

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2190462	(X3) Date Survey Completed 09/09/2021
Name of Provider or Supplier Family Medical Management	Street Address, City, State 880 Mull Ave, #100, Akron, OH	
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
D5200	<p>GENERAL LABORATORY SYSTEMS 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 an interview with the Office Manager, the laboratory failed to establish and follow policies and procedures to ensure the overall quality of the general laboratory systems and correct identified problems in the speciality of chemistry. This deficient practice had the potential to affect 26 out of 26 patients tested in the speciality of chemistry at this laboratory from 08/20/2021 through 09/09/2021. 1. The laboratory failed to establish and follow policies and procedures for the competency assessment for two out of two Testing Personnel (TP) performing moderate complexity testing in the speciality of chemistry. (Refer to D5209) 2. The laboratory failed to establish and follow policies and procedures to verify the accuracy of the moderately complex Vitamin D testing procedures, at least twice annually. (Refer to D5217) 4. The laboratory failed to 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. (Refer to D5291)</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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,</p>

consultant competency.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Office Manager, the laboratory failed to establish and follow policies and procedures for the competency assessment for two out of two Testing Personnel (TP) performing moderate complexity testing in the specialty of chemistry. This deficient practice had the potential to affect 26 out of 26 patients tested in the speciality of chemistry at this laboratory from 08/20/2021 through 09/09/2021. Findings include: 1. Review of the laboratory's manual failed to find an approved policy and procedure (by Laboratory Director's signature and date) for TP competency assessment. 2. Review of the laboratory's documentation failed to find evidence of initial training prior to patient testing for TP #1 and TP #2. 3. The surveyor requested competency assessment policy, procedure and associated documentation from the Office Manager, on 09/09/2021 at 1:08 PM. An interview with the Office Manager, on 09/09/2021 at 1:08 PM, confirmed that the laboratory failed to establish and follow policies and procedures for the competency assessment of TP #1 and TP #2. 4. An interview with the Office Manager, on 09/09/2021 at 1:08 PM, confirmed that although they recalled training for both TP #1 and TP #2 on the new instrument form Qualigen (the instrument provider), no documentation could be produced at the time of the inspection.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Laboratory Director (LD), the laboratory failed to establish and follow policies and procedures to verify the accuracy of the moderately complex Vitamin D testing procedures, at least twice annually. This deficient practice had the potential to affect 26 out of 26 patients tested in the speciality of chemistry at this laboratory from 08/20/2021 through 09/09/2021. Findings include: 1. Review of the laboratory's manual failed to find a policy and procedure to verify the accuracy of the moderately complex Vitamin D testing procedures at least twice annually. 2. An interview with the Manager, on 09/09/2021 at 1:11 PM, confirmed that although the lab had planned to enroll with American Family Physicians program to verify the accuracy of the moderately complex vitamin D, they had not enrolled at the time of the inspection. 3. Review of the laboratory's records failed to find evidence that the lab planned to verify the accuracy of the moderately complex Vitamin D testing procedures at least twice annually, as required. 4. The surveyor requested evidence that the laboratory had enrolled with American Family Physicians program to verify the accuracy of the moderately complex vitamin D analyte. An interview with the Office Manager, on 09/09/2021 at 1:11 PM, confirmed that the lab failed to establish and follow a policy to verify the accuracy of the moderately complex Vitamin D testing, and failed to provide evidence of enrollment with American Family Physicians to verify the accuracy of the moderately complex Vitamin D testing twice annually, as required.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1239(a)

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 through 493.1236.

This STANDARD is not met as evidenced by:

Based on document review and an interview with the Office Manager, the laboratory failed to 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. This deficient practice had the potential to affect 26 out of 26 patients tested in the speciality of chemistry at this laboratory from 08/20/2021 through 09/09/2021. Findings include: 1. Review of the laboratory's manual failed to find policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated correct problems in the general lab systems. 2. Review of the laboratory's documentation failed to find evidence that the laboratory monitored, assessed and corrected problems identified in the General Laboratory Systems. 3. The surveyor requested policies for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems. An interview with the Office Manager, on 09/09/2021 at 1:11 PM, confirmed that the lab failed to establish and follow policies and procedures to monitor assess and correct problems in the general laboratory systems.

