Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0669380	03/24/2021
Name of Provider or Supplier	**Street Address, City, State**	
Family Medical Center	1415 Mosley Dr, Thomasville, 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
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on reviews of proficiency testing (PT) records, quality assurance (QA) records, personnel records, and an interview, the laboratory failed to ensure the corrective actions taken effectively remediated problems identified in the general laboratory systems. This was noted from August 2018 to January 2021. This is a repeat deficiency. The findings include: 1. A review of the 2018 - 2020 AAFP (American Academy of Family Physicians) Proficiency Testing records revealed the laboratory failed four out of seven of Urine Sediment PT challenges, and three out of seven Vaginal Wet Prep PT challenges as follows: a) 2019 - A: Urine Sediment score of 50% and Vaginal Wet Prep score of 50% b) 2019 - B: Urine Sediment score of 75% c) 2019 - C: Vaginal Wet Prep score of 50% d) 2020 - A: Urine Sediment score of 50% e) 2020 - B: Urine Sediment score of 75% f) 2020 - C: Vaginal Wet Prep score of 50% 2. The corrective actions documented for the above listed failures revealed the following: a) 2019 - A: "We agree we got the answers wrong. Pictures were blurry and not clear." b) 2019 - B: "We agree we were wrong. We submitted the wrong answer." c) 2019 - C: "We mistakenly pressed the wrong answer." It was noted by the surveyor the result documented on the program forms was the result submitted to AAFP. d) 2020 - A: "We agree we were wrong." e) 2020 - B: "We all agree that it was yeast/fungi instead of fecal/contamination." The results were not signed by the Laboratory Director on this event. f) 2020 - C: "We agree it was RBC and not WBC." 3. A review of the 2019 - 2020 testing personnel records (four out of four individuals)

	revealed semiannual evaluations and annual evaluations were not reviewed by the Technical Consultant or Laboratory Director. The forms documented the name of the Testing Personnel and "Y" (Yes) or check marks by each item on the Semi-Annual and Annual Laboratory Test Personnel Evaluation - Personnel Observation Checklist. 4. A review of August 2018 - January 2021 monthly Quality Assurance Checklist covered Proficiency Testing and Personnel Policies. The reviewer always answered "Y"(Yes) or checked the box. No problems or corrective action documented on the QA Checklist forms, nor were they reviewed (by evidence of signature) by the Laboratory Director or Technical Consultant. 5. During an interview on 03/24/2021 at 12:45 PM, the surveyors discussed the above findings with the Laboratory Director, Testing Personnel #1, and #4.
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 the review of procedure manual, lack of maintenance records, and an interview with Testing Personnel #1, the laboratory failed to document daily maintenance on the Microscope and monitor rotator speed for the centrifuge. This was noted from August 2018 - February 2021. The findings include: 1. A review of the procedure manual revealed a procedure "Daily Cleaning of the Microscope" that covered how the microscope should be cleaned daily. The KOVA Stain package insert revealed in step 1 the centrifuge revolutions per minute (rpm) should be approximately 1500 revolutions per minute. 2. A review of the maintenance records revealed there was no form to document the maintenance of the Microscope or centrifuge. 3. During an interview on 03/24/2021 at 12:20 PM, Testing Personnel #1 stated they did not have a form to document daily maintenance of the microscope. For the centrifuge Testing Personnel #1 stated they didn't know how to check the speed of the centrifuge and could not locate the user manual.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on a review of quality control records and an interview with Testing Personnel #1, the laboratory failed to have a control procedure for Urine Sediment examinations. This was noted from August 2018 - January 2021. The findings include: 1. A review of quality control records revealed the laboratory has not been performing quality controls on urine sediment examinations. 2. During an interview on 03/24/2021 at 12: 30 PM, Testing Personnel #1 confirmed the laboratory has not performed quality control for urine sediment examinations.
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 reviews of proficiency testing (PT) records, quality assurance (QA) records, personnel records, and an interview, the Laboratory Director did not fulfill the Laboratory Director's responsibilities; 1) to ensure corrective action was implemented for failed PT 2) to ensure personnel was competent for patient testing 3) to ensure a QA program was implemented to monitor laboratory processes and identify problems. This was noted from August 2018 to January 2021. The findings include: 1. A review of the 2018 - 2020 AAFP (American Academy of Family Physicians) Proficiency Testing records revealed the laboratory failed four out of seven of Urine Sediment PT challenges, and three out of seven Vaginal Wet Prep PT challenges. However, the Laboratory Director effect corrective actions were implemented. Refer to D6018. 2. A review of the 2019 - 2020 testing personnel records revealed semiannual evaluations and annual evaluations were not reviewed by the Laboratory Director, as evidence by no signature. Refer to D6029. 4. A review of August 2018 - January 2021 monthly Quality Assurance Checklist covered Proficiency Testing and Personnel Policies. The reviewer always answered "Y"(Yes) or checked the box. No problems or corrective action documented on the QA Checklist forms, nor were they reviewed by the Laboratory Director. Refer to D6019. 5. During an interview on 03/24/2021 at 12:45 PM, the surveyors discussed the above findings with the Laboratory Director, Testing Personnel #1, and #4.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by:

