Reference D6065. Based on record review and

interview, the laboratory failed to have verification of the educational qualifications (degrees) of 1 (B) out of 2 (A, B) Testing Personnel.

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to verify the educational qualifications (degrees) of 1 (B) out of 2 (A, B) Testing Personnel. Findings: Review of the CMS 209 Laboratory Personnel Report, signed by the Laboratory Director on 8/7/2020, revealed there were 2 employees listed as moderate complexity testing personnel. Review of personnel documentation showed no documentation of the educational qualifications (degrees) for Testing Personnel B. During an interview on 8/7/2020 at 5:38 PM, the Laboratory Consultant stated that Testing Personnel B was unable to locate his degree.