Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0702573	06/30/2022
Name of Provider or Supplier	**Street Address, City, State**	
Family Medical Associates	42320 Hwy 195, Haleyville, AL	

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 recertification survey was conducted on 6/29/2022- 6/30/2022. An Immediate Jeopardy situation was determined based on failures in the analytical systems (493.1250) (refer to D5400). The facility was found to be NOT in compliance with the following Clinical Laboratory Improvement Amendments (CLIA) conditions: 42 CFR 493.1230 Condition: General Laboratory Systems. 42 CFR 493.1250 Condition: Analytic Systems 42 CFR 493.1403 Condition: Moderate Complexity Laboratory Director
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with Testing Personnel #1, the laboratory failed to review and evaluate PT results and implement corrective actions for failures. This affected four of eight PT events, reviewed by the surveyor. The findings include: 1. A review of the API PT records revealed the following unsatisfactory scores, in which the laboratory failed to implement and document corrective action: a) 2021 Chemistry 1st Event 1) Total Cholesterol - 60% 2) Blood Urea Nitrogen (BUN) - 20% (The laboratory documented remedial kit ordered, but failed to determine the cause for the failure and implement corrective actions.) b) 2021 Chemistry 3rd Event: 1) Total Bilirubin - 40% c) 2022 Chemistry 1st Event: 1) Calcium - 40% d) 2021 Hematology

	2nd Event: 1) MCH - 60% 2. During an interview on 06/29/2022 at 1:20 PM, Testing Personnel #1 confirmed corrective action was not documented for all scores less than 100%.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 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. This CONDITION is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with Testing Personnel #1, the laboratory failed to meet the General Laboratory systems as evidenced by: 1. The laboratory failed to verify the accuracy of chemistry analytes, assigned artificial scores by the PT provider (refer to D5215). 2. The laboratory failed to verify the accuracy at least twice a year for Folate, Ferritin, Vitamin D, and Vitamin B12, non-regulated analytes (refer to D5217).
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records, Proficiency Testing Policy, and an interview with Testing Personnel #1, the laboratory failed to verify accuracy of analytes assigned an artificial score of 100% due to results not graded for four of four Chemistry PT events. The findings include: 1. A review of the API PT records revealed the following results, which were not graded by the PT provider and not evaluated by the laboratory to verify accuracy: a) 2021 Chemistry 1st Event i) D-Dimer (CM-01 to CM-05) - Not graded due to less than 10 participants. ii) Alanine Transaminase (ALT) (CH-02) - Not graded due to no consensus. iii) Direct Bilirubin (CH-01) - Not graded due to no consensus. iv) Sodium (CH-02 and CH-04) - Not graded due to no consensus. v) Uric Acid (CH-01 to CH-05) - Not graded due to less than 10 participants. b) 2021 Chemistry 2nd Event: Uric Acid (CH-01 to CH-05) - Not graded due to less than 10 participants. c) 2021 Chemistry 3rd Event: Uric Acid (CH-01 to CH-05) - Not graded due to less than 10 participants. d) 2022 Chemistry 1st Event: i) Alanine Transaminase (ALT) (CH-03) - Not graded due to no consensus. ii) Sodium (CH-02 and CH-03) - Not graded due to no consensus. iii) Uric Acid (CH-01 to CH-05) - Not graded due to less than 10 participants. 2. A review of the Proficiency Testing Policy revealed "...Ungraded PT Surveys require internal assessment of performance, documented evaluation, and approval by the Medical Director or designee..." 3. During an interview on 06/29

	/2022 at 1:20 PM, Testing Personnel #1 confirmed the above noted results were not graded by API nor evaluated by the laboratory.
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 a review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with Testing Personnel #1, the laboratory failed to verify accuracy at least twice a year for Folate (FOL), Ferritin (FERR), Vitamin B12 (Vit B12) and Vitamin D (Vit D). This was noted from previous survey (04/27/2021) to current survey (06/30/2022). The findings include: 1. A review of the API PT records revealed the laboratory failed to assess the accuracy twice annually for non-regulated analyte; FOL, FERR, Vit B12, and Vit D. 2. During an interview on 06/29 /2022 at 1:20 PM, Testing Personnel #1 confirmed the laboratory failed to verify accuracy at least twice a year for the above listed analytes.
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 a review of Biolis maintenance records, operator's manuals, TOSOH and Biolis calibration/calibration verification records, Biolis and TOSOH quality control records, and an interview with Testing Personnel #1 and the Laboratory Director, the laboratory failed to monitor and evaluate the quality of performance of these Chemistry Analyzers, as evidenced by: 1) The laboratory failed to perform and document maintenance at the frequency specified by the manufacturer for the TOSOH (refer to D5429). 2) The laboratory failed to perform calibration verifications every six months for the TOSOH and Biolis (refer to D5439). 3) The laboratory failed to establish or verify acceptable ranges for quality control for analytes tested on the Biolis (refer to D5469). 4) The laboratory failed to provide quality control values (actual measurements) for analytes run on the TOSOH (refer to D5481). Due to the above mentioned laboratory failures, the surveyor determined an Immediate Jeopardy (IJ) exists, and notified the Laboratory Director on 6/30/2022 at 12:00 PM. This potentially affected approximately 112,953 analytes performed on patients annually (volume provided on CMS - 116 for Chemistry - Routine and Endocrinology).
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory

	must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of Sysmex XP 300 (Hematology) maintenance records, Biolis (Chemistry) maintenance records, operator's manuals, and an interview with Testing Personnel #1, the laboratory failed to perform and document maintenance at the frequency specified by the manufacturer. This was noted for four of four quarters from May 2021 to May 2022 for the System XP 300 and Biolis. The findings include: 1. A review of Sysmex XP 300 Operator's Manual revealed on page 12-1 "...Every 3 months (or every 4,500 samples) Clean SRV..." 2. A review of Sysmex XP 300 maintenance records revealed quarterly (every 3 months) maintenance was not documented from May 2021 to May 2022. 3. A review of Biolis Operator's Manual revealed the following in Chapter 5 Maintenance: a) Quarterly - ISE Pump Tubing Replacement b) Semi-annual - Replace the probe wash pump o'ring 4. A review of Biolis maintenance records revealed quarterly and semi-annual maintenance was not documented from May 2021 to May 2022. 5. During an interview on 06/30/2022 at 1: 12 PM, Testing Personnel #1 confirmed the required maintenance was not documented.
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 a review of TOSOH calibration/calibration verification records, Biolis calibration verification records, and an interview with Testing Personnel #1, the laboratory failed to perform calibration verifications every six month, from April 2021 to June 2022 for the TOSOH and Biolis (Chemistry analyzers). This is a repeat deficiency. The findings include: 1. A review of TOSOH calibration/calibration verification records revealed Prostatic Specific Antigen (PSA), Follicular Stimulating Hormone (FSH), and Ferritin each have a two-point calibration. Analytes calibrated

	with less than three calibrators must have a calibration verification performed every six months. The laboratory could not provide documentation of calibration verifications for PSA, FSH, and Ferritin since previous survey (04/27/2021). 2. A review of Biolis calibration verification records revealed calibration verifications were performed on 06/08/2021 and 05/10/2022, but did not include all analytes with less than three calibrators. The following analytes were not covered by the calibration verifications performed on the following dates: a) 06/08/2021 - Calcium, Cholesterol, Triglyceride, Creatinine, Carbon Dioxide, Glucose, Cholesterol HDL, Total Protein, Blood Urea Nitrogen, and Uric Acid b) 05/10/2022 - Blood Urea Nitrogen and Uric Acid The laboratory failed to perform the calibration verification in December 2021. 3. During an interview on 06/30/2022 at 1:00 PM, Testing Personnel #1 confirmed the above findings.
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 a review of the Sysmex XP 300 [Hematology analyzer] quality control records, patient test records, and an interview with Testing Personnel #1, the laboratory failed to analyze two control materials of different concentration for each day of patient testing for two days out of 365 days in 2022 on the Sysmex XP 300. The findings include: 1. A review of the quality control records revealed the following days patient testing occurred with no Sysmex XP 300 quality control performed: a) 02 /24/2022 - 27 patients Complete Blood Count (CBC) performed b) 02/25/2022 - 30 patients CBC performed 2. During an interview on 06/29/2022 at 1:00 PM, Testing Personnel #1 confirmed CBC testing was performed on patients with no documentation of quality controls for the days listed above.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

