Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1021708	06/16/2026
Name of Provider or Supplier	**Street Address, City, State**	
Family Medical Group Of Texarkana, Llp	2101 Galleria Oaks, Texarkana, 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	As result of a recertification survey conducted on 6/16/2026, the laboratory was found out of compliance with the following condition level deficiencies: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant;
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 review of laboratory documentation, laboratory policies and procedures, laboratory control records, and patient testing, the laboratory failed to ensure the overall quality of the analytic system through the monitoring of chemistry calibration verification acceptability every six months from March 2025 through March 2026 (D5439), and failed to ensure the accuracy of the test system through daily quality control acceptability before patient testing occurred on the Chemistry Architect C4100 analyzer (D5481) for records reviewed in January and February 2026.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 laboratory calibration documentation and confirmed in interview the laboratory failed to ensure calibration verification was assessed for acceptability on the Chemistry Architect C4100 analyzer, for records reviewed from March 2025 through March 2026. The findings included: 1. Review of laboratory calibration verification documentation included the following 32 analytes that the laboratory performed calibration verification on the Chemistry Architect C4100 system: Free Thyroxine, Testosterone, Thyroid Stimulating Hormone, Thyroxine, Vitamin B12, 25-OH Vitamin D, Albumin, Alkaline Phosphatase, ALT / SGPT, AST / SGOT, Direct Bilirubin, Calcium, Carbon dioxide, Chloride, HDL, Cholesterol, Creatinine, Ferritin, Glucose, Hemoglobin A1c, Iron, Total, Magnesium, Potassium, PSA, Sodium, Total Protein, Triglycerides, UIBC, measured, Urea Nitrogen, Uric Acid, Urine Creatinine, Urine Microalbumin. 2. Review of laboratory calibration verification documentation for 2025 and 2026 included the following analytes where calibration verification was performed, but their had been no assessment for acceptability. 3/26/2025: CO2, Glucose, Total Cholesterol, Total Protein, Potassium, Magnesium, Sodium, Triglycerides, Uric Acid: raw data available, no assessment for acceptability. September 2025 - raw data available, no assessment for acceptability, for all analytes. March 2026 - raw data available, no assessment for acceptability, for all analytes. Surveyor asked for testing person 1 for the assessment of acceptability for the above, and none could be provided. 3. In an interview on 6/16/2026 at 1435, in the office, TP 1 and the technical consultant confirmed the calibration verification for the above had not been assessed for accuracy and acceptability.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory quality control documentation, patient test list, and interview, the laboratory failed to ensure quality control (QC) was acceptable prior to the resulting of 237 of 237 patient results from the Architect

C4100 chemistry analyzer for QC records reviewed from January to March 2026. The findings included: 1. Review of the laboratory policy titled "Quality Control Policy", section "Remedial Action", included the following information: "A. When an analysis is found to be out of control (outside +/- 2SD), a Systematic effort must be made to resolve the problem. ... 5. If the value is still out, rerun with a new reagent or kit, and or recalibrate if necessary. Contact technical services if necessary. Do not report patients until the outliers are within acceptable limits. " 2. Review of quality control records included the following analytes and days where QC was out of laboratory acceptability for two or more levels of QC and patients had testing performed: Total Protein QC Level 1, Lot 14407241, exp 6/30/27 Mean 4.3403 g/dL SD 0.10485 g/dL QC Acceptability [4.3403 - 4.7597g/dL] 01/12/2026 11:26 - 5.1 g/dl 14:34 - 5 g/dL 16: 32 - 5 g/dL QC Level 2, lot ctrl 14407242, exp 6/30/2027 Mean 5.67846 g/dL SD 6.14 g/dL QC Acceptability [5.67846 - 6.60154 g/dL] 1/12/2026 11:36 - 6.9 