Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0651901	09/24/2020
Name of Provider or Supplier	**Street Address, City, State**	
Winston Medical Center	17550 E Main St, Louisville, 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: 1. Based on review of the Laboratory Policy and Procedure Manual, interview with the general supervisor on 9/24/20 at 10:00 a.m., and lack of documentation of calibration of the Clay Adams Sero-Fuge II centrifuge, used in ABO/Rh testing, the laboratory failed to follow its Centrifuge Calibration Procedure since the last survey on 4/18/18. Findings include: Review of the Laboratory Policy and Procedure Manual revealed the Centrifuge Calibration Procedure states, "The blood bank centrifuge is to be verified every 6 months by the technical consultant for proper performance." There was no documentation of calibration of the Clay Adams Sero-Fuge II centrifuge since the last survey on 4/18/18. In an interview on 9/24/20 at 10:00 a.m., the general supervisor confirmed there was no documentation of calibration of the centrifuge since the last survey. 2. Based on review of the Laboratory Policy and Procedure Manual, lack of documentation of speed and timer checks for the Clay Adams Sero-Fuge II centrifuge since the last survey on 4/18/18, and interview with the general supervisor on 9/24/20 at 10:00 a.m., the laboratory failed to establish a written procedure for speed and timer checks for the Clay Adams Sero-Fuge II centrifuge, used in ABO/Rh testing. Findings include: Review of the Laboratory Policy and Procedure Manual revealed no written procedure for performing speed and timer checks for the Clay Adams Sero-Fuge II centrifuge. In an interview on 9/24/20 at 10: 00 a.m., the general supervisor confirmed there was no written procedure for performing speed and timer checks for the Clay Adams Sero-Fuge II centrifuge. 3. Based on review of the Laboratory Policy and Procedure Manual, the Ortho

	Workstation Reference Guide, and the ID-Tipmaster Repetitive Dispense Pipettor Instructions for Use, the laboratory failed to establish written procedures for Ortho Workstation centrifuge speed and timer checks, incubator temperature and timing checks, and ID-Tipmaster Repetitive Dispense Pipettor maintenance and quality checks. Refer to D5431 (Failure to perform function checks since the last survey.)
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for the Sysmex CA-620 coagulation system, documentation of establishment of the geometric mean of the normal patient reference range, and observation of the Normal Value in the Sysmex CA-620 coagulation system on 9/23/20 at 10:30 a.m., the laboratory failed to follow manufacturer's instructions for INR (International Normalized Ratio) calculation for Dade Innovin prothrombin time (PT) reagent Lot #549766, put in use for patient PT testing on 5/11/20. A total of 166 patient PT/INR results were reported since 5/11/20, according to the laboratory information system. Findings include: Manufacturer's instructions for the Sysmex CA-620 coagulation system state to use the geometric mean of the normal patient reference range for INR calculation. Review of documentation of the calculation of the geometric mean of the normal patient reference range for Dade Innovin PT reagent Lot #549766 revealed the geometric mean was calculated at 10.7. On 9/23/20 at 10:30 a.m., the Normal Value observed in the Sysmex CA-620 coagulation system for calculation of patients' INR was 10.3. A total of 166 patient PT/INR results were reported since 5/11/20, according to the laboratory information system.
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: 1. Based on review of the Reference Guide for the Ortho Workstation, used in antibody screening and compatibility testing, interview with the general supervisor on 9/24/20 at 9:30 a.m., and lack of documentation of Ortho Workstation centrifuge speed and timing verification and incubator temperature and timing verification, the laboratory failed to perform and document these function checks since the last survey on 4/18/18. 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. The Qualification Procedures also state that the incubator temperature must read 37 degrees Celsius plus or minus 2 degrees and the incubator must not be used if the

	timer is out of specification. There was no documentation of Ortho Workstation centrifuge speed and timing verification or of incubator temperature and timing verification since the last survey on 4/18/18. In an interview on 9/24/20 at 9:30 a.m., the general supervisor confirmed there was no documentation of these function checks since the last survey. 2. Based on review of the Instructions for Use for the Micro Typing System (MTS) ID-Tipmaster repetitive dispense pipettor, used in antibody screening and compatibility testing, interview with the general supervisor on 9/24/20 at 10:15 a.m., and lack of documentation of pipettor maintenance or quality checks, the laboratory failed to perform and document MTS ID-Tipmaster repetitive dispense pipettor maintenance and quality checks since the last survey on 4/18/18. Findings include: Review of the MTS ID-Tipmaster repetitive dispense pipettor Instructions for Use revealed the manufacturer recommends that the maintenance procedure should be performed at regular intervals and after the maintenance procedure, a Quality Check should be performed to check the volume. There was no documentation of performance of the maintenance procedure or Quality Check since the last survey on 4 /18/18. In an interview on 9/24/20 at 10:15 a.m., the general supervisor confirmed there was no documentation of the maintenance procedure or Quality Check since the last survey. 3. Based on review of the Instruction Manual for the Diamond Pro 10-microliter single channel pipettor, used in antibody screening and compatibility testing, interview with the general supervisor on 9/24/20 at 10:15 a.m., and lack of documentation of pipettor calibration, the laboratory failed to perform and document calibration of the pipettor since the last survey on 4/18/18. Findings include: Review of the Instruction Manual for the Diamond Pro 10-microliter single channel pipettor revealed the manufacturer recommends checking the calibration at least once a year. There was no documentation of calibration of the pipettor since the last survey on 4/18 /18. In an interview on 9/24/20 at 10:15 a.m., the general supervisor confirmed there was no documentation of calibration of the Diamond Pro 10-microliter single channel pipettor since the last survey.