Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0029746	08/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Copiah County Medical Center	27190 Hwy 28, Hazlehurst, 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
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 review of blood bank maintenance logs, lack of documentation of verification of performance specifications for the Ortho Clinical Diagnostics Micro-Typing System (MTS) Workstation, and interview with the general supervisor on 8-8-18 at 4:30 p.m., the laboratory failed to document, as performed, verification of performance specifications for the Ortho Clinical Diagnostics MTS Workstation, before it was put in use for ABO/Rh, antibody detection, and compatibility patient testing on 3-28-17. Findings include: Review of blood bank maintenance logs revealed the Ortho Clinical Diagnostics MTS Workstation was put in use for ABO /Rh, antibody detection, and compatibility patient testing on 3-28-17. There was no documentation of verification of performance specifications available for review on the day of the survey, 8-8-18. In an interview on 8-8-18 at 4:30 p.m., the general supervisor, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, confirmed there was no documentation of verification of performance specifications for the Ortho Clinical Diagnostics MTS Workstation.
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 interview with the technical consultant on 8-8-18 at 4:35 p.m. and review of maintenance logs and the instrument printout for monthly maintenance for the Ortho Clinical Diagnostics Vitros 5600 Integrated immunoassay and chemistry system from 2-23-17 through 8-8-18, the laboratory failed to document, as performed, the monthly maintenance, as defined by the manufacturer, for the Vitros 5600 system for eleven months during this time frame. Findings include: Review of maintenance logs and the instrument printout for monthly maintenance for the Ortho Clinical Diagnostics Vitros 5600 Integrated immunoassay and chemistry system from 2-23-17 through 8-8-18 revealed the following monthly maintenance procedures were not documented as performed from 4-12-17 until 6-24-17, from 8-24-17 until 2-14-18, and from 2-14-18 through 8-8-18: Clean Cuvette Arm. Clean Cuvette Supply. Clean Cuvette Incubator. Clean PM Discard Chute. Clean and replace PM Evaporation Caps. Clean PM Incubator Slot and Insert Blade Channels. Clean CuveTip Cover and Ring area. Inspect and clean MicroTip Supply. Inspect and clean Supply 3 Reagent Carousel. Inspect and clean Supply 3 Housing and Cover. Inspect and clean Supply 3 MicroTip Pack Opener. Clean Supply 3 Tub and Bar Code Reader Window. Clean Vitros VersaTip Supply Registration Rails. Perform System Backup. In an interview on 8-8-18 at 4:35 p.m., the technical consultant confirmed there was no documentation of performance of monthly maintenance for the Vitros 5600 system for these time frames.
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 the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and personnel records since the last survey on 12-7-16, the technical consultant failed to evaluate and document the performance of Testing Personnel #1, #2, #3 and #10, responsible for moderate complexity testing at least semiannually during the first year these individuals tested patient specimens.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and personnel records since the last survey on 12-7-16, the technical

	consultant failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually. Findings include: Review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and personnel records since the last survey on 12-7-16 revealed the technical consultant failed to evaluate and document the performance of Testing Personnel #8 from 12-7-16 until 8-8-18.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 Centers for Medicare and Medicaid Services (CMS) 209 personnel form and review of personnel records since the last survey on 12-7-16, the laboratory director failed to ensure that prior to testing patient specimens Testing Personnel #10 received the appropriate training for moderate and high complexity testing and demonstrated that they could perform all testing operations reliably to provide and report accurate results. Findings include: Review of personnel records since the last survey on 12-7-16 revealed no documentation of training for Testing Personnel #10, date of hire 10-17-17, listed on the CMS 209 personnel form prior to performing moderate and high complexity testing on patient specimens.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high 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 the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and personnel records since the last survey on 12-7-16, the technical supervisor failed to evaluate the competency and document the performance of Testing Personnel # 1, #2, #3 and #10 responsible for high complexity testing at least semiannually during the first year these individuals tested patient specimens.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

	This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and personnel records since the last survey on 12-7-16, the technical supervisor failed to evaluate and document the performance of Testing Personnel #8 responsible for high complexity testing from 12-7-16 until 8-8-18.