Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D1078297	09/16/2020
Name of Provider or Supplier	**Street Address, City, State**	
Corinth Family Medical Center	1921 Droke Road, Corinth, 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
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 surveyor review of proficiency testing (PT) records for the 2nd and 3rd events of 2019, 1st and 2nd events of 2020, the (CMS) Centers for Medicare & Medicaid Services 209 personnel form and confirmation by laboratory testing personnel (TP) #2 at 3:00 pm on 9/16/2020, the laboratory failed to ensure that all testing personnel who routinely perform CBC (complete blood count) testing participated in proficiency testing for CBC's. Findings include: 1. Review of attestation statements for proficiency testing revealed that all PT testing for CBC was performed by TP#2. 2. The CBC proficiency testing was not rotated between TP#1 and TP#2 who routinely test CBC's. 3. During an interview with TP #2 at 3:00 pm on the day of survey she confirmed that all CBC proficiency testing events had been performed by her.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

	This STANDARD is not met as evidenced by: Based on review of laboratory specimen collection and labeling policies, observation of CBC (Complete Blood Count) samples, and interview with Testing Personnel (TP) at 2:00 pm on the day of survey, 9/16/20, the laboratory failed to follow the written policy and procedure for labeling of patient specimens. Findings include: 1. Review of the laboratory's written labeling policy states specimens will be labeled with the patient's full name or chart number, date and time of collection. 2. Hematology microtubes observed in the lab were labeled with the patient's initials and date of birth only. 2. Interview with TP #1 and #2 at 2:00 pm on the day of survey confirmed CBC specimens were not labeled according to the laboratory labeling policy.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on Cell Dyn 1800 hematology analyzer records available the day of survey and interview with Testing Personnel (TP) at 2:30 pm, the laboratory director failed to ensure that verification procedures were performed during installation of the hematology analyzer to determine accuracy, precision and reportable ranges. The Cell Dyne 1800 was installed for CBC (complete blood count) testing in February 2019. Findings: 1. Review of installation records for the Cell Dyn 1800 hematology analyzer revealed only a calibration and correlation with another clinic were performed during installation. There was no documentation of performance verification to include accuracy, precision and reportable ranges on the day of survey to ensure the analyzer was properly installed and adequate for patient testing. 2. Interview with TP#1 and TP#2 at 2:30 pm on the day of survey revealed that the installation records available included all testing done during installation. There was no documentation of verification that the normal ranges in use were appropriate for the laboratory's patient population.
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 review of the Cell Dyn 1800 hematology analyzer maintenance records from its installation on 2/11/19 until the day of survey, 9/16/20, and interview with laboratory Testing Personnel (TP) #2 as listed on the CMS Personnel Form 209 at 3: 30 pm on the day of survey, the laboratory failed to document as performed the

	monthly maintenance on the Cell Dyn 1800 analyzer as required by the manufacturer. Findings include: 1. Review of the Cell Dyn 1800 records revealed the following maintenance--required monthly--had only been documented as performed once on the hematology analyzer since installation on 2/11/19. performed in March 2019: a. Rinse Lyse Inlet Lines b. Rinse Reagent Inlet Lines 2. Interview with the laboratory TP #2 at 3:30 pm on the day of survey confirmed monthly maintenance was not documented as performed on the Cell Dyn 1800 for the period from April 2019 through September 2020.
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 from 2018, 2019 and 2020 and lack of 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. Review of the Casper Proficiency report and the laboratory proficiency result records for 2018, 2019 and 2020, confirmed the following proficiency results had scores less than 80% and were not documented as reviewed or corrective action performed: a. HCT - 3rd event 2019 - 60% b. MCV - 3rd event 2019 - 40%
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 review of the personnel testing records on 9/16/20 (day of survey) and the lack of education documentation, the laboratory director had not ensured that testing personnel (TP) #2 and #3 as listed on the CMS (Centers for Medicare and Medicaid Services) 209 personnel form had the appropriate education to perform moderate complexity testing prior to testing patients. Findings Include: 1. Review of the personnel records available the day of survey, TP #2 was trained and started testing on 6/1/18, according to QC (quality control) and personnel training records. There was no documentation on the day of survey to indicate the laboratory director had ensured TP #2 had the proper education required to perform any moderate testing in the

	laboratory prior to testing patients. 2. Review of the personnel records available the day of survey, TP #3 as listed on the CMS 209 form was in training for moderate complexity testing and started performing waived testing on 9/2/20 according to personnel training records. There was no documentation on the day of survey, to indicate the laboratory director had ensured testing personnel #3 had the proper education required to perform moderate testing in the laboratory prior to testing patients.