g/dL 14: 34 - 6.9 g/dL 16:32 - 6.9 g/dL On 1/12/2026 the following 51 patients had total protein testing performed when 2 or more levels of quality control failed laboratory acceptability: 306917, 306937, 307041, 306908, 306892, 307066, 306940, 306997, 307030, 306925, 306907, 306982, 306995, 306936, 306971, 306906, 306963, 307021, 307051, 306884, 307026, 306974, 307009, 307095, 307097, 307013, 307077, 306960, 307003, 307114, 306894, 307047, 306970, 307058, 306881, 307090, 307101, 307083, 306896, 306914, 306929, 306945, 306955,306955, 306973, 307007, 307061, 307069, 307070, 307128, 307129 Urea QC Level 1, Lot 14407241, exp 6.30.2026 Mean 8.89 mg/dL SD 0.42728 mg/dL QC Acceptability [8.03544 - 9.74456 mg/dL] Date 01/13/2026 11:21 - 12 mg/dL QC Level 2, lot 14407242, exp 6 /30/3037 Mean 40.3 mg/dL SD 1.84108 mg/dL QC Acceptability [36.61784 - 43.98216 mg/dL] 01/13/2026 11:26 - 45 mg/dL On 1/13/2026 the following 39 patient has urea testing performed when 2 or more levels of quality control failed laboratory acceptability: 307170, 307168, 307132, 307191, 307249, 307184, 307318, 307146, 07247, 307220, 307314, 307219, 307227, 307163, 307144, 307261, 307295, 307321, 307325, 307214, 307278, 307172, 307244, 307286, 307277, 307238, 307269, 307274, 307272, 307261, 307333, 307181, 307188, 307238, 307269, 307274, 307298, 307302, 307309, FT4 - Free Thyroxine QC Level 1, lot 1003941, exp 8/31/2027 Mean 0.97813 ng/dL SD 0.0358 ng/dL QC Acceptability [0.90653 - 1.04973 ng/dL] 02/03/2026 12:45 - 0.88 ng/dL 15:03 - 0.88 ng/dL 02/05/2026 16:10 - 0.89 ng/dL QC Level 2, lot 1003942, exp 8/31/2027 Mean 2.22778 ng/dL SD 0.163 ng /dL QC Acceptability [1.90178 - 2.55378 ng/dL] 02/03/2026 12:50 - 1.88 ng/dL 15:20 - 1.83 ng/dL QC Level 3, lot 1003943, exp 8/31/2027 Mean 4.38 ng/dL SD 0.246 ng /dL QC Acceptability [3.888 - 4.872 ng/dL] 02/03/2026 12:57 - 3.55 ng/dL 15:14 - 3.71 ng/dL 02/05/2026 16:22 - 3.69 ng/dL On 2/3/2026 the following four patients had FT4 testing performed when 2 or more levels of quality control failed laboratory acceptability: 309906, 309763, 309782, 309912. On 2/5/2026 the following four patients had FT4 testing performed when 2 or more levels of quality control failed laboratory acceptability: 310415, 310304, 310267, 310283 ALT - Alanine transaminase QC Level 1, lot 14407241, exp 6/30/2027 Mean 26.5 U/L SD 1.42147 U /L QC Acceptability [23.65706 - 29.34294 U/L] 02/06/2026 14:31 - 30 U/L 16:04 - 30 U/L QC Level 2, lot 14407243, exp 6/30/2027 Mean 225.78161 U/L SD 7 .997 U/L QC Acceptability [209.78761 - 241.77561 U/L] 02/06/2026 14:40 - 243 U/L 16:05 - 243 U/L On 2/6/2026 the following 43 patients had ALT testing performed when 2 or more levels of QC failed laboratory acceptability: 310474, 310558, 310626, 310643, 310490, 340582, 310592, 310514, 310464, 310547, 310455, 310485, 310501, 310493, 310528, 310489, 310621, 310459, 310539, 310466, 310478, 310509, 310541, 310525, 310444, 310607, 310511, 310530, 310483, 310585, 310521, 310569, 310570, 310470, 310495, 310515, 310534, 310536, 310555, 310556, 310567, 310577, 310651. AST - Aspartate aminotransferase QC Level 1, lot

	14407241, exp 6/30/2027 Mean 49.15 U/L SD 2.275 U/L QC Acceptability [44.6 - 53.7 U/L] 02/05/2026 11:56 - 55 U/L 12:57 - 54 U/L 02/06/2026 16:04 - 55 U/L 20: 53 - 55 U/L QC Level 2, lot 14407242, exp 6/30/2027 Mean 149.55263 U/L SD 3.96 U/L QC Acceptability [141.63263 - 157.47263 U/L] 02/05/2026 12:00 - 159 U/L 12: 57 - 158 U/L 02/06/2026 14:36 - 159 U/L 16:04 - 161 U/L Level 3, ctrl 14407243, exp 6/30/2027 Mean 334.69136 U/L SD 11.995 U/L QC Acceptability [310.70136 - 358.68136 U/L] 02/05/2026 12:05 - 359 U/L 12:58 - 362 U/L On 2/5/2026 the following 53 patients had AST testing performed when 2 or more levels of quality control failed laboratory acceptability: 310355, 310431, 310307, 310424, 310356, 310276, 310294, 310337, 310381, 310346, 310262, 310327, 310305, 310360, 310310, 310273, 310289, 310258, 310379, 310311, 310239, 310297, 310416, 310339, 310368, 310428, 310296, 310237, 310432, 310435, 310413, 310285, 310246, 310420, 310243, 310266, 310406, 310319, 310240, 310451, 310343, 310282, 310402, 310272, 310300, 310312, 310324, 310332, 310373, 310375, 310382, 310388, 310449 On 2/6/2026 the following 43 patients has AST testing performed when 2 or more levels of quality control failed laboratory acceptability: 310474, 310558, 310626, 310643, 310490, 310582, 310592, 310514, 310464, 310547, 310455, 310485, 310501, 310493, 310528, 310489, 310621, 310459, 310539, 310466, 310478, 310509, 310541, 310525, 310444, 310607, 310511, 310530, 310483, 310585, 310521, 310569, 310570, 310470, 310495, 310515, 310534, 310536, 310555, 310556, 310567, 310577, 310651. 