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 and interview with the Office Manager, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct problems. This deficient practice had the potential to affect 26 out of 26 patients tested in the speciality of chemistry at this laboratory from 08/20/2021 through 09/09/2021. Findings Include: 1. Based on record review and an interview with the Office Manager, the laboratory failed to include in the their policies and procedures the chemistry requirements for specimen collection, labeling, storage, preservation, processing and referral, criteria for specimen acceptability and rejection, step-by-step performance of the procedure, interpretation of the results based on the manufacturer's instructions, limitations in the testing, the laboratory's system for entering and reporting the results in the patient record and the laboratory's course of action to take if a test system becomes inoperable. (Refer to D5403) 2. Based on record review and an interview with the Office Manager, the laboratory failed to establish and verify performance specifications of the Qualigen FastPack test system for Vitamin D before reporting patient test results. (Refer to D5421) 3. Based on record review and an

interview with the Office Manager, the laboratory failed to establish, and verify performance specifications of the Qualigen FastPack test system for Vitamin D before reporting patient test results. (Refer to D5445)

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 an interview with the Office Manager, the laboratory failed to include in their policies and procedures the chemistry requirements for specimen collection, labeling, storage, preservation, processing and referral, criteria for specimen acceptability and rejection, step-by-step performance of the procedure, interpretation of the results based on the manufacturer's instructions, limitations in the testing, the laboratory's system for entering and reporting the results in the patient record and the laboratory's course of action to take if a test system becomes inoperable. This deficient practice had the potential to affect 26 out of 26 patients tested in the speciality of chemistry at this laboratory from 08/20/2021 through 09/09/2021. Findings Include: 1. A review of the laboratory's manual failed to find policies and procedures that were approved, signed, and dated by the Laboratory Director prior to implementation, for specimen collection, labeling, storage, preservation, processing and referral, criteria for specimen acceptability and rejection, step-by-step performance of the procedure, interpretation of the results based on the manufacturer's instructions, limitations in the testing, the laboratory's system for entering and reporting the results in the patient record and the laboratory's course of action to take if a test system becomes inoperable. 2. A review of the laboratory's documentation found manufacturer's instructions provided by Qualigen; however, review of this manual failed to find evidence that it was reviewed, approved, signed, and dated by the Lab Director prior to implementation. 3. Further review of the manufacturer's instructions provided by Qualigen failed to find information that fulfilled the required regulation for a procedure manual regarding specimen collection, labeling, storage, preservation, processing and referral, criteria for specimen acceptability and rejection, step-by-step performance of the procedure, interpretation of the results based on the manufacturer's instructions, limitations in the testing, the laboratory's system for entering and reporting the results in the patient record and the laboratory's course of

action to take if a test system becomes inoperable. 4. The surveyor requested additional procedure manual documents on 09/09/2021 at 1:12 PM. An interview with the Office Manager, on 09/09/2021 at 1:12 PM, confirmed that the lab failed to provide a procedure manual, approved, signed, and dated by the Laboratory Director prior to implementation, that included specimen collection, labeling, storage, preservation, processing and referral, criteria for specimen acceptability and rejection, step-by-step performance of the procedure, interpretation of the results based on the manufacturer's instructions, limitations in the testing, the laboratory's system for entering and reporting the results in the patient record and the laboratory's course of action to take if a test system becomes inoperable.

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 an interview with the Office Manager, the laboratory failed to establish and verify performance specifications of the Qualigen FastPack test system for Vitamin D before reporting patient test results. This deficient practice had the potential to affect 26 out of 26 patients tested in the speciality of chemistry at this laboratory from 08/20/2021 through 09/09/2021. Findings Include: 1. A review of the laboratory's manual failed to find a policy and procedure to verify performance specifications of the Qualigen FastPack test system for Vitamin D, prior to testing patient specimens. 2. Further review of the laboratory's Qualigen FastPack test system for Vitamin D method validation for accuracy, precision and reportable range failed to find evidence of review and/or approval, signed and dated by the Laboratory Director prior to testing patient specimens. 3. An interview with the Office Manager, on 09/09/2021 at 2:21 PM, confirmed that although the validation was performed in conjunction with Qualigen, the validation was not reviewed and/or approved by the Laboratory Director prior to testing patient specimens.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interviews with the Office Manger and Testing Personnel (TP) #1, the laboratory failed to complete the required three parts to implement an Individualized Quality Control Plan (IQCP) in order to reduce the frequency of Qualigen FastPack testing system for Vitamin D Quality Control (QC) testing from daily to weekly. This deficient practice had the potential to affect 26 out of 26 patients tested in the speciality of chemistry at this laboratory from 08/20/2021 through 09/09/2021. Findings Include: 1. Review of Qualigen's Manufacturer Instructions found the following statements: "When to Control Test... -When patient testing is performed * *Review the Individualized Quality Control Plan (IQCP) Guidelines implemented by CMS. These guidelines are based on individual risk factors involved in the performance of each test run in your laboratory. IQCP is voluntary and provides laboratories with flexibility in customizing QC policies and procedures based on the unique aspects and test systems found in your laboratory and may allow for the reduction in the frequency of control testing required." 2. Review of the laboratory's QC data found two days in which patients were tested without QC performed: Patient Date QC #1 09/02/21 None #2 09/03/21 None 3. An interview with TP #1, on 09/09/2021 at 1:41 PM, revealed that the lab had used IQCP in order to reduce the frequency of QC testing from daily to weekly. The surveyor requested IQCP data and policies reviewed and approved by the Laboratory Director. An interview with TP #1 confirmed that the approved IQCP policy and data could not be produced. 4. The surveyor requested an IQCP data, policy and procedure on 09/09/2021. An interview with the Office Manager, on 09/09/2021 at 1:43 PM, confirmed that they used IQCP to reduce the frequency of QC from daily to weekly, but failed to provide an approved IQCP policy, IQCP data, or the required parts of an IQCP to include Risk Assessment; Quality Control Plan; and a Quality Assessment.

