Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0393406	09/02/2021
Name of Provider or Supplier	**Street Address, City, State**	
Uw Health-Union Corners Lab	2402 Winnebago St, Madison, WI	

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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on surveyor observation of stored blood samples, review of patient test reports and laboratory procedures, and interview with a technical consultant, the laboratory did not follow their procedures for specimen acceptability and rejection for one of one short filled blood tube collected for hematology testing on August 29, 2021. Findings include: 1. Observation of stored blood samples on September 2, 2021 at 2:30 PM revealed an EDTA (ethylenediaminetetraaceticacid) anticoagulated sample collected on August 29, 2021 with less than one milliliter of blood in the tube. The tube was identified as a sample from patient 1, collected at 5:10 PM. 2. Review of the test report for patient 1 showed the laboratory reported hematology results from the Sysmex XS-1000i on August 29, 2021. 3. The laboratory procedure, 'UWMF Satellites Sysmex XS-1000i Procedure' included the following steps in part III, Specimen Information: "Specimen should be visually inspected for hemolysis, clots and proper fill level", and "Minimum acceptable volume is a half-filled tube". 4. Interview with a technical consultant (staff A) on September 2, 2021 at 2:40 PM confirmed the EDTA tube from patient 1 did not meet the acceptability requirements for testing and the laboratory staff did not follow their procedures for specimen rejection.
D5407	PROCEDURE MANUAL

	CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on surveyor review of serum hCG (human chorionic gonadotropin) quality control and patient testing records and laboratory procedures, and interview with a technical consultant, the laboratory used the SURE-VUE Serum/Urine hCG-STAT test kit for one of one serum hCG patient tests performed between January 1, 2021 and February 1, 2021 prior to approval of the laboratory's procedure by the laboratory director. Findings include: 1. Review of quality control records for 2021 showed the laboratory was using the SureVue test kit lot HCG0042106 from January 1 through 25, 2021 and lot HCG0092078 on January 26 and February 1, 2021. On January 25, 2021, the laboratory tested two positive and one negative quality control samples using the SureVue test kit lot # HCG0042106. 2. Review of patient testing records from January 1 through February 1, 2021 showed one serum pregnancy test was performed on a sample from patient 2 on January 25, 2021. 3. Review of the "UWMF SureVue Serum Pregnancy" procedure showed the director approved the procedure on February 10, 2021. 4. Interview with a technical consultant (staff A) on September 2, 2021 at 3:00 PM confirmed testing personnel used the SureVue hCG STAT test kit to test a patient serum sample prior to the approval of the test procedure by the laboratory director.
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 surveyor review of maintenance logs for the Architect Chemistry analyzer and interview with a technical consultant, the laboratory did not ensure replacement of the ICT (Integrated Chip Technology) module every 90 days as required by the manufacturer. Findings include: 1. Review of maintenance logs for the Architect analyzer showed the ICT module is to be replaced every 90 days or as needed. The logs show the following replacement and expiration dates for the ICT module in 2021: Replaced February 19 (module expiration date June 18, 2021) Replaced August 19 (module expiration date December 16, 2021) Maintenance logs from February through August 2021 showed no evidence of review. 2. Interview with a technical consultant (staff A) on September 2, 2021 at 10:50 AM confirmed the laboratory had no records to show the ICT module was replaced in May 2021 or that the module in place on February 19, 2021 was not used past the expiration date of June 18, 2021.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials

	using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of two approved IQCP (Individualized Quality Control Plan) and interview with a technical consultant, two of the two new or revised IQCP did not specify the type of external control material used for testing and one did not specify the number of controls required. Findings include: 1. Review of the IQCP for the SureVue Serum/Urine hCG STAT test kit and the IQCP for Troponin I and D dimer testing on the Siemens Stratus CS showed the type of external control was not specified in either IQCP. Further review of the IQCP for the Siemens Stratus CS showed the quality control plan did not identify how many controls would be tested for Troponin I or D dimer testing. 2. Interview with a technical consultant (staff A) on September 2, 2021 at 11:20 AM confirmed the control material was not specified in the IQCP for the Sure Vue test kit or the Stratus analyzer. Further interview confirmed the laboratory did not specify the number of controls required for Troponin I or D dimer testing on the Stratus.