3. In an interview on 6/16 /2026 at 12:30 hours, in a patient exam room, the technical consultant confirmed that patients had testing performed when QC documentation was out of laboratory acceptability.
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: Review of laboratory humidity records, laboratory documentation, patient results, and interview, the laboratory failed to ensure corrective action was taken and documented for 10 of 41 days where the recorded humidity was outside of the laboratory specifications for the Sysmex hematology analyzer for records reviewed from January 2026 to February 2026. The findings included: 1. Review of the laboratory document titled "Specification of Analyzers, Operations Environmental Conditions" included the following operator specifications for the Sysmex hematology analyzer: Humidity: 30% - 85% 2. Review of the humidity log for January and February 2026 included the following 10 days the humidity was out of laboratory specifications: January 2026: 7 days 1/12/2026: 28% 1/13/2026: 28% 1/14/2026: 26% 1/15/2026: 26% 1/19/2026: 27% 1/20/2026: 27% 1/21/2026: 28% February 2026: 3 days 2/03/2026: 26% 2/19 /2026: 28% 2/20/2026: 28% Surveyor asked if corrective action was documented for the above days, and none was provided. 3. Review of patient test records included 427

	patients with hematology testing on the Sysmex XS1000i when the humidity was documented outside of the laboratory operating specifications. On 1/12/2026 39 patients had CBC testing on the Sysmex to include the following 5: 306884, 306925, 306929, 306945, 306952 On 1/13/2026 34 patients had CBC testing on the Sysmex to include the following 5: 307147, 307149, 307158, 307181, 307212 On 1/14/2026 16 patients had CBC testing on the Sysmex to include the following 5: 307461, 307464, 307492, 307501, 307524 On 1/15/2026 37 patients had CBC testing on the Sysmex to include the following 5: 307695, 307696, 307702, 307712, 307718 On 1/19/2026 49 patients had CBC testing on the Sysmex to include the following 5: 308127, 308047, 308186, 308062, 308102 On 1/20/2026 41 patients had CBC testing on the Sysmex to include the following 5: 308320, 308307, 308300, 308330, 308486 On 1/21/2026 44 patients had CBC testing on the Sysmex to include the following 5: 308608, 308672, 308718, 308587, 308543 On 2/03/2026 48 patients had CBC testing on the Sysmex to include the following 5: 309894, 309837, 309888, 309900, 309883 On 2/19/2026 42 patients had CBC testing on the Sysmex to include the following 5: 312656, 312599, 312526, 312579, 312506 On 2/20/2026 29 patients had CBC testing on the Sysmex to include the following 5: 312804, 312767, 312827, 312779, 312824 On 2/3/2026 48 patients had CBC testing on the Sysmex to include the following 5: 309866, 309911, 309926, 309931, 309935 4. In an interview on 6/16/2026 at 11:35 hours, in the office, testing personnel 1 confirmed corrective action had not been documented for the humidity operation specification variance for the Sysmex hematology analyzer.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory documentation, and interview, the laboratory failed to correct problems identified throughout the analytic system for testing hematology and chemistry for records reviewed from January 2026 to March 2026. The findings included: 1. Review of the laboratory policy titled "Quality Assurance Protocol Procedure" included the following monthly monitoring to be performed by the technical consultant (TC) and the medical director. "B. Monthly 1. Temperature logs 2. Instrument maintenance logs 3. Quality Control logs 4. Patient daily logs and results as a QA monitor request. 