D5801

TEST REPORT
CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:
Based on record review and an interview with the Office Manager, the laboratory failed to have a system in place to ensure the accuracy of the manually transcribed Qualigen FastPack test result for Vitamin D. This deficient practice had the potential to affect 26 out of 26 patients tested in the speciality of chemistry at this laboratory from 08/20/2021 through 09/09/2021. Findings include: 1. Review of the laboratory's manual failed to find a policy to ensure the accuracy of the manually transcribed Qualigen FastPack test for Vitamin D patient results. 2. Review of the laboratory's documentation found the "Laboratory Results" worksheet, where Vitamin D test results are manually transcribed from the Qualigen FastPack analyzer are written. The "Laboratory Results" worksheet is placed into the patient's paper chart. 3. The surveyor requested a policy and procedure to ensure the accuracy of the manually

entered data. An interview with the Office Manager, on 09/09/2021 at 2:20 PM, confirmed that the lab failed to have a policy and procedure in place to ensure the accuracy of the manually transcribed Qualigen FastPack test for Vitamin D.

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on record review and an interview with the Office Manager, the laboratory failed to ensure "reference intervals" or "normal values" provided to its clients are accurate and approved. This deficient practice had the potential to affect 26 out of 26 patients tested in the speciality of chemistry at this laboratory from 08/20/2021 through 09/09/2021. Findings include: 1. A review of the laboratory's documentation found that a validation study was performed on 07/30/21 in conjunction with Qualigen prior to testing patient specimens, including accuracy, precision and reportable range. 2. Review of the laboratory's test records found the reference range listed as: "Vitamin D, 25-Hydroxy Ref. Range 30.0 - 100.0 ng/mL" 3. Further review of the laboratory's documentation for the Qualigen FastPack test system for Vitamin D failed to find evidence of review and/or approval, signed and dated by the Laboratory Director prior to testing patient specimens. No evidence of an approved reference range, signed and dated by the Laboratory Director was found. 4. The surveyor requested documentation of an approved reference range signed and dated by the Laboratory Director. An interview with the Office Manager, on 09/09/2021 at 2:08 PM, confirmed that the laboratory failed to ensure that the Vitamin D reference range was approved, signed, and dated by the Laboratory Director prior to testing patients.

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 an interview with Office Manager, the Laboratory Director failed to provide overall management and direction in accordance with 493.1407 of this subpart. This deficient practice had the potential to affect 26 out of 26 patients tested in the speciality of chemistry at this laboratory from 08/20/2021 through 09/09/2021. Findings Include: 1. The Laboratory Director failed to ensure that verification procedures were established, approved and adequate to determine accuracy, precision, and other pertinent performance characteristics of the method of Vitamin D testing. (Refer to D6013) 2. The Laboratory Director failed to ensure that the quality control (QC) and quality assessment (QA) programs were established, approved and maintained to identify failures in quality as they occur. (Refer to D6022) 3. The Laboratory Director failed to ensure that prior to testing patients' specimens the Testing Personnel (TP) had received the appropriate training. (Refer to D6029) 4. The Laboratory Director failed to ensure that policies and procedures were

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. (Refer to D6030) 5. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. (Refer to D6031)

D6013

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(ii)

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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:
Based on record review and an interview with the Office Manager, the Laboratory Director failed to ensure that verification procedures were established, approved and adequate to determine accuracy, precision, and other pertinent performance characteristics of the method for Vitamin D testing. This deficient practice had the potential to affect 26 out of 26 patients tested in the speciality of chemistry at this laboratory from 08/20/2021 through 09/09/2021. Findings Include: 1. A review of the laboratory's manual failed to find a policy and procedure to verify performance specifications of the Qualigen FastPack test system for Vitamin D prior to testing patient specimens. 2. A review of the laboratory's Vitamin D documentation found that a validation study for Qualigen FastPack test system was performed on 07/30/21, prior to testing patient specimens, that included accuracy, precision and reportable range. 3. Further review of the laboratory's Vitamin D validation documentation for the Qualigen FastPack test system failed to find evidence of review and/or approval, signed and dated by the Laboratory Director prior to testing patient specimens. 4. The surveyor requested evidence that the validation was approved, signed, and dated by the Laboratory Director prior to testing. An interview with the Office Manager, on 09/09/2021 at 2:21 PM, confirmed that the validation was not reviewed and/or approved, signed and dated by the Laboratory Director prior to testing patient specimens.

