Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0710758	07/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Family Medical Center	1024 Martin Luther King Drive, Marks, MS	

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
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on Cell Dyn Emerald calibration documentation and interview with testing personnel at 3:00 pm on the day of survey, 7/25/18, the laboratory failed to perform the required calibration on the Cell Dyn Emerald hematology analyzer at least once every 6 months as required by the manufacturer. Since the last survey on 7/19/16, calibration was documented as performed on 1/9/17 and 1/29/18. This time frame exceeds the 6 month requirement.
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 review of Proficiency Testing (PT) records and lack of corrective action documentation available for review, the laboratory director failed to ensure an approved corrective action plan was followed when the laboratory scored below 80% (unacceptable or unsatisfactory.) Findings include: 1. 1st Event 2017: Cell ID/WBC Diff was scored 20%. 2. 2nd Event 2017: RBC was scored 20%. THIS IS A REPEAT DEFICIENCY
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor review of written quality assessment (QA) policies and procedures, the laboratory director failed to ensure that a comprehensive QA program designed to monitor and evaluate the overall quality of the total testing process (General Laboratory, Preanalytic, Analytic, and Postanalytic Systems) was maintained. Findings include: The laboratory director had not ensured that these portions of the written QA program were being followed. 1. Proficiency Testing - The technical consultant did not review results within one week of receipt as stated in the QA plan for the following reports: 2016-3rd Event 2017-1st Event 2017-2nd Event 2017-3rd Event 2. Performance and periodic review of Quality Control (QC), Proficiency Testing (PT), and Patient Results - The technical consultant did not review and sign every 3 months as stated in the QC policy for the following: Maintenance Proficiency Testing Results Calibration See D6049 THIS IS A REPEAT DEFICIENCY
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of laboratory records (including Quality Control, Calibrations, Temperatures, Maintenance, and Proficiency Testing) since the last survey 7/19/16, through the day of survey 7/25/18, and confirmation with staff at 3:30 pm, the technical consultant listed on the Centers for Medicare and Medicaid (CMS) 209 form before the day of the survey failed to document as reviewed the laboratory records. The following records were not reviewed by the technical consultant appointed during that time: 1. Cell-Dyn Emerald maintenance: 7/19/16 through 1/29/18 2. Cell-Dyn Emerald Quality Control (QC): October 2016 through April 2018 3. Cell-Dyn

	Emerald Calibration: 1/9/17 4. Proficiency Testing Results: 2016-3rd Event, 2017-1st Event, 2017-2nd Event, 2017-3rd Event THIS IS A REPEAT DEFICIENCY