Based on a review of the Biolis (chemistry analyzer) Quality Control (QC) records, and an interview with the Laboratory Director and Testing Personnel #1, the laboratory failed to establish or verify acceptable ranges for Biolis chemistry analyzer for QC for Level 1 (Lot # 29796) and Level 2 (Lot # 21391) used for 12 months from May 2021 to May 2022. Review of two months of QC records found greater than 600 patient specimens, where the laboratory had not established nor verified the ranges for the Basic Metabolic Panel (BMP), Complete Metabolic Panel (CMP), Lipid Panel, and Uric Acid (UA) analytes from May 2021 to May 2022. The findings include: 1. A review of the Biolis QC records revealed the laboratory's acceptable ranges were wider than the package insert acceptable ranges for both Level 1 and 2. The following quality controls ranges were in use versus the package insert (Ser-T-Fy Level 1 and 2 Control Serum) ranges: I. Level 1 Level 1 (Lot number: 29796) (Lot number: 29796) Laboratory's Range Package Insert Range a) Alb: 1.3 to 3.3 1.8 to 2.8 b) ALKP: 53 to 121 70 to 104 c) ALT: 35 to 79 46 to 68 d) AST: 39 to 91 52 to 78 e) TBil: 0.3 to 1.5 0.6 to 1.2 f) BUN: 7 to 21 11 to 17 g) Ca: 5.0 to 11.8 6.7 to 10.1 h) Chol: 81 to 189 108 to 162 i) Creat: 0.7 to 1.5 0.6 to 1.4 j) Glu: 58 to 138 78 to 118 k) HDL: 6 to 86 37 to 55 l) TP: 2.5 to 5.7 3.3 to 4.9 m) Trig: 65 to 153 87 to 131 n) UA: 2.8 to 6.8 3.8 to 5.8 o) CO2: -2 to 18 3 to 13 p) Na: 120 to 144 126 to 138 q) K: 2.0 to 5.2 2.8 to 4.4 r) Cl: 70 to 102 79 to 93 II. Level 2 (Lot number: 21391) Level 2 (Lot number: 21391) Laboratory's Range Package Insert Range a) ALB: 2.5 to 5.7 3.3 to 4.9 b) ALKP: 163 to 379 217 to 325 c) ALT: 82 to 194 110 to 166 d) AST: 145 to 337 193 to 289 e) TBil: 2.1 to 8.1 3.6 to 6.6 f) BUN: 23 to 62 35 to 53 g) Ca: 7.0 to 16.6 9.4 to 14.2 h) Chol: 184 to 432 246 to 370 i) Creat: 3.3 to 9.7 4.3 to 7.9 j) Glu: 190 to 446 254 to 382 k) HDL: 8 to 232 86 to 128 l) TP: 4.3 to 10.3 5.8 to 8.8 m) Trig: 132 to 308 176 to 264 n) UA: 5.5 to 12.7 7.3 to 10.9 o) CO2: 13 to 33 18 to 28 p) Na: 161 to 193 163 to 175 q) K: 4.3 to 7.5 5.2 to 6.8 r) Cl: 94 to 130 109 to 127 2. Due to the ranges being wider than the package insert ranges, the following analytes were outside the package insert ranges for the following dates reviewed by the Surveyor in September 2021 and January 2022: a) Alb: Level 2 - 9/7/2021 b) ALKP: Level 1 - 1/4 /2022, 1/5/2022, and 9/14/2022 Level 2 - 9/7/2021 c) ALT: Level 2 - 9/7/2021 d) AST: Level 2 - 9/7/2021 e) TBil: Level 1 - 1/4/2022, 1/10/2022, 1/13/2022, 1/14 /2022, and 1/16/2022 f) BUN: Level 2 - 9/7/2021 g) Ca: Level 1 - 9/17/2021, 1/16 /2022, 1/18/2022, and 1/19/2022 Level 2 - 1/18/2022 h) Chol: Level 2 - 9/7/2021 and 1 /10/2022 i) Creat: Level 2 - 9/7/2021 j) Glu: Level 1 - 9/1/2021, 9/2/2021, 9/3/2021, 9 /5/2021, 9/7/2021, 9/8/2021, and 1/7/2022 Level 2 - 9/1/2021, 9/2/2021, 9/3/2021, 9/5 /2021, 9/7/2021, 9/8/2021, and 9/16/2021 k) HDL: Level 1 - 1/10/2022, 1/14/2022, 1 /18/2022, 1/24/2022, 1/25/2022, and 1/26/2022 Level 2 - 9/1/2021, 9/2/2021, 9/3 /2021, 9/5/2021, 9/7/2021, 9/8/2021, 9/9/2021, 9/10/2021, 9/11/2021, 9/13/2021, 9/14 /2021, 9/15/2021, 9/16/2021, 9/17/2021, 9/20/2021, 9/21/2021, 9/22/2021, 9/23/2021, 9/24/2021, 9/27/2021, 9/28/2021, 9/29/2021, and 9/30/2021 l) TP: Level 2 - 9/7/2021 m) Trig: Level 2 - 9/7/2021 n) UA: Level 2 - 9/7/2021 o) CO2: Level 1 - 9/14/2021, 1 /4/2022, 1/10/2022, 1/13/2022, and 1/14/2022 Level 2 - 9/22/2021, 9/23/2021, 1/4 /2022, 1/10/2022, 1/13/2022, 1/14/2022, 1/17/2022, and 1/24/2022 p) Na: Level 1 - 9 /15/2021, 9/20/2021, 9/21/2021, 1/16/2022, 1/20/2022, 1/27/2022, 1/28/2022, and 1/31 /2022 Level 2 - 9/7/2021, 9/15/2021, 1/16/2022, 1/17/2022, and 1/18/2022 q) K: Level 2 - 9/7/2021 r) Cl: Level 1 - 1/4/2022, 1/5/2022, 1/6/2022, 1/7/2022, 1/10/2022, 1/11/2022, 1/13/2022, 1/14/2022, 1/16/2022, 1/17/2022, 1/21/2022, 1/25/2022, 1/26 /2022, 1/27/2022, 1/28/2022, and 1/31/2022 Level 2 - 9/1/2021, 9/2/2021, 9/3/2021, 9 /5/2021, 9/7/2021, 9/8/2021, 9/9/2021, 9/10/2021, 9/11/2021, 9/13/2021, 9/14/2021, 9 /15/2021, 9/16/2021, 9/17/2021, 9/22/2021, 9/23/2021, 9/24/2021, 9/27/2021, 9/29 /2021, 1/4/2022, 1/5/2022, 1/6/2022, 1/10/2022, 1/11/2022, 1/18/2022, 1/19/2022, 1 /24/2022, 1/25/2022, 1/26/2022, and 1/28/2022 3. During an interview on 06/30/2022 at 1:20 PM, the Laboratory Director and Testing Personnel #1 confirmed the ranges

