Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0669380	08/07/2018
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, the laboratory procedure manual, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to ensure the corrective actions taken effectively remediated problems identified in the general laboratory systems. The findings include: 1. A review of the 2016-2017 AAFP (American Academy of Family Physicians) PT records revealed the laboratory failed three out of six Vaginal Wet Prep PT challenges, and four out six of Urine Sediment Exam PT challenges as follows: A) 2016-A: Vaginal Wet Prep with a score of 50% (performed by a previous TP) B) 2016-B: Urine Sediment Exam with a score of 50% (performed by TP #2) C) 2016-C: Vaginal Wet Prep with a score of 50% and Urine Sediment Exam with a score of 75% (performed by TP #4) D) 2017-A: Vaginal Wet Prep with a score of 0% and Urine Sediment Exam with a score of 75% (performed by TP #1) E) 2017-C: Urine Sediment Exam with a score of 50% (performed by TP #4) 2. The only corrective action documented for the above noted failures was the testing personnel reviewed the returned results, and documented their consensus of agreement on the identification of the elements. 3. A review of the 2016-2017 monthly QA Checklist under PROFICIENCY TESTING included, "A corrective action was taken, has the problem been corrected over time". The reviewer always answered "Y" [Yes], or checked the box. No problems were identified by the laboratory. 4. A review of the 2016 - 2018 records for the testing personnel revealed

	the following: A) TP #1: Training completed on 9/23/2016; Competency assessment checklists dated 1/2017, 7/2017, 1/2018, all signed only by TP #1 B) TP #2: Competency assessment checklists dated 1/2017, 7/2017, 1/2018 with no signature C) TP #4: Competency assessment checklists dated 7/2016, 1/2017, 7/2017, 1/2018, all signed only by TP #4 The surveyor noted none of the competency assessments were performed or signed by the Laboratory Director (also Technical Consultant #1), or the second Clinical Consultant (also Technical Consultant #2). The surveyor further noted there was no documentation of remedial training with additional assessments to ensure testing personnel correctly identified "unknown" microscopic elements, following the PT failures (as noted in #1 above). 5. A review of the Laboratory Policy and Procedure manual under Laboratory Personnel on page 13 revealed, "...VIII. Criteria Used for Competency Evaluations ... B. ... 3. "Unknowns"-In addition to participation in PT programs, "unknowns" ... will be used to evaluate testing personnel. ...". 6. During an interview on 8/7/2018 at 2:45 PM, TP #1 was asked if the corrective action after the PT failure had been effective to ensure the failures would not recur. TP #1 stated she believed the corrective action she documented was all that was required. The surveyor then asked who performed the competency assessments, and how competency was assessed. TP #1 stated TP #2 had performed this task until the middle of 2017, and now she currently assessed competency by reviewing work the testing personnel had performed over the last year. TP #1 further stated she was not really sure about how she should be evaluating competency. When asked if staff were ever evaluated using "unknown" specimens (such as using photomicrographs from old PT surveys or the internet) as per the criteria cited in their policy (see #4 above), TP #1 stated they were not doing that. Thus the above noted findings were confirmed.
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 laboratory procedure manual, personnel records, and an interview with Testing Personnel (TP) #1, the surveyor determined the Laboratory Director (or a qualified designee such as the Technical Consultant) failed to perform /review competency assessments 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 five out of six of the 2016-2017 proficiency testing surveys. The findings include: 1. A review of the Laboratory Policy and Procedure manual under Laboratory Personnel on page 13 revealed, "... VIII. Criteria Used for Competency Evaluations ... B. ... 3. "Unknowns"-In addition to participation in PT programs, "unknowns" ... will be used to evaluate testing personnel. ...". 2. A review of the 2016 - 2018 testing personnel records revealed the following: A) TP #1: Training completed on 9/23/2016; Competency assessment checklists dated 1/2017, 7/2017, 1/2018, all signed by only TP #1 B) TP #2:

	Competency assessment checklists dated 1/2017, 7/2017, 1/2018 with no signature C) TP #4: Competency assessment checklists dated 7/2016, 1/2017, 7/2017, 1/2018, all signed by only TP #4 The surveyor noted none of the competency assessments were performed or signed by the Laboratory Director (also Technical Consultant #1), or the second Clinical Consultant (also Technical Consultant #2). The surveyor further noted there was no documentation of remedial training with additional assessments to ensure testing personnel correctly identified "unknown" microscopic elements, following failures on five out of six of the 2016-2017 proficiency testing surveys (refer to D5293). 3. During an interview on 8/7/2018 at 3:00 PM, TP #1 was asked who performed the competency assessments, and how competency was assessed. TP #1 stated TP #2 had performed this task until the middle of 2017, and now she currently assessed competency by reviewing work the testing personnel had performed over the last year. TP #1 then stated she was not really sure about how she should be evaluating competency. When asked if staff were ever evaluated using "unknown" specimens (such as using photomicrographs from old PT surveys or the internet) as per the criteria cited in their policy (see #1 above), TP #1 stated they were not doing that. Thus the above noted findings were substantiated. SURVEYOR:Laura T. Williams, BS, MT (ASCP)Licensure and Certification Surveyor