Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0673541	01/19/2022
Name of Provider or Supplier	**Street Address, City, State**	
East Texas Family Medicine Pa	4201 South Loop 256, Palestine, TX	

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	A routine recertification survey conducted on January 19, 2022 found the laboratory out of compliance with the following CONDITION LEVEL DEFICIENCIES: D5018 - 42 C.F.R. 493.1211 Condition: Urinalysis; D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant;
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of the QuickVue SARS Antigen test instructions for use, Abbott ID NOW test instructions for use, patient records, and interview with facility personnel, the laboratory failed to report negative SARS-COV-2 antigen test results as required for twenty-one of twenty-one days of testing performed between December 20, 2021 and January 19, 2022. The findings included: 1. Based on review of the QuickVue SARS Antigen test instructions for use (Ref 20387), under CONDITIONS OF AUTHORIZATION FOR THE LABORATORY AND PATIENT CARE SETTINGS, the instructions stated "Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." 2. Based on review of the Abbott ID NOW test

	instructions for use (Rev. 8, 2021/08), under Intended Use, the instructions stated, "Testing facilities within the United States and its territories are required to report all results to the appropriate public health authorities." 3. Based on review of patient records, the laboratory performed 492 patient tests under SARS-COV-2 COVID19W /OPTIC and 34 patient tests with IADNA SARS-COV-2 COVID-19 AMPLIFIED PROBE TQ for twenty-one testing days between December 20, 2021 and January 19, 2022. 4. In an interview at 13:54 hours on January 19, 2022 hours in the office, the Practice Manager stated the laboratory had not reported negative SARS-COV-2 test results to HHS. The Practice Manager stated, "we send all of our positive tests to the state, but we don't even keep track of the negative tests." Key: SARS-COV-2 - severe acute respiratory syndrome coronavirus 2 HHS - Health and Human Services
D3007	FACILITIES CFR(s): 493.1101(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs. This STANDARD is not met as evidenced by: - Based on surveyor observation, review of laboratory policy, instrument manual, review of the Center for Medicare and Medicaid Services (CMS) form 116, and confirmed in interview, the laboratory failed to have an appropriate centrifuge for the centrifugation of urine sediment for one of one provider performed microscopy (PPM) test; "Urine Microscopy". The findings include: 1. During a tour of the laboratory on 1 /19/2022 at 9:20 hours, surveyor observed the fixed speed "VanGuard Centrifuge" placed near a sink in a patient processing area, surrounded by open patient urine containers. Surveyor queried if this was the only centrifuge in use for the centrifugation of urine specimens and the practice manager stated, "I think so,". Further query with the medical assistants in the processing area confirmed that the "VanGuard Centrifuge" was the one used for urine centrifugation. 2. Review of the policy titled "Urine Microscopy", section "Procedure", bullet point 3. stated: "Centrifuge urine specimen according to manufacturer's directions at a RCF (relative centrifugal force) of 400 x g for 5-10 minutes. To calculate the RPM (rotations per minute) for a specific centrifuge ..." 3. Review of the "VanGuard Compact Centrifuge Operator Manual", section "VanGuard Centrifuge Models", stated the following: "NOTE: ALL VANGUARD CENTRIFUGE MODELS PERFORM AT 3400 RPM FULLY LOADED AND RELATIVE CENTRIFUGAL FORCE 1318." 4. Review of the CMS116, section VII "PPM Testing" lists the estimated total annual volume for the PPM test "Urine Sediment Examinations" as 500. 5. In an interview on 1/19/2022 at 09:50 hours, the practice manager confirmed the laboratory did not have a centrifuge that could be used for the processing of urine specimens at 400 RCF. .
D5018	URINALYSIS CFR(s): 493.1211 If the laboratory provides services in the subspecialty of Urinalysis, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on review of the laboratory's policy and procedures, procedure manuals, the