	Based on reviews of proficiency testing (PT) records, and an interview, the Laboratory Director failed to identify any problems that require corrective actions. This was noted six out of seven Proficiency Testing events reviewed. The findings include: 1. A review of the 2018 (Event C) - 2020 AAFP (American Academy of Family Physicians) Proficiency Testing records revealed the laboratory failed four out of seven of Urine Sediment PT challenges, and three out of seven Vaginal Wet Prep PT challenges as follows: a) 2019 - A: Urine Sediment score of 50% and Vaginal Wet Prep score of 50% b) 2019 - B: Urine Sediment score of 75% c) 2019 - C: Vaginal Wet Prep score of 50% d) 2020 - A: Urine Sediment score of 50% e) 2020 - B: Urine Sediment score of 75% f) 2020 - C: Vaginal Wet Prep score of 50% 2. The corrective actions documented for the above listed failures revealed the following: a) 2019 - A: "We agree we got the answers wrong. Pictures were blurry and not clear." b) 2019 - B: "We agree we were wrong. We submitted the wrong answer." c) 2019 - C: "We mistakenly pressed the wrong answer." It was noted by the surveyor the result documented on the program forms was the result submitted to AAFP. d) 2020 - A: "We agree we were wrong." e) 2020 - B: "We all agree that it was yeast/fungi instead of fecal/contamination." The results was not signed by the Laboratory Director on this event. f) 2020 - C: "We agree it was RBC and not WBC." 3. During an interview on 03 /24/2021 at 12:45 PM, the surveyors discussed the above findings with the Laboratory Director, Testing Personnel #1, and #4.
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 reviews of proficiency testing (PT) records, quality assurance (QA) records, and an interview, the Laboratory Director failed to ensure corrective action plans were established and followed when any proficiency testing results were found to be unacceptable. This was noted on six out of seven Proficiency Testing events reviewed. The findings include: 1. A review of the 2018 (Event C) - 2020 AAFP (American Academy of Family Physicians) Proficiency Testing records revealed the laboratory failed four out of seven of Urine Sediment PT challenges, and three out of seven Vaginal Wet Prep PT challenges as follows: a) 2019 - A: Urine Sediment score of 50% and Vaginal Wet Prep score of 50% b) 2019 - B: Urine Sediment score of 75% c) 2019 - C: Vaginal Wet Prep score of 50% d) 2020 - A: Urine Sediment score of 50% e) 2020 - B: Urine Sediment score of 75% f) 2020 - C: Vaginal Wet Prep score of 50% 2. The corrective actions documented for the above listed failures revealed the following: a) 2019 - A: "We agree we got the answers wrong. Pictures were blurry and not clear." b) 2019 - B: "We agree we were wrong. We submitted the wrong answer." c) 2019 - C: "We mistakenly pressed the wrong answer." It was noted by the surveyor the result documented on the program forms was the result submitted to AAFP. d) 2020 - A: "We agree we were wrong." e) 2020 - B: "We all agree that it was yeast/fungi instead of fecal/contamination." The results was not signed by the Laboratory Director on this event. f) 2020 - C: "We agree it was RBC and not WBC." The corrective actions documented above failed to remediate the testing personnel for

	performing Urine Sediments and Vaginal Wet Preps. 3. A review of August 2018 - January 2021 monthly Quality Assurance Checklist covered Proficiency Testing. The reviewer always answered "Y"(Yes) or checked the box. No problems or corrective action documented on the QA Checklist forms, nor were they reviewed by the Laboratory Director. 4. During an interview on 03/24/2021 at 12:45 PM, the surveyors discussed the above findings with the Laboratory Director, Testing Personnel #1, and #4.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of the testing personnel records and an interview, the Laboratory Director failed to ensure all personnel have the appropriate education, to review semiannual and annual evaluations for the testing personnel, and ensure remedial training was performed with documentation of additional assessments demonstrating the competency of the testing personnel after failures on six out of seven 2018 - 2020 proficiency testing surveys. This is a repeat deficiency. The findings include: 1. A review of the testing personnel records revealed the following: a) Testing Personnel #1: Previously qualified personnel; Evaluations performed on 01/2019, 03/08/2019, 05 /05/2020, and 10/06/2020 b) Testing Personnel #2: Education on file; Training completed on 05/05/2020; Evaluation performed on 11/07/2020 c) Testing Personnel #3: Education not on file; Training completed on 05/05/2020; Evaluation performed on 01/18/2021 d) Testing Personnel #4: Education not on file; Training completed on 05/05/2020; Evaluation performed on 09/10/2020 A review of the evaluation forms "Semi-Annual and Annual Laboratory Test Personnel Evaluation - Personnel Observation Checklist" completed revealed the Technical Consultant or Laboratory Director did not review the evaluations listed above. The forms documented the name of the Testing Personnel and "Y" (Yes) or check marks by each item on the form. 2. After Proficiency Testing failures (refer to D5293) the surveyor noted there was no documentation of remedial training. 3. During an interview on 03/24/2021 at 12:45 PM, the Laboratory Director confirmed the evaluations were not signed.
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 reviews of proficiency testing (PT) records, personnel records, and an