	were wider than the package insert ranges and did not know how these control ranges were established. The surveyor asked how long these two lots of controls had been used for testing. Testing Personnel #1 stated since at least May 2021. The Laboratory Director stated he was unaware the ranges were wider than those indicated by the package insert, but confirmed he reviewed QC monthly. According to the CMS-116 submitted during the recertification survey, the laboratory's estimated annual chemistry test volume is 112,953.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's 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 a review of Quality Control (QC) records for the TOSOH (Chemistry analyzer) and an interview with Testing Personnel #1, the laboratory failed to document all quality control procedures (actual measurements/values) for Chemistry testing [Vitamin B12, Folate, Ferritin, Thyroid Stimulating Hormone (TSH), Thyroxine (T4), Estradiol, Testosterone, Follicle Stimulating Hormone (FSH), Prostate Specific Antigen (PSA), Creatine Kinase MB (CK-MB), and Troponin] performed from May 2021 - May 2022. The findings include: 1. A review of the TOSOH quality control records revealed the laboratory documented the following from May 2021 to May 2022 on the "TOSOH 900 QC" log : a) Date performed b) Cardiac - check mark placed beside the day performed in this box c) Immunoassay - check mark placed beside the day performed in this box d) Corrective Action Documentation - periodic documentation of "Clinic closed", "Just Cardiacs today", "No Vitamin D", etc e) Tech - initials of personnel who performed the testing for that day 2. During an interview on 06/30/2022 at 1:30 PM, Testing Personnel #1 confirmed the laboratory could only provide the "TOSOH 900 QC" log, because the analyzer could only go back to 06/06/2022 to print out quality control records which provided the actual measurements and level of quality control run.
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 a review of the American Proficiency Institute (API) proficiency testing records, Sysmex XP 300 (Hematology) and Chemistry analyzers (Biolis and TOSOH) quality control records, and an interview with the Laboratory Director and Testing Personnel #1, the Laboratory Director failed to fulfill the Laboratory Director's responsibilities. This was noted from previous survey (04/27/2021) to current survey (06/30/2022). The findings include: 1. The Laboratory Director failed to ensure an approved corrective action plan was put in place when any proficiency testing results

	are found to be unacceptable or unsatisfactory (refer to D6019). 2. The Laboratory Director failed to ensure the quality control program was maintained to assure the quality of laboratory services provided (refer to D6020).
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing records and an interview with Testing Personnel #1, the Laboratory Director failed to ensure an approved corrective action plan was put in place when any proficiency testing results are found to be unacceptable or unsatisfactory. This was noted from the previous survey (04/27/2021) to current survey (06/30/2022). The findings include: 1. The laboratory failed to review and evaluate PT results and implement corrective actions for failures (refer to D2094).
D6020	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 program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of the Sysmex XP 300 Hematology analyzer and Chemistry analyzers (Biolis and TOSOH) quality control records and an interview with the Laboratory Director and Testing Personnel #1, the Laboratory Director failed to ensure the quality control program was maintained to assure the quality of laboratory services provided. This was noted from previous survey (04/27/2021) to current survey (06/30/2022). The findings include: 1. Failed to analyze two control materials of different concentration for each day of patient testing for two days out of 365 days in 2022 on the Sysmex XP 300 (refer to D5447). 2 . Failed to establish or verify acceptable ranges for quality control for analytes tested on the Biolis (refer to D5469). 3. Failed to provide quality control values (actual measurements) for analytes run on the TOSOH (refer to D5481).