Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0672386	05/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
George Regional Hospital	859 Winter Street, Lucedale, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, lack of documentation of speed verification of the Clay Adams Sero-Fuge 2002 centrifuge, used in ABO/Rh testing, and confirmation by the technical consultant, the laboratory failed to follow its "Centrifuge Accuracy Verification of RPM" policy since 12/20/18. Findings include: Review of the laboratory procedure manual revealed the Centrifuge Accuracy Verification of RPM policy states, "The serologic centrifuge RPM accuracy shall be verified upon receipt of a new centrifuge, upon repair affecting the RPM or timer of the centrifuge and/or annually." There was no documentation of speed verification of the Clay Adams Sero-Fuge 2002 centrifuge since 12/20/18. The technical consultant confirmed there was no documentation of speed verification of the centrifuge since 12 /20/18.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

	This STANDARD is not met as evidenced by: Based on review of the Reference Guide for the Ortho Workstation, used in antibody screening and compatibility testing, lack of documentation of Ortho Workstation centrifuge speed and timing verification, and confirmation by the general supervisor, the laboratory failed to perform and document these function checks since the last survey on 10/17/18. Findings include: Review of the Ortho Workstation Reference Guide revealed the Qualification Procedures state that the centrifuge must not be used if speed is outside of specification or if the timer is out of specification. There was no documentation of Ortho Workstation centrifuge speed and timing verification since the last survey on 10/17/18. The general supervisor confirmed there was no documentation of these function checks.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: 1. Based on review of quality control records and the Lab Specimen Log for Clostridium (C.) difficile testing with the Quidel Solana test system from 4/1/21 through 5/15/21, lack of documentation of an Individualized Quality Control Plan (IQCP), and interview with the technical consultant on 5/20/21 at 12:45 p.m., the laboratory failed to include a positive and negative control for seven days of testing during this time frame, when a total of seven patient C. difficile tests were performed and reported. Findings include: Review of quality control records and the Lab Specimen Log for C. difficile testing with the Quidel Solana test system from 4/1/21 through 5/15/21 revealed a positive and negative control were not documented, as performed, for the following days when patient testing was performed and results reported: 4/2/21 - Patient #M005238787. 4/9/21 - Patient #M000017764. 4/16/21 - Patient #M000017045. 4/18/21 - Patient #M008111437. 5/1/21 - Patient #M000001375. 5/9/21 - Patient #M000534366. 5/15/21 - Patient #M000003985. Interview with the technical consultant on 5/20/21 at 12:45 p.m. revealed no IQCP was established for C. difficile testing with the Quidel Solana test system. 2. Based on review of quality control records and the Lab Specimen Log for Respiratory Panel 2.1 testing with the BioFire Film Array Torch test system from 11/20/20 through 5/19/21, lack of documentation of an Individualized Quality Control Plan (IQCP), and interview with the technical consultant on 5/20/21 at 12:45 p.m., the laboratory failed to include a positive and negative control each day of patient testing during this time frame, when a total of 570 patient respiratory panels were performed and reported. Findings include Review of quality control records for the BioFire Film Array Torch test system from 11/20/10 through 5/19/21 revealed a positive and negative control for all twenty-two organisms tested on the Respiratory Panel 2.1 were performed on 12/4 /20, 2/19/21, 3/16/21, and 5/14/21. Review of the Lab Specimen Log revealed a total of 570 patient Respiratory Panel 2.1 tests were performed and results reported on the days quality control was not performed from 11/20/20 through 5/19/21. Interview with the technical consultant on 5/20/21 at 12:45 p.m. revealed no IQCP was established for respiratory panel testing with the BioFire Film Array Torch test system.

D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records for the Instrumentation Laboratories (IL) ACL-TOP coagulation test system from 9/29/20 through 3/31/21 and lack of documentation of the establishment of acceptable ranges for the controls in use during this time frame, the laboratory failed to document, as performed, the establishment of statistical parameters for acceptable ranges for prothrombin time (PT) and activated partial thromboplastin time (APTT) testing with HemosIL Normal Control Level 1, Lot #N0604779, and HemosIL Abnormal Level 3, Lot #N0604774. Findings include: Review of QC records for the IL ACL-TOP coagulation test system from 9/29/20 through 3/31/21 revealed HemosIL Normal Control Level 1, Lot #N0604779, was put in use 10/20/20, and HemosIL Abnormal Level 3, Lot #N0604774, was put in use 9/29 /20. On the day of the survey, 5/20/21, there was no documentation of the establishment of statistical parameters for the PT and APTT ranges listed on the ACL-TOP coagulation test system QC records..