	Centers for Medicare and Medicaid Services (CMS) form 116, surveyor observation, and staff interview the laboratory failed to meet the requirements specified in in 493. 1230 through 493.1256, and 493.1281 through 493.1299 for the subspecialty of Urinalysis. The findings included: 1. The laboratory failed to follow its own policy for specimen processing for the centrifugation of urine sediment for one of one provider performed microscopy (PPM) test; "Urine Microscopy". Refer to D5311. 2. The laboratory failed to define a function check protocol to ensure the laboratory equipment was accurate for reliable testing for one of one centrifuged used for the Provider Performed Microscopy (PPM) test; Urine sediment examinations. Refer to D5435. 3. The laboratory failed to record patient results for one of one provider performed microscopy (PPM) test; Urine sediment examination. Refer to D5787. .
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: . Based on surveyor observation, review of laboratory policy, instrument manual, review of the Center for Medicare and Medicaid Services (CMS) form 116, and confirmed in interview, the laboratory failed to follow its own policy for specimen processing for the centrifugation of urine sediment for one of one provider performed microscopy (PPM) test; "Urine Microscopy". The findings include: 1. During a tour of the laboratory on 1/19/2022 at 9:20 hours, surveyor observed the fixed speed "VanGuard Centrifuge" placed near a sink in a patient processing area, surrounded by open patient urine containers. Surveyor queried if this was the only centrifuge in use for the centrifugation of urine specimens and the practice manager stated, "I think so,". Further query with the medical assistants in the processing area confirmed that the "VanGuard Centrifuge" was the one used for urine centrifugation. 2. Review of the policy titled "Urine Microscopy", section "Procedure", bullet point 3. stated: "Centrifuge urine specimen according to manufacturer's directions at a RCF (relative centrifugal force) of 400 x g for 5-10 minutes. To calculate the RPM (rotations per minute) for a specific centrifuge ..." 3. Review of the "VanGuard Compact Centrifuge Operator Manual", section "VanGuard Centrifuge Models", stated the following: "NOTE: ALL VANGUARD CENTRIFUGE MODELS PERFORM AT 3400 RPM FULLY LOADED AND RELATIVE CENTRIFUGAL FORCE 1318." 4. Review of the CMS116, section VII "PPM Testing" lists the estimated total annual volume for the PPM test "Urine Sediment Examinations" as 500. 5. In an interview on 1/19/2022 at 09:50 hours, the practice manager confirmed the laboratory was not following its own policy for the processing of urine specimens for the urine sediment examinations. .
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 quality control records, reagent records, laboratory policies and procedures, manufacturer instructions,operator's manuals, and staff interview, the laboratory failed to meet the analytic system requirements in 493.1251 through 493.1283. The findings included: 1. The laboratory failed to follow the manufacturer's instructions for the processing of Interpretive Program (IP) messages on the Sysmex XM-330 hematology analyzer, for eight of ten patient complete blood cell (CBC) tests reviewed in January 2022. Refer to D5411. 2. The laboratory failed to verify the patient normal ranges for complete blood cell (CBC) tests prior to performing patient testing for the Sysmex XM-330 hematology analyzer. Refer to D5421. 3. The laboratory failed to follow manufacturer calibration instructions for forty-one of forty-one months for the Sysmex XN-330 hematology analyzer, since its installation in August 2018. Refer to D5439. 4. The laboratory failed to perform QC after a change of reagent for the Sysmex XN-330 for sixty-seven of sixty-seven reagent changes reviewed in 2020 and 2021. Refer to D5461.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: . Based on review of manufacturer's instruction, patient printouts, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions for the processing of Interpretive Program (IP) messages on the Sysmex XM-330 hematology analyzer, for eight of ten patient complete blood cell (CBC) tests reviewed in January 2022. The findings include: 1. Review of the "XN-530/XN-430/XN-330 Troubleshooting" manual (BW212660), chapter 5 "IP Messages", stated the following: a: Section 5.1 "Overview of IP Messages" had the following statement: "A Positive or Error Judgement indicated the possibility of an abnormality. It is not a diagnosis of the patient. If a Positive or Error judgement occurs, check the data and repeat the analysis, or examine carefully in accordance with the protocol of your laboratory. b: Section 5.2 "Lists of IP messages" had the following statement: "Message types" There are 2 types of IP messages that may be displayed for WBC, RBC/RET, and PLT: abnormal messages and suspect messages. Abnormal messages: Indicates that the sample is clearly abnormal. Suspect messages: Indicates a possibility that the sample is abnormal. "Positive/Negative judgment" [Positive] Indicates that a blood cell analysis value or cell morphology exceeds the preset criteria for the IP message (abnormal sample). A Positive judgement is classified into the 3 types shown below. - [Diff. Abnormal]: Indicates an abnormal blood cell differentiation value. - [Morph. Abnormal]: Indicates an abnormal cell morphology. - [Count Abnormal]: Indicates an abnormal blood cell count. [Negative] Indicates that there were no analysis errors or abnormalities, and that there is no IP message (normal