D6022

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 the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on record review and interviews with the Office Manager and Testing

Personnel (TP) #1, the Laboratory Director failed to ensure that the quality control (QC) and quality assessment programs were established, approved and maintained to identify failures in quality as they occur. This deficient practice had the potential to affect 26 out of 26 patients tested in the speciality of chemistry at this laboratory from 08/20/2021 through 09/09/2021. Findings Include: 1. Review of Qualigen's Manufacturer Instructions found the following statements: "When to Control Test... - When patient testing is performed * *Review the Individualized Quality Control Plan (IQCP) Guidelines implemented by CMS. These guidelines are based on individual risk factors involved in the performance of each test run in your laboratory. IQCP is voluntary and provides laboratories with flexibility in customizing QC policies and procedures based on the unique aspects and test systems found in your laboratory and may allow for the reduction in the frequency of control testing required." 2. Review of the laboratory's QC data found two days in which patients were tested without QC performed: Patient Date QC #1 09/02/21 None #2 09/03/21 None 3. An interview with TP #1, on 09/09/2021 at 1:41 PM, revealed that the laboratory had used IQCP in order to reduce the frequency of QC testing from daily to weekly. The surveyor requested IQCP data and policies reviewed and approved by the Laboratory Director. And interview with TP #1 confirmed that the approved IQCP policy and data could not be produced. 4. The surveyor requested an IQCP data, policy and procedure on 09/09/2021. An interview with the Office Manager, on 09/09/2021 at 1:43 PM, confirmed that they used IQCP to reduce the frequency of QC from daily to weekly, but failed to provide an approved IQCP policy, IQCP data, or the required parts of an IQCP to include Risk Assessment; Quality Control Plan; and a Quality Assessment.

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 an interview with the Office Manager, the Laboratory failed to ensure that policies and procedures were established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and are able to 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 deficient practice had the potential to affect 26 out of 26 patients tested in the speciality of chemistry at this laboratory from 08/20/2021 through 09/09/2021. Findings include: 1. Review of the laboratory's manual failed to find an approved policy and procedure signed and dated by the Laboratory Director for TP competency assessment. 2. Review of the laboratory's documentation failed to find evidence of initial training prior to patient testing for TP #1 and TP #2. 3. The surveyor requested the approved competency assessment policy, procedure and

documentation. An interview with the Office Manager, on 09/09/2021 at 1:08 PM, confirmed that the laboratory failed to establish and follow policies and procedures for the competency assessment of TP #1 and TP #2. 4. An interview with the Office Manager, on 09/09/2021 at 1:08 PM, confirmed that although they recalled training for both TP #1 and TP #2 on the new instrument form Qualigen (the instrument provider), no documentation could be produced at the time of the inspection.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(13)

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)(13) 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 record review and an interview with the Office Manager, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. This deficient practice had the potential to affect 26 out of 26 patients tested in the speciality of chemistry at this laboratory from 08/20/2021 through 09/09/2021. Findings Include: 1. A review of the laboratory's manual failed to find policies and procedures that were approved, signed, and dated by the Laboratory Director prior to implementation, for specimen collection, labeling, storage, preservation, processing and referral, criteria for specimen acceptability and rejection, step-by-step performance of the procedure, interpretation of the results based on the manufacturer's instructions, limitations in the testing, the laboratory's system for entering and reporting the results in the patient record and the laboratory's course of action to take if a test system becomes inoperable. 2. A review of the laboratory's documentation found manufacturer's instructions provided by Qualigen; however, review of this manual failed to find evidence that it was reviewed and approved, signed, and dated by the Lab Director, prior to implementation. 3. An interview with the Office Manager, on 09/09/2021 at 1: 12 PM, confirmed that the laboratory failed to provide a procedure manual, approved, signed, and dated by the Laboratory Director prior to implementation, that included specimen collection, labeling, storage, preservation, processing and referral, criteria for specimen acceptability and rejection, step-by-step performance of the procedure, interpretation of the results based on the manufacturer's instructions, limitations in the testing, the laboratory's system for entering and reporting the results in the patient record and the laboratory's course of action to take if a test system becomes inoperable.