	interview, the Technical Consultant did not fulfill the Technical Consultant's responsibilities; 1) to ensure training needs are identified, and assure each individual performing patient testing received training and educational in-services. 2) to ensure evaluations are performed on testing personnel at least semiannually during the first year of patient testing. 3) to ensure evaluations are performed on testing personnel at least annually. This was noted from August 2018 to January 2021 for two out of two Technical Consultants listed on the CMS-209 form. The findings include: 1. A review of the 2018 - 2020 AAFP (American Academy of Family Physicians) Proficiency Testing records revealed the laboratory failed four out of seven of Urine Sediment PT challenges, and three out of seven Vaginal Wet Prep PT challenges. However, the Technical Consultant failed to ensure training needs were identify and assure each individual performing patient testing received training and educational in-services. Refer to D6045. 2. A review of the personnel records revealed the Technical Consultant failed to evaluate the performance of testing personnel at least semiannually during the first year of patient testing. Refer to D6053. 3. A review of the personnel records revealed the Technical Consultant failed to evaluate the performance of testing personnel at least annually. Refer to D6054 4. During an interview on 03/24/2021 at 12:45 PM, the surveyors discussed the above findings with the Laboratory Director, Testing Personnel #1, and #4.
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 reviews of proficiency testing (PT) records, and an interview, the Technical Consultant failed to identify training needs and assure each individual performing patient testing received training and educational in-services. This was noted from August 2018 to January 2021. The findings include: 1. A review of the 2018 - 2020 AAFP (American Academy of Family Physicians) Proficiency Testing records revealed the laboratory failed four out of seven of Urine Sediment PT challenges, and three out of seven Vaginal Wet Prep PT challenges. No remedial training was performed for individuals who failed a PT event. Refer to 5293. 2. During an interview on 03/24/2021 at 12:45 PM, the surveyors discussed the above findings with the Laboratory Director, Testing Personnel #1, and #4.
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 the testing personnel records and an interview, the Technical Consultant failed to evaluate the performance of testing personnel at least semiannually during the first year of patient testing. This was noted on three out of

	four testing personnel. The findings include: 1. A review of the testing personnel records revealed the following: a) Testing Personnel #2: Training completed on 05/05 /2020; Evaluation performed on 11/07/2020 b) Testing Personnel #3: Training completed on 05/05/2020; Evaluation performed on 01/18/2021 c) Testing Personnel #4: Training completed on 05/05/2020; Evaluation performed on 09/10/2020 A review of the evaluation forms "Semi-Annual and Annual Laboratory Test Personnel Evaluation - Personnel Observation Checklist" completed revealed the Technical Consultant did not review the evaluations listed above. The forms documented the name of the Testing Personnel and "Y" (Yes) or check marks by each item on the form. 2. During an interview on 03/24/2021 at 12:45 PM, the Laboratory Director /Technical Consultant confirmed the evaluations were not signed.
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 the testing personnel records and an interview, the Technical Consultant failed to evaluate the performance of testing personnel at least annually. This was noted on one out of four testing personnel. The findings include: 1. A review of the testing personnel records revealed the following: a) Testing Personnel #1: Evaluations performed on 01/2019, 03/08/2019, 05/05/2020, and 10/06/2020 A review of the evaluation forms "Semi-Annual and Annual Laboratory Test Personnel Evaluation - Personnel Observation Checklist" completed revealed the Technical Consultant or Laboratory Director did not review the evaluations listed above. The forms documented the name of the Testing Personnel and "Y" (Yes) or check marks by each item on the form. 2. During an interview on 03/24/2021 at 12:45 PM, the Laboratory Director/Technical Consultant confirmed the evaluations were not signed.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with Testing Personnel #1, the laboratory failed to maintain qualifying education requirements for personnel performing patient testing. This was noted on two out of four testing personnel. The

	findings include: 1. A review of the personnel records revealed that Testing Personnel #3 and #4 did not have qualifying education requirements. Testing Personnel #3 had no educational documentation and Testing Personnel #4 had Medical Assistant certification on file. 2. During an interview at 12:20 PM on 03/24/2021, Testing Personnel #1 confirmed that Testing Personnel #3 and #4 did not have their diploma onsite.