Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D2114823	05/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
St Dominic's Family Medicine-Magee	360 Simpson Hwy 149 Ste 370, Magee, 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
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: A. Based on review of two patient in-house testing patient reports in the electronic medical record (EMR) from 1/29/19 and 5/16/19, and confirmation by the Technical Consultant (TC) and testing personnel at 1:30 pm, the patient test reports for complete blood count (CBC) testing records did not include the name and address of the laboratory where the testing was performed. Findings Include: 1. Observation of 2 patient test CBC reports (cumulative and encounter forms) performed at the St Dominic's Family Medicine - Magee clinic and printed from the clinic EHR revealed the CBC report has the letters "Lab: RM" beside those results and no annotation on the report to indicate where that CBC (or any tests performed in the clinic) was performed. 2. The technical consultant and testing personnel on the day of survey, 5/2 /19 at 1:30 pm, confirmed the letters "Lab: RM" would print on both the patient cumulative and encounter result forms from the EMR which means those tests were performed at the St Dominic Family Medicine - Magee clinic. The Clinic's name and address was not included on the report to indicate where the testing was performed as the regulations state. B. Based on review of 2 patient test reports (cumulative and encounter forms) printed from the EMR from 1/29/19 and 5/16/19 where testing was performed by both the clinic laboratory and the reference laboratory (St. Dominic's

	Hospital Laboratory), the reference laboratory reports did not include the name and address of the labs where the samples were tested. This was confirmed by the technical consultant (TC) and testing personnel on 5/21/19 at 1:30 pm. 1. The cumulative report printed from the EHR had the reference laboratory name and address at the top of the report. Patient results from the St Dominic Family Medicine clinic laboratory had "RM" and the test name and results listed. There was no name and address of the clinic where the tests designated as "RM" were performed. 2. The patient results tested at the reference laboratory (St Dominic Hospital Laboratory) had the name of the tests and results with no annotation indicating where the testing was performed. While the reference laboratory name and address appeared at the top of this cumulative report, there was no indication which testing was performed by the clinic laboratory and which was performed at the reference laboratory. It appeared that all laboratory testing on this report had been performed at the reference laboratory. 3. The patient encounter report, which includes physician notes and patient history, also has tests results from clinic testing and reference laboratory testing combined. According to interviews with the TC and testing personnel on the day of survey at 1:30 pm, the testing performed at St Dominic Family Medicine - Magee had "Lab:RM" beside those results and the reference laboratory test results had "Lab" beside those results. Use of codes to indicate the different sites of testing is acceptable, but these codes must be clearly annotated on the patient test report and the names and addresses of all testing sites must be included on the report as well.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory proficiency testing records, Centers of Medicare and Medicaid Services (CMS) database proficiency testing report and confirmation with technical consultant at 1:00 pm, on 5/21/19, the laboratory director failed to ensure the laboratory was enrolled and participated in an HHS approved proficiency testing (PT) program for CBC (complete blood count) performed on the Sysmex XP 300 hematology analyzer, for the first testing event of 2019. The laboratory director must ensure the laboratory is enrolled and participates in all 3 events in an approved proficiency program for the testing performed by the laboratory. Findings include: 1. Observation of the CMS database proficiency testing report revealed no scores for the 1st event of 2019. 2. Observation of laboratory records since installation of Sysmex XP 300 on 2/6/19 through the day of survey, 5/21 /19, revealed no evidence of proficiency testing enrollment prior to survey. 3. Interview with technical consultant at 1:00 pm on day of survey and observation of recent proficiency enrollment forms revealed the laboratory did not enroll in proficiency in time to participate in the 1st event of 2019 when installation of analyzer was 2/6/19 and testing began 2/14/19.