5. Specimen rejection log 6. Remedial action logs 7. Calibration-Calibration verification logs." 2. Review of laboratory quality control records included the following documentation of QC review, by the technical consultant, and issues identified without correction or remedial action: Total protein QC for January 2026 included the following days where QC failures were identified by the TC on 3/3/2026: 1/12/2026 Urea QC for January 2026 included the following days where QC failures were identified by the TC on 3/3/2026: 1/13/2026, 1 /30/2026 FT4 QC for February 2026 included the following days where QC failures were identified by the TC review (no date of review indicated), with the note "See if pts, tested!": 2/3/2026, 2/5/2026, 2/13/2026, 2/17/2026, 2/23/2026, 2/24/2026. Surveyor asked for documentation the TC followed up on the patients as the note indicated, and no documentation was provided. ALT QC for February 2026 included the following days where QC failures were identified by the TC review (no date of review indicated): 2/6/2026 AST QC for February 2026 included the following days where QC failures were identified by the TC review (no date of review indicated): 2/5

	/2026, and 2/6/2026. 3. In interviews with testing personnel one, and the technical consultant, remediation had not been performed for the QC failures. On 6/16/2026 at 12:30 hours, in an empty patient room, the technical consultant stated verbal instructions had been given to the testing personnel, and that TP1 failed to provide them with patients to perform remedial action, so it had not been completed.
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 review of laboratory policy and procedures, laboratory quality control records, and interview, the laboratory director failed to ensure overall management and oversite of laboratory operations to provide accurate and reliable patient results when test systems fail to meet laboratory acceptability requirements (see D6020) and failed to ensure patient test results were not reported until all corrective actions had taken place for test systems to ensure accurate and reliable results for records reviewed in 2026 (see D6024).
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory quality control records, laboratory instrument maintenance and, interview the laboratory director failed to ensure remedial action was taken when the chemistry test system failed to meet the laboratory acceptability for records reviewed in 2026, see D5481.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratorys established performance specifications are identified, and that patient test results are reported only when the system is functioning properly; This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory quality control records, laboratory instrument maintenance and, interview the laboratory director failed to ensure remedial action was taken when chemistry and hematology test systems failed to meet the laboratory acceptability for records reviewed in 2026, see D5781 and D5791.
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY

	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 laboratory policy and procedures, laboratory quality control records, and interview, the technical consultant failed to ensure technical oversight by ensuring remedial actions are taken when test systems fail to meet laboratory acceptability requirements (see D6043) and failed to ensure patient test results were not reported until all corrective actions had taken place for test systems to ensure accurate and reliable results for records reviewed in 2026 (see D6044).
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratorys established performance specifications; This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory quality control records, laboratory instrument maintenance and, interview the technical consultant failed to ensure remedial action was taken when chemistry and hematology test systems failed to meet the laboratory acceptability for records reviewed in 2026, see D5791 and D5781.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory quality control records, laboratory instrument maintenance and, interview the technical consultant failed to ensure remedial action was taken when the chemistry test system failed to meet the laboratory acceptability for records reviewed in 2026, see D5481.