Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0441828	08/31/2020
Name of Provider or Supplier	**Street Address, City, State**	
Madison Medical Center	611 West Main, Fredericktown, MO	

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 chemistry procedure manual's and interview with the general supervisor on August 31, 2020 at 12:15 PM the laboratory failed to have a written procedure for the Vitros XT 7600 analyzer.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in

	the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of Immunohematology procedures and interview with the general supervisor the laboratory failed to have procedures for issuing blood units and blood storage. Review of written procedure "Blood Bank-History Check" was not consistent with what testing personnel actually perform. Findings: 1. Review of Immunohematology procedures showed laboratory did not have Immunohematology procedures for issuing blood units, a procedure for determining blood suitability for reissue and a procedure for potentially infectious units and reagents are stored and segregated to prevent contamination. 2. Review of "Blood bank -History Check" procedure states "A Blood bank history file is maintained within the CPSI computer system", the general supervisor stated "the steps the testing personnel are suppose to take are checking the patient history file in the drawer and in the CPSI system before testing". The CPSI system only has the data from the last 2 years of patient testing. 3. Interview with the general supervisor on August 31, 2020 at 12:15 PM confirmed the laboratory failed to provide a procedure for issuing blood units, storage and history check procedure was not consistent with what testing personnel actually perform.
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 the performance verification procedures for the Vitros XT 7600 chemistry analyzer and interview with the general supervisor, the laboratory failed to verify manufacturer's reference intervals(normal values) for 64 of 64 analytes. Findings: 1. Review of the verification procedures for the Vitros XT 7600 chemistry analyzer for Albumin, Alkaline Phosphatase, Alanine Aminotransferase (ALT), Amalyse, Aspartate Aminotransferase (AST), Bilirubin, Calcium, Chloride, Cholesterol, Creatine Kinase (CK), Carbon Dioxide, Creatinine, Glucose, High-density lipoprotein (HDL), Iron, Lactic Acid, Lipase, Magnesium, Phosphorus, Potassium, Sodium, total Bilirubin, Total Protein, Tryglycerides, Urea, Uric Acid, total iron-binding capacity (TIBC), Free T3, Total T3, Total T4, Ferritin, Folate, Free T4, Thyroid Stimulating Hormone (TSH), Vitamin B12, Vitamin D, Acetaminophen, Carbamazepine, Beta HCG, Insulin, Prostrate specific antigen (PSA), Salcylate, Testosterone, Valproic Acid, Vancomycin, Lithium, Pro BNP, Troponin, Creatine Kinase MB (CKMB), Parathyroid hormone (PTH), Alcohol, Ammonia, urine Creatinine, urine Protein, urine Microalbumin, HGB A1C, C-Reactive Protein (CRP), Amphetamine, Barbiturate, Benzodiazepine, Cocaine, Methadone, Opiate, PCP and THC showed no verification of normal values. 2. Interview with the general supervisor on August 31, 2020 at 12:15 PM confirmed the laboratory failed to ensure

	the verification procedures for normal values for the Vitros XT 7600 analyzer were appropriate for the laboratory's patient population.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Review of 2020 Immunohematology quality control (QC), Immunohematology QC procedure and interview with the general supervisor the laboratory director failed to ensure Immunohematology QC program was maintained to assure the quality of laboratory services and to identify failures in quality as they occur. Findings: 1. Review of May Immunohematology QC showed patient testing was completed on 5/7 /20 and 5/30/20 and no QC was completed. 2. Review of Immunohematology QC procedure states "perform the following procedures (as needed) on each day of testing". 3. Interview with the general supervisor on August 31, 2020 at 12:15 PM confirmed the laboratory director failed to ensure Immunohematology QC program was maintained to assure the quality of laboratory services and to identify failures in quality as they occur.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of Immunohematology procedure manual and interview with the general supervisor the laboratory director failed to approve the Immunohematology procedure manual. Findings: 1. Review of the Immunohematology procedure manual showed 80 percent of Immunohematology procedures not approved by the laboratory director. 2. Interview with the general supervisor on August 31, 2020 at 12:15 PM confirmed the laboratory director failed to approve the Immunohematology procedure manual.