	sample). 2. Review of patient printouts from the Sysmex XN-330 has the following eight of ten patients with positive IP messages that were not repeated or assessed before reporting in January 2022. 1/3/2022 Patient ID: 0000016884 - Positive: Diff. 1 /4/2022 Patient ID: 45087 - Positive: Morph Patient ID: 0000015521 - Positive: Morph. Patient ID: 00000000479 - Positive: Diff. Morph. 1/6/2022 Patient ID: 0000015907 - Positive: Diff. 1/11/2022 Patient ID: 0000004334 - Positive: Morph. 1 /12/2022 Patient ID: 0000015750 - Positive: Diff. Morph. Count Patient ID: 47666 - Positive: Diff 3. In an interview on 1/19/2022 at 10:40 hours in the laboratory, the practice manager confirmed that it was not policy to rerun CBC results with positive IP messages as defined by the manufacturer. Key: WBC - White blood cell RBC - Red blood cell RET - Reticulocyte PLT - Platelet Diff. - Differential Morph. - Morphology .
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 review of the manufacturer instructions, verification study records, laboratory procedures, and interview with facility personnel, the laboratory failed to verify the patient normal ranges for complete blood cell (CBC) tests prior to performing patient testing for the Sysmex XM-330 hematology analyzer for one of one hematology analzyers. The findings included: 1. Based on review of the Sysmex "Method Verification Manual" (Rev 2, Dec 2016), in Section 3 Method Verification Protocols, the document stated "It is the customer's responsibility to perform additional studies, following the requirements of their accrediting agency. The follow protocols are provided: Correlation Studies, Sensitivity Study, Reference Range Verification, Stability Study, Mixing Study". In Section 5 of the Application Manual, under Reference Range Study, the document stated, "Reference ranges describe analyte levels associated with person who are considered "healthy". Multiple factors can influence a reference range including, population selection (geography and demographics) and, specimen collection and handling. Assuming the study that resulted in the current reference range was performed correctly, that the population has not changed, and the new analyzer is determined to be comparable (correlation), a study to verify the current reference ranges with the new analyzer is appropriate. The outcome of this study either verifies the current reference range or determines whether a new reference ranges needs to be established." 2. Based on review of the hematology analyzer verification studies, the Sysmex XN was approved for use on 8 /29/2018. 3. Based on review of the laboratory's policy, "Complete Blood Count: Whole Blood on the Sysmex XN-350/Xn-330 Automated Hematology Analyzer", under section VIII Report Results, the laboratory Adult Reference Ranges were listed. Examples: Hemoglobin (HGB) 11.7 - 17.1 Hematocrit (HCT) 35.0 - 50.0 4. Based on review of the Sysmex XN530/XN-430/XN-330 General Information manual, on page 5-19, the manufacturer provided the following "Reference intervals (normal population reference ranges) were developed using normal individuals. The range for

	each parameter is calculated for 95% confidence intervals. The table below shows the Normal Population Reference Ranges". Examples: Female Hemoglobin (HGB) 11.2 - 15.7 Female Hematocrit (HCT) 34.1 to 44.9 Male Hemoglobin (HGB) 13.7 to 17.5 Male Hematocrit (HCT) 40.1 to 51.0 5. In an interview at 14:56 hours on 1/19/2022, the surveyor requested documentation of the verification of patient normal ranges for the Sysmex XN hematology analyzer. The Practice Manager stated the only studies that were performed were the ones that the Sysmex representatives performed at the time of installation.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: . Based on review of the operator's manual and confirmed in interview, the laboratory failed to define a function check protocol to ensure the laboratory equipment was accurate for reliable testing for one of one centrifuged used for the Provider Performed Microscopy (PPM) test; Urine sediment examinations. The findings include: 1. Review of the "VanGuard Compact Centrifuge Operator Manual", section "VanGuard Centrifuge Models", stated the following: "NOTE: ALL VANGUARD CENTRIFUGE MODELS PERFORM AT 3400 RPM FULLY LOADED AND RELATIVE CENTRIFUGAL FORCE 1318." 2. On 1/19/2022 at 10:40 hours, surveyor queried the practice manager for documentation of maintenance, timer checks, and tachometer checks for the VanGuard centrifuge in use for the urine sediment examination. The practice manager stated that no maintenance or function checks had ever been performed on the centrifuge. .
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 procedure, laboratory documents, and confirmed in interview, the laboratory failed to follow manufacturer calibration instructions for forty-one of forty-one months for the Sysmex XN-330 hematology analyzer, since its installation in August 2018. The findings include: 1. Review of the "Sysmex XN-350/330 CLSI Procedure" (1236-LLS), section IV. "Calibration and Precision" stated the following: "The laboratory must verify calibration every six months or on an "as-needed" basis to ensure the accuracy of system." 2. Review of the "Sysmex Service Maintenance Certificate" for a contract date range of 8/16/2019 to 8/15/2023 has the following date for calibration of the Sysmex XN-330: Calibration - Completed - 8/17/2018 3. In an interview on 1/19/2022 at 1340, the practice manager confirmed that calibration was not performed every six months on the Sysmex XN-330 hematology analyzer, and that they "thought the Sysmex service technicians were performing it for them". .
D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(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--Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on review of manufacturer's instructions, review of reagent change logs, review of the Centers for Medicare and Medicaid Services (CMS) form 116, and confirmed in interview, the laboratory failed to perform QC after a change of reagent for the Sysmex XN-330 for sixty-seven of sixty-seven reagent changes reviewed in 2020 and 2021. The findings include: 1. Review of the "XN-L Series XN-530/XN-430 /XN-330 Basic Operation" manual, chapter 3 "Performing Quality Control (QC)", section 3.2.2 "When QC analysis is performed" stated: "QC is performed at the following times. - Before sample analysis - After replacement/replenishment of reagents - After instrument maintenance - When there is a concern about the accuracy of analysis values" 2. Review of the reagent change log for January through December 2020, and January through December 2021 list the following sixty-seven times a reagent was changed on the Sysmex XN-330 hematology analyzer. 2020 - January through December Sulfolyser - 8 times CellPack DCL - 13 times Fluorocell WDF - 6 times Lysercell WDF - 3 times 2021 - January through December Sulfolyser - 8 times CellPack DCL - 16 times Fluorocell WDF - 9 times Lysercell WDF -4 times 3. Review of the CMS-116 section VII. "Non-Waived Testing" list the total annual volume for the specialty Hematology at 2,500. 4. In an interview at 1/19/2022 at 13: 30 hours the practice manager confirmed that QC was not being performed after reagent change on the Sysmex XM-330 hematology analyzer. .

