

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0396797	(X3) Date Survey Completed 04/25/2024
Name of Provider or Supplier Adventhealth Durand	Street Address, City, State 1220 3rd Ave West, Durand, 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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and procedures and interview with the technical consultant, the laboratory director did not approve, sign and date four of four new Stago Satellite coagulation procedures prior to patient use. Findings include: 1. Review of verification of performance specifications on the Stago Satellite showed the go-live date for the analyzer was October 23, 2023. 2. Review of Stago Satellite coagulation testing procedures showed the following procedures were approved and signed by the laboratory director on October 30, 2023. Coagulation01 Stago Satellite Protime Coagulation02 Stago Satellite APTT Coagulation03 Stago Satellite Coag N and ABN Plus Controls Coagulation04 Stago Satellite Desorb 3. Interview with the technical consultant on April 24, 2024, at 3:00 PM confirmed the laboratory director did not approve, sign and date new coagulation procedures prior to patient use.</p>
D5545	<p>HEMATOLOGY CFR(s): 493.1269(b)(d)</p> <p>(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of procedures, quality control (QC) records, patient reports,</p>

U.S. Food and Drug Administration (FDA) Clinical Laboratory Improvement Amendments (CLIA) classification database and Individualized Quality Control Plans (IQCP) and interview with the technical consultant, the laboratory did not perform QC each eight hours of patient testing on the Roche c501 D-Dimer test for two of forty-one patient tests between February 1, 2024 and April 24, 2024, and had not developed an IQCP. Findings include: 1. Review of the "Chem32 Tina-quant D-Dimer" procedure stated QC was performed "every 24 hours when test is in use and following calibration". 2. Review of QC records for D-dimer testing on the Roche c501 chemistry analyzer showed QC was run one time every 24 hours of patient testing from February 1, 2024, through April 24, 2024. 3. Review of patient testing performed between February 1, 2024, and April 24, 2024, showed the following: Patient 1: D-Dimer testing performed on March 7, 2024, at 1:42 AM. QC had been performed on March 6, 2024, at 8:26 AM and March 7, 2024, at 2:46 PM. Patient 2: D-Dimer testing performed on March 9, 2024, at 10:53 PM. QC had been performed on March 9, 2024, at 10:38 AM with no additional QC performed on March 9, 2024. 4. Review of the FDA CLIA classification database showed D-dimer testing on the Roche c501 chemistry analyzer is classified as a hematology test. 5. Review of the laboratory's IQCP's showed no evidence of an IQCP for the Roche c501 D-dimer test. 6. Interview with the technical consultant on April 25, 2024, at 11:00 AM confirmed the laboratory did not perform QC each eight hours of patient testing on the Roche c501 D-dimer test and had not developed an IQCP.