Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 01D0702573	**(X3) Date Survey Completed** 04/27/2021
Name of Provider or Supplier Family Medical Associates	**Street Address, City, State** 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**
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records, and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to ensure proficiency testing samples were rotated between all personnel who performed patient testing. This was noted on three out of four 2020 -2021 Chemistry Events and three out of three 2020 Hematology Events. The findings include: 1. A review of API attestation statements revealed Testing Personnel #1 had performed all the testing on three of four of the 2020 -2021 Chemistry surveys, and Testing Personnel #1 had performed all testing on three of three of the 2020 Hematology surveys. 2. During an interview on 04/27/2020 at 12:35 PM, Testing Personnel #1 confirmed Proficiency Testing was not rotated since 2020 1st Event Chemistry and 2019 3rd Event Hematology due to previous failures by Testing Personnel #2 and #3. Testing Personnel #2 and #3 have been testing patient samples during 2020 and 2021.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty,

	subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on a review of Proficiency Testing records and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to successfully participate in Chemistry - Blood Urea Nitrogen (BUN) testing for two of three consecutive events (Event #2 of 2020 and Event #1 2021). The failures resulted in an initial unsuccessful participation for the laboratory. The findings include: 1. A review of the proficiency testing revealed the laboratory scored twenty percent (20%) for Event #2 2020 and twenty percent (20%) for Event #1 2021 for Blood Urea Nitrogen (BUN) - Chemistry. 2. During an interview on 04/27/2021 at 12:30 PM, Testing Personnel #1 confirmed the laboratory failed to successfully participate in two of three consecutive events for BUN - Chemistry.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of Proficiency Testing records and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to successfully participate in Chemistry - Blood Urea Nitrogen (BUN) testing for two of three consecutive events (Event #2 of 2020 and Event #1 2021). The failures resulted in an initial unsuccessful participation for the laboratory. The findings include: 1. Refer to D2016.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of Proficiency Testing records and an interview with Testing Personnel #1, the Laboratory failed to verify the accuracy of D-Dimer that was not evaluated by American Proficiency Institute (API). This was noted on seven out of eight 2018 - 2020 Chemistry - Core Proficiency Testing Events. The findings include:

	1. A review of Proficiency Testing records revealed 2019, 2020 Events #1, #2, #3, and 2021 Event #1 results obtained on proficiency testing were not graded for D-Dimer and the laboratory failed to perform a self-evaluation of the results. 2. During an interview on 04/27/2021 at 12:30 PM, Testing Personnel #1 confirmed the above events were not graded by API and a self evaluation of the results were not performed.
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 the PSA (Prostatic Specific Antigen) and FSH (Follicular Stimulating Hormone) calibration and calibration verification records for the Tosoh AIA-360, calibration verification records for the Biolis 24i, and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to perform calibration verifications every six months. This was noted as missing opportunities for five out of six calibration verification from September 2018 to April 2021 for the Tosoh AIA-360 and four out of six calibration verification from September 2018 to April 2021 for the Biolis 24i. This is a repeat deficiency for the Tosoh AIA-360. The findings include: 1. A review of the records for the Tosoh revealed PSA and FSH each have a two-point calibration. Analytes calibrated with less than three calibrators must have a calibration verification performed every six months. 2. A review of the Chemistry records revealed a calibration verification was performed on 09/27/2018 for PSA and FSH and none thereafter. 3. A review of the calibration verification records for the Biolis 24i revealed the calibration verification was not performed in 2019. The calibration verification was performed on 09/24/2018, 01/29/2020, 08/05 /2020, and 04/19/2021. Not all analytes had calibration verification performed each time the calibration verification was performed. The following analytes were not performed for the following dates: a) 08/05/2020 - Triglyceride, Total Cholesterol, Creatinine, Glucose, Cholesterol HDL, Total Protein, Carbon Dioxide, and Uric Acid. b) 04/19/2021 - Triglyceride, Total Cholesterol, Creatinine, Glucose, Cholesterol HDL, Total Protein, Carbon Dioxide, and Uric Acid. 4. During an interview on 04/27 /2021 at 3:55 PM, Testing Personnel #1 confirmed no other calibration verifications

	were performed for PSA and FSH after 09/27/2018 and confirmed the above findings for the calibration verification for Biolis 24i.
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 a review of personnel evaluation records and an interview with Testing Personnel #1, the surveyor determined the Technical Consultant (also the Laboratory Director) failed to evaluate and document the performance of individuals, failed to assure training for serum Human Chorionic Gonadotropin, and failed to review training/evaluations for individuals. This affected three of three testing personnel. This is a repeat deficiency. The findings include: 1. Refer to D6045. 2. Refer to D6053. 3. Refer to D6054.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on a review of personnel evaluation records and an interview with Testing Personnel #1, the Technical Consultant failed to assure training and evaulations were performed for serum Human Chorionic Gonadotropin and failed to review the initial trainings and semiannual evaluation performed on employees. This was noted on three out of three employees since the previous survey. This is a repeat deficiency. The findings include: 1. A review of personnel evaluation records revealed the initial training/evaulations performed for Testing Personnel #1, #2, and #3 did not include serum Human Chorionic Gonadotropin and as evidenced by lack of Technical Consultant's signature. Testing Personnel #1's initial evaluation was performed on 08 /05/2018 and was performed/reviewed by previous Testing Personnel. Testing Personnel #2's semiannual evaluation was performed on 03/20/2018 and was performed/reviewed by previous Testing Personnel. Testing Personnel #3's initial evaluation was performed on 12/31/2019, and was performed/reviewed by Testing Personnel #1. 2. During an interview on 04/27/2021 at 12:20 PM, Testing Personnel #1 confirmed the above findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: Based on a review of personnel evaluation records and an interview with Testing Personnel #1, the Technical Consultant failed to evaluate and document the performance of individuals at least semiannually during the first year of performing chemistry and hematology patient testing. This was noted on two out of two new employees since the previous survey. The findings include: 1. A review of personnel evaluation records revealed the semiannual performance was not evaluated or documented for Testing Personnel #1 and #3. Testing Personnel #1's initial training was performed on 08/05/2018 and Testing Personnel #3's initial training was performed on 12/31/2019. 2. During an interview on 04/27/2021 at 12:20 PM, Testing Personnel #1 confirmed the semiannual evaluations were not performed on the above testing personnel.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of personnel evaluation records and an interview with Testing Personnel #1, the Technical Consultant failed to evaluate and document the performance of individuals at least annually after the first year of performing chemistry and hematology patient testing. This was noted on three out of three employees since the previous survey. This is a repeat deficiency. The findings include: 1. A review of personnel evaluation records revealed the annual performance was not evaluated or documented for Testing Personnel #1, #2, and #3. Testing Personnel #1's initial evaluation was performed on 08/05/2018, after the initial evaluation no other evaluations were performed and documented. Testing Personnel #2's semiannual evaluation was performed on 03/20/2018, after the semiannual evaluation no other evaluations were performed and documented. Testing Personnel #3's initial evaluation was performed on 12/31/2019, after the initial evaluation no other evaluations were performed and documented. 2. During an interview on 04/27 /2021 at 12:20 PM, Testing Personnel #1 confirmed the above findings.