D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: . Based on review of the Centers for Medicare and Medicaid Services (CMS) form 116, review of laboratory policy, and confirmed in interview, the laboratory failed to record patient results for one of one provider performed microscopy (PPM) test; Urine sediment examination. The findings include: 1: Review of the CMS-116 section VII. "PPM Testing" lists the following PPM procedure being performed: "Urine sediment examinations" With an estimated total annual test volume of 500. 2. Review of laboratory policy titled "Urine Microscopy" signed by the lab director 10/30/2018, section "Reporting Results" states: "Results should be recorded in the patient record done with the date/time the sample was collected and the name of the provider performing the examination." 3. On 1/19/2022 at 10:20 hours, in the breakroom, surveyor queried the practice manager for urine microscopic patient final reports. The practice manager informed the surveyor that they could not provide any patient final reports, because they were not reported, and that the providers "just looked at the urine sediment to asses the next step of treatment" for the patient. 4. In an interview on 1/19/2022 at 15:00, in the practice managers office, the practice manager confirmed that the urinalysis sediment exams we're being performed to make clinical decisions, but not reported in the patient's chart. .
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of testing personnel competency assessments and hematology analzyer verification studies, one of two the technical consultants failed to provide technical and scientific oversight of the laboratory for two of two years. Refer to D6035, D6040, and D6046.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of

	Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on review of the laboratory personnel credentials and interview with facility personnel, one of two Technical Consultants did not meet the education and experience requiments to perform duties of a Technical Consultant for two of two years. The findings included: 1. Based on review of the laboratory personnel credentials, the individual performing testing personnel competeny assessments did not have documentation of education to qualify at 493.1411. 2. In an interview at 11: 56 hours on 1/19/2022, the Practice Manager confirmed the signatures attesting to the testing personnel competency were that of the previous Practice Manager, listed as Techincal Consultant 2 and that this individual did not have the qualification necessary to qualify for Technical Consultant.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the 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 the manufacturer instructions, verification study records, patient final reports, and interview with facility personnel, the Technical Consultant failed to verify the patient normal ranges for complete blood cell (CBC) tests prior to performing patient testing for the Sysmex XM-330 hematology analyzer for one of one hematology analzyers. Refer to D5421.

D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(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: Based on review of policies and procedures, testing personnel competency assessments, and interview with facility personnel, the Technical Consultant failed to assess the competency of seven of seven testing personnel for 2020 and 2021. The findings included: 1. Based on review of the laboratory policy "East Texas Family Medicine, PA Quality Assurance Policies and Procedures" under 6. PERSONNEL ASSESSMENT" stated the following: "The Laboratory Director will use the results of Proficiency testing and direct observation to perform an annual evaluation of all testing personnel to ensure competency in job performance" 2. Based on a review of seven of seven testing personnel, all competency assessments for 2020 and 2021 were signed by the individual listed as Technical Consultant 2 on the CMS-209 Laboratory Personnel Report. The individual listed as Technical Consultant 2 does not meet the qualifications for a Technical Consultant at 493. 1411. Refer to D6035. 3. In an interview at 11:56 hours on 1/19/2022, the Practice Manager confirmed the signatures attesting to the testing personnel competency were that of the previous Practice Manager, listed as Techincal Consultant 2 and that this individual did not have the qualification necessary to qualify for Technical Consultant at 493.1411.