Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D1078297	07/20/2022
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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the Centers of Medicare and Medicaid Services (CMS) database proficiency Casper report and interview with laboratory TP #3 at 12:30 p.m. on 7/20 /22, the laboratory failed to enroll and participate in an HHS approved proficiency testing (PT) program for Hematology - CBC (Complete Blood Count) performed on the Cell Dyn 1800 hematology analyzer. The laboratory must enroll and participate in an approved program for the specialties performed by the laboratory. Findings Include: 1. Based on review of the CMS data base proficiency Casper report, the laboratory did not enroll in an approved program for CBC for the year 2022. 2. There was no documentation on the day of survey of enrollment in an HHS approved proficiency program for hematology for 2022. 3. TP #3 confirmed in an interview at 12:30 p.m. on 7/20/22 that the laboratory was not enrolled in proficiency testing for CBC testing.
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 2020 and 2021, surveyor review of the Centers for Medicare & Medicaid Services (CMS) 209 personnel form and confirmation by testing personnel (TP) #3 at 11:00 a.m. on 7/20 /22, the laboratory failed to allow TP who routinely perform CBC testing on the patient samples to participate in proficiency testing events for 2020 and 2021. Findings include: 1. Review of proficiency records since the last survey on 9/16/20 revealed all 3 events for CBC for 2020 and 2021 were performed by TP #3. 2. TP #3 in an interview at 11:00 a.m. on 7/20/22 confirmed that CBC testing on patient samples is routinely performed by TP#1, TP#2, and TP#3 as listed on the CMS-209. 3. Neither TP #1 nor TP#2 participated in the proficiency testing events for CBC in the years 2020 and 2021. THIS IS A REPEAT DEFICIENCY
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 9/16/20 through 7/20/22 and interview with the testing personnel (TP) #3 as listed on the CMS-209 at 11:00 a.m. 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 had not been documented as performed for 5/21, 7/21, 12/21 and 2/22 since the last survey 9/16/20. Monthly required maintenance: a. Rinse Lyse Inlet Lines b. Rinse Reagent Inlet Lines B. TP #3 in an interview at 12:30 p.m. on 7/20 /22 confirmed that maintenance was not documented on the Cell Dyn 1800 log. THIS IS A REPEAT DEFICIENCY
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 review of the Cell Dyn 1800 hematology calibration records from 9/16/20 through 7/20/22 and interview with TP #3 at 12:30 p.m. on 7/20/22, the laboratory failed to perform calibration on the Cell Dyn 1800 hematology every 6 months as required by the manufacturer. Findings include: 1. Review of the Cell Dyn 1800 calibration records revealed calibration was performed on 10/1/20 and 10/3/20 and has not been performed since then. These calibration time frames exceed the 6 month mandatory calibration requirement of the manufacturer. 2. Interview with TP #1 at 12: 30 p.m. on 7/20/22 confirmed that CBC calibrations were not performed every 6 months as evidenced by the calibration records available.
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 2020 and 2021 and lack of documentation of corrective action 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 2020 and 2021 confirmed the following proficiency results had scores less than 80% and were not reviewed with correction action: a. MPV -2nd event 2020 - 40% b. MPV- 1st event 2020 - 60% 2. Interview with the laboratory TP#3 confirmed the unsuccessful proficiency scores for MPV were not reviewed and documented corrective action taken when scores received were below 80%.
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 review of testing personnel records from 9/16/20 through 7/20/22, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and interview with testing personnel (TP) #3, the technical consultant (TC) failed to evaluate and document the performance of TP #2 at least semiannually during the first year of employment. Findings include: 1. Review of the laboratory personnel records indicated that TP #2 had an initial training performed on 4/28/21 and began testing on patients. 2. An annual evaluation/competency was performed on 4/20/22. 3. There was no six month evaluation/competency available for review on the day of survey which is required in the first year of testing. 2. TP #3 confirmed in an interview at 12: 30 p.m. on 7/20/22 that there was no 6 month evaluation/competency performed on TP